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Part 15 Public Hearing 09-17-2014

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FOOD AND DRUG ADMINISTRATION (FDA)  
OFFICE OF THE COMMISSIONER

GENERIC DRUG USER FEE AMENDMENTS OF 2012  
PUBLIC HEARING ON POLICY DEVELOPMENT --  
REQUEST FOR COMMENTS  
PART 15 PUBLIC HEARING

Wednesday, September 17, 2014

College Park Marriott Hotel and Conference Center  
3501 University Boulevard, East  
Hyattsville, MD 20783

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<p style="text-align: right;">7</p> <p style="text-align: center;">A G E N D A (Continued)</p> <p style="text-align: center;">PAGE</p> <p>Comments by Ken Cappel, RPh, JD 166 Amneal Pharmaceuticals</p> <p>Comments by Carolyn Huntentburg 176 Momenta Pharmaceuticals</p> <p>Comments by Carole Ben-Maimon, MD 180 Impax Laboratories</p> <p>Comments by Leonard Lawrence 195 Sovereign Pharmaceuticals</p> <p>Break 204</p> <p>Comments by John Ducker 204 Fresenius Kabi USA</p> <p>Comments by Tim Ames 215</p> <p>Comments by Candis Edwards 217 Amneal Pharmaceuticals</p> <p>John Diloreto 222 BULK Pharmaceuticals</p> <p>Closing Remarks 226 Keith Flanagan, JD Office of Generic Drug Policy Office of Generic Drugs, CDER</p>	<p style="text-align: right;">9</p> <p>do a great job, and we need your help to do that.</p> <p>So with that in mind, again thanks for investing the time in preparing remarks. Thanks for coming all the way out here, and we earnestly welcome your comments. Thank you.</p> <p>MS. NGUYEN: Good morning, everyone. My name is Martha Nguyen, and I am a Senior Policy Advisor in the Office of Generic Drug Policy. I am the presiding officer for the first panel today, and I would like to welcome you to this Part 15 hearing on policy development related to GDUFA implementation.</p> <p>Before we begin, I would like to go over some logistics. First, please turn off any mobile devices because they might interfere with the audio in this room, but I am going to now give you conflicting information because I am also going to give you the Wi-Fi password for this hotel space, but you can write that down and use it during the breaks. The network is "Guest Net," and the user name and password are both "FDA," and those are case sensitive, so uppercase "FDA" for username</p>

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10	<p>1 and password.</p> <p>2 Also, we ask that all attendees sign in</p> <p>3 at the registration desk so that we can track the</p> <p>4 number of attendees and follow up with you</p> <p>5 afterwards if there is anything else we think</p> <p>6 would be useful to share by e-mail.</p> <p>7 The agenda includes two 15-minute breaks</p> <p>8 and a 1-hour lunch break. We'll try to end the</p> <p>9 hearing at 5:00, and if we finish before that,</p> <p>10 we'll end before.</p> <p>11 For any media present, the press officer</p> <p>12 for today is Jordana O'Grady (ph). She is waving</p> <p>13 her hand in the back there. She will be the</p> <p>14 contact for any media in the room today.</p> <p>15 So here are a few rules and procedures</p> <p>16 to keep the hearing moving as efficiently as</p> <p>17 possible. Each registered speaker will have 15</p> <p>18 minutes to present. There are timekeeping lights</p> <p>19 on the podium that will let you know when your 15</p> <p>20 minutes are up, but please also be mindful of your</p> <p>21 time allotment.</p> <p>22 There is a little remote on the podium,</p>	12
11	<p>1 and once the slides are on the screen, you will</p> <p>2 advance your own slides by pressing the right</p> <p>3 arrow.</p> <p>4 After each presentation, the panel</p> <p>5 members will have 10 minutes to ask questions</p> <p>6 about the presentation.</p> <p>7 No participant may interrupt the</p> <p>8 presentation of any other participant, and only</p> <p>9 FDA panel members may ask questions during or</p> <p>10 after the presentation.</p> <p>11 If a speaker's presentation takes less</p> <p>12 than 15 minutes, we will move right into the</p> <p>13 questions from the panel members and then on to</p> <p>14 the next presentation.</p> <p>15 If presentations from the registered</p> <p>16 speakers wrap up ahead of schedule, we will allow</p> <p>17 additional commenters to speak for up to 5 minutes</p> <p>18 each in open comment sessions after the first and</p> <p>19 second panels.</p> <p>20 If you signed up to speak at the</p> <p>21 registration desk this morning, please look for</p> <p>22 your name on the list of commenters, which we will</p>	13
10	<p>1 project onto the screen at the start of the open</p> <p>2 comment sessions.</p> <p>3 Please approach the microphone in the</p> <p>4 order shown on the list. We will allow as many</p> <p>5 commenters as time permits. And a recording of</p> <p>6 this meeting will be transcribed, so please</p> <p>7 remember to use the microphone when speaking. The</p> <p>8 transcript will be accessible through</p> <p>9 Regulations.gov and on FDA's GDUFA website in</p> <p>10 about 30 days.</p> <p>11 I think there was some miscommunication</p> <p>12 about whether this hearing would be webcast, and</p> <p>13 it's my understanding that FDA is not webcasting</p> <p>14 the hearing today.</p> <p>15 So, as Keith mentioned, the purpose of</p> <p>16 today's public hearing is to seek input on GDUFA</p> <p>17 implementation from a broad range of stakeholders.</p> <p>18 In the first panel, we are seeking</p> <p>19 comments on the five draft guidance documents that</p> <p>20 we have issued to date to facilitate</p> <p>21 implementation of GDUFA. We would especially like</p> <p>22 to hear if there are GDUFA implementation issues</p>	12
11	<p>1 related to the draft guidances that have not been</p> <p>2 addressed; if there are other GDUFA implementation</p> <p>3 topics that need development of guidance; and,</p> <p>4 finally, if there are any generic drug development</p> <p>5 issues unrelated to GDUFA implementation that need</p> <p>6 the development of guidance. We will consider all</p> <p>7 information from this public hearing, including</p> <p>8 the public docket, when developing our future</p> <p>9 policy priorities. So any comments that aren't</p> <p>10 presented today can be submitted through</p> <p>11 Regulations.gov using the docket number for this</p> <p>12 hearing, which is FDA-2014-N-1168.</p> <p>13 We have two distinguished panels of FDA</p> <p>14 experts to listen to the presentations today.</p> <p>15 Kathleen (Cook) Uhl, Acting Director of</p> <p>16 the Office of Generic Drugs, will preside over the</p> <p>17 second panel, and we'll ask her to introduce</p> <p>18 herself when she arrives, but before the first</p> <p>19 panel members introduce themselves, I want to</p> <p>20 thank them, our presenters, and all of you in the</p> <p>21 audience for participating in this hearing today.</p> <p>22 We value your input, are grateful for your active</p>	13

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<p style="text-align: right;">14</p> <p>1 engagement, and look forward to a very productive 2 rest of the day. 3 Thank you. 4 Keith? Just introduce yourself. 5 MR. FLANAGAN: Again, I'm Keith 6 Flanagan. I'm the Transition Lead for Policy in 7 CDER's Office of Generic Drugs. 8 MS. KIM: I'm Nam Kim. I'm the Director 9 of the Division of Regulatory Policy III in the 10 Office of Regulatory Policy in CDER. 11 MR. YOUNG: I'm Johnny Young. I am the 12 Acting Division Director for the Division of 13 Filing Review in the Operations Office. 14 MS. GIAQUINTO: And I'm Elizabeth 15 Giaquinto. I'm a Regulatory Counsel in the Office 16 of Generic Drug Policy, Division of Policy 17 Development. 18 MS. NGUYEN: So we'll now have our first 19 presenter. 20 Priscilla? 21 MS. ZAWISLAK: Thank you, and thanks to 22 FDA for allowing us to speak today. I'm here on</p>	<p style="text-align: right;">16</p> <p>1 filing is resulting in increased delays in filing, 2 and in the generics pharmaceutical industry 3 they're not able to make high quality submissions 4 and reduce the number of review cycles unless 5 these inactive ingredient issues are adequately 6 addressed. 7 With respect to the Refuse-to-acceptance 8 Standards draft guidance, one of the biggest 9 concerns that IPEC has had is on the acceptance of 10 the family approach, and by that, we mean that 11 materials that are compositionally similar and 12 expected to have some toxicity, the same toxicity, 13 profile, are considered excipient families. For 14 example, they might differ in physical attributes, 15 such as viscosity, but they are the same chemical 16 entity, so the tox profile is similar. 17 Further, toxicology studies are 18 typically conducted on representative material 19 based on similarity across an entire family, not 20 every grade within the family. There may be 10, 21 20, 50 grades within a product family, and these 22 all have the same tox profile. This approach has</p>
<p style="text-align: right;">15</p> <p>1 behalf of the International Pharmaceutical 2 Excipients Council, IPEC-Americas. 3 And the scope of what we would like to 4 comment on today are some critical issues related 5 to two of the draft guidances where active 6 ingredients are included. One of them is the ANDA 7 submissions refuse to receive standards, and the 8 other is on the content and format of the ANDAs. 9 With respect to just general comments, 10 there is confusion in the industry on FDA's policy 11 on inactive ingredients, which needs to be 12 clarified and communicated consistently in 13 publications and guidance documents. The draft 14 guidances that we've seen do not reflect 15 historical practices both in industry and FDA in 16 reviewing inactive ingredients, and the failure to 17 clarify inactive ingredient issues prior to 18 finalizing guidance documents is going to impact 19 the GDUFA primary tenets of predictability and 20 timeliness in the review process. 21 Further, FDA's increased emphasis on 22 using the controlled correspondence prior to</p>	<p style="text-align: right;">17</p> <p>1 been used for decades in the food and chemical 2 industry. FDA CFSAN has typically used this 3 approach for food additives, and the excipients 4 are generally made in many cases in the same 5 plants, the same process, as food additives. FDA 6 CDER and OGD has also used this approach in the 7 past until about 2011. So it's unclear to IPEC 8 why OGD now thinks that this approach is not 9 acceptable because this approach has been used for 10 a very long time. 11 Also, with respect to the acceptance of 12 the family approach, most of the inactive 13 ingredients that are in drugs today have been 14 safely used for over 50 years in a variety of 15 uses, not just in pharmaceuticals but also as food 16 additives and cosmetic ingredients. The 17 expectation that data will be generated on each 18 grade of the excipient is just not realistic. A 19 lot of the data has been generated over the years, 20 and to do new studies would be a major issue for a 21 lot of companies. 22 There is also no evidence that using the</p>

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18	<p>1 family approach creates any significant patient 2 safety risk. This also contradicts the IPEC- 3 Americas work with FDA's OGD excipients working 4 group on justifying the level of inactive 5 ingredients by citing the level for a related 6 excipient within the same family. 7 And then, finally, on the content format 8 of the ANDA's draft guidance, this guidance refers 9 to information included in the RTR to ensure 10 submission of high quality ANDAs, but there are 11 many issues in the RTR that should be clarified 12 and resolved in regard to the inactive 13 ingredients. This guidance also reiterates that 14 information in the RTR should be followed without 15 addressing the significant issues raised by IPEC 16 and others. So due to our concerns over the 17 comments previously provided which have not been 18 acted on, IPEC-Americas will also be submitting 19 more further detailed comments in writing after 20 the hearing. 21 Thank you. 22 MS. NGUYEN: Thank you.</p>	20
19	<p>1 Questions from the panel? 2 MR. FLANAGAN: So I understand policy 3 concerns you raised concerning IID issues? 4 MS. ZAWISLAK: Mm-hmm. 5 MR. FLANAGAN: What has the experience 6 of your members been with respect to the inactive 7 ingredients database, and how could the 8 functionality of that be improved to be more 9 useful to you? 10 MS. ZAWISLAK: We've had an IPEC FDA OGD 11 working group now for a couple of years, and we 12 had provided some background information on some 13 of the issues that caused our industry. I 14 think we've made a lot of good progress. We have 15 a draft question and answer document that is now 16 going through I believe the Office of Policy to be 17 issued that will address some of the more basic 18 questions with a Phase II document, hopefully to 19 follow that. But especially since the RTR draft 20 guidance was published last year for comment, the 21 number of issues that we, as excipient 22 seller/manufacturers, are getting from our</p>	21
20	<p>1 customers who are filing ANDAs has increased 2 exponentially because there is so much confusion 3 and the conflicting information that we're getting 4 with regards to policy has been a lot of questions 5 around that, and even some of the things that our 6 working group has tentatively agreed on as to what 7 we can communicate to industry, we're still now 8 getting a lot of questions particularly after 9 yesterday's publication, the final guidance, and 10 we anticipate even more. So the policy issues 11 have been a major impact on our organization. 12 MS. NGUYEN: Other questions from the 13 panel? 14 (No audible response.) 15 MS. NGUYEN: Thank you. 16 Up next we have Steven Pressman. 17 MR. PRESSMAN: Thank you very much for 18 having me here today. I appreciate the 19 opportunity to speak. The area that I want to 20 address today are the GDUFA fees, facility fees, 21 associated with small business where the areas of 22 certain businesses, I don't know that it was</p>	21

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<p style="text-align: right;">22</p> <p>1 reduction or reasserting how they need to be 2 assessed against the different businesses. 3 Now, these fees may be a minor impact to 4 some of the multibillion dollar businesses out 5 there, but to a small business that's, let's say, 6 under the \$100 million range, it's a big impact, 7 especially on some of these drugs we're waiting 2 8 to 3 years to get approvals. The dollars, the 9 annual fees, add up when there are no other drugs 10 in the marketplace that are currently being 11 marketed. 12 And what this is doing, based on my 13 discussions with other companies in the industry, 14 it's discouraging competition and creating a 15 barrier to entry, which I know the FDA is not 16 looking to create a barrier to entry, but this is 17 the impact that it's having. Perhaps one way to 18 look at it would be if a company is under a 19 certain threshold in generic drug volume out 20 there, maybe the fees don't kick in until they hit 21 a certain number of annual revenue. 22 So what's happening now are the major</p>	<p style="text-align: right;">24</p> <p>1 oligopoly, innovation is being hampered, 2 elimination of consumer generic drug choices, 3 there are drug shortages, and the inflation of 4 drug prices because the competition is being 5 eliminated, and I know that that was not the 6 purpose of implementing these fees, it was to get 7 things through the process more quickly. 8 So the fees need to be looked at in more 9 detail now that we have 2 years of data on hand. 10 Company size should be a consideration. There are 11 many other government agencies that use the size 12 or dollar revenue of businesses to determine how 13 the fees are going to be collected and how they 14 are going to be utilized, and that will create a 15 level playing field in the marketplace, and again, 16 the ultimate recipient of this is going to be the 17 American consumers who are paying for the drugs. 18 So, again, financial strength needs to 19 be taken into consideration, and that seems to be 20 the main theme here, and again what also needs to 21 be looked at is, does a company have any ANDAs 22 that have been approved with drugs in the market?</p>
<p style="text-align: right;">23</p> <p>1 companies just keep gaining market share and 2 eliminating any competition from coming in, and 3 it's increasing prices in the market place to the 4 American public. 5 Also the issue of drug shortage comes 6 into play with this type of situation, and again, 7 as I said, drug price inflation. 8 So we now have 2 years of data on hand 9 to see how the fees have been applied and the 10 impact it's had on the Agency. 11 Sorry. I was thinking someone else was 12 doing this, that's my mistake. So we can go back. 13 So, again, so as I said, the fees have 14 been increased since their implementation. The 15 impact to these larger companies out there is 16 minor or no impact at all. And no offense to 17 anyone in this room, but if I was a multibillion 18 dollar company, I might want the fees to be \$10 19 million a year so I will never have any 20 competition coming against me. 21 And, again, as said, discouraging 22 competition due to barrier of entry, creating an</p>	<p style="text-align: right;">25</p> <p>1 Because there is a big difference if it's going to 2 take 3 years to get a drug approved and you're 3 going to pay \$750,000 in GDUFA fees, which may not 4 have been even considered before the drug 5 development process started versus just paying on 6 an annual basis going forward. 7 And again the area that we referenced in 8 the Federal Register. 9 Any questions? 10 MR. FLANAGAN: Yes. Thank you very 11 much. The last slide proposes that if there were 12 changes made in this space, that the financial 13 strength of the company should be taken into 14 consideration. Did you have any thoughts 15 regarding how to do that? Would small companies 16 self-certify as to their financial strength? 17 MR. PRESSMAN: Well, if, for an example 18 -- and I'll just throw out round numbers for 19 easiness sake -- let's say a company is only doing 20 -- has no approvals per se. I don't think there 21 should be any facility fee until they receive an 22 approval because we're at the mercy, for lack of a</p>

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<p style="text-align: right;">26</p> <p>1 better term, of the FDA of whenever the FDA gives 2 the approval, if they ever give the approval. So 3 what is the purpose of paying an annual facility 4 fee if we're not producing any drugs out of that 5 facility and selling them to the public? 6 And as far as again any thoughts on how 7 to certify, we all file tax returns. That's 8 probably the simplest way of looking at it. There 9 has to be some honor and integrity in the business 10 world, and if, let's say, are you doing more than 11 \$10 million a year in generic drug business? No? 12 Okay, maybe that needs to be the number. If 13 you're doing less than \$10 million, maybe you 14 don't pay a facility fee, maybe you only pay one- 15 tenth of a facility fee. Perhaps if you're doing 16 a billion dollars of business and this could 17 result in more income for the GDUFA program versus 18 less income, if there was a sliding scale, maybe a 19 company doing a billion dollars a year in generic 20 drug business needs to be paying \$2 million a year 21 in fees versus only \$250,000 in fees. 22 So it needs to be sat down obviously and</p>	<p style="text-align: right;">28</p> <p>1 you pay these fees. We said, well, they didn't 2 exist before we made our submissions. We just got 3 a letter now that we paid the fees, the clock was 4 now rolled back for us to when we originally did 5 the submissions, which is how it should have been. 6 In other words, we should not have been told, "Oh, 7 you haven't paid your fees." Well, the fees didn't 8 exist when we submitted. I see a puzzled look on 9 your face, so that's why I'm explaining. The fees 10 weren't in place when we made the submissions, so 11 why would we be now delayed a year when it was a 12 policy that didn't exist before? And it's not a 13 crime, but my analogy was, well, you can't be 14 convicted of a crime that wasn't a crime when you 15 did it and now you made it a law and, oh, by the 16 way, you did this a year ago. 17 MR. FLANAGAN: Thank you. Thanks for 18 clarifying it. Thanks for traveling all the way 19 out here. 20 MR. PRESSMAN: My pleasure. Thank you. 21 MS. NGUYEN: Up next we have David 22 Gaugh.</p>
<p style="text-align: right;">27</p> <p>1 the discussion needs to take place in a more 2 detailed manner than just in a 15-minute 3 conversation, but I've gone and met with 4 Congressman Waxman about this. He was actually 5 shocked when I explained these things to him. I 6 said, did anyone even think for one second to take 7 into consideration how this is going to impact 8 small business and again ultimately the American 9 public that all you're doing is pushing out 10 companies, you're not encouraging competition, 11 you're stifling it? And he immediately said 12 you're 100 percent right. It's now been into law, 13 we don't know how to change it, but again if the 14 fees are able to be changed upward, I know the 15 fees can be changed downward. 16 So, again, I'm open to come out and meet 17 with anybody at the FDA and have discussions. We 18 just got a letter recently where -- and this was 19 an argument that I had, we had ANDAs on file at 20 our company before the fees were put into place, 21 and we were told, oh, you're stopped right now. 22 The process is stopped for you at the FDA until</p>	<p style="text-align: right;">29</p> <p>1 MR. GAUGH: Thank you. And thanks to 2 the FDA and the panel for holding this open public 3 hearing. We greatly appreciate it, and this is a 4 very important topic for the generic drug 5 industry. 6 So let me just give a little bit of 7 background. So GPhA represents the manufacturers 8 and distributors of generic pharmaceutical 9 products; manufacturers and distributors of the 10 bulk active chemical industry; and suppliers of 11 other goods and services for the industry. Our 12 manufacturers produce 90 percent of all 13 pharmaceuticals dispensed in the United States, 14 and their products are used in more than 3 billion 15 prescriptions every year. And the generic 16 products represent greater than -- and this slide 17 says 84 percent, but we just have some new data 18 out that that number has now jumped up to 86 19 percent of all prescriptions dispensed in the 20 United States. 21 I show this slide just to show a 22 representation of who we are and how much we</p>



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30	<p>1 affect from a different company's standpoint. And  2 GPhA has two different member organizations or  3 categories I should say, not different  4 organizations. One is a member, full member,  5 which is this representation. These are 29 of  6 these member companies. We also have 42 associate  7 member companies that we represent. So upwards of  8 70 companies.</p> <p>9 And I would also like to point out that  10 this is an important enough issue to us today that  11 we have 21 of those companies here in  12 representation and 52 members of those companies.  13 So very important topics for us and you'll have  14 several later today at the open mic session  15 providing some input and some clarity to some of  16 this information that you provided us.</p> <p>17 So first off, I do want you to know that  18 GPhA and its member companies are very committed  19 to GDUFA. We were at the table when GDUFA was  20 negotiated, and, no, not everything got negotiated  21 perfectly necessarily in GDUFA1, but there will be  22 a GDUFA2 we would anticipate, and so we'll have</p>	32
31	<p>1 some clarity from some of the speakers we hear  2 today and that we've heard at other times on what  3 we can do to get to GDUFA2, but it is very  4 important to us. It helps speed the process and  5 enhancement of the approvals, and so we must equip  6 the FDA to be able to do that. We know that and  7 that's why the industry stepped up to \$300 million  8 a year roughly, or 1.5 billion over the course of  9 the 5 years to provide those resources for the FDA  10 to be able to do the things that they need to do  11 to get to our ANDA and ANDA approvals in a more  12 efficient and timely manner. But with that said,  13 we do need to be working together to ensure that  14 the millions of Americans and patients around the  15 world continue to receive the timely access to  16 safe, effective, and affordable drugs.</p> <p>17 And I would like to point out just as a  18 reminder that GDUFA has three key public health  19 aims:  20 safety, access, and transparency. So I  21 think those are words that we all know very well,  22 but I don't want us to forget that those are three</p>	33
30	<p>1 very important tenets of GDUFA.  2 And as I go through some of these  3 slides, they are going to be pretty high level  4 slides, and the reason for that is that we're  5 going to be providing much more granular detail as  6 we get to comments into the open docket over the  7 next several weeks, so we're pulling those  8 together with our member companies.</p> <p>9 As part of this slide deck -- and I'm  10 not going to go through all of it because I only  11 have 15 minutes, but it is a 25-slide deck, and  12 there is some significant detail in what we're  13 calling the appendix to the deck, so I'll refer to  14 that a little bit. I'm not going to go through it  15 now, but I do put that out for you to be able to  16 reference as you go through this meeting and then  17 also as you go through the open comments period in  18 the coming days and weeks as you go through that  19 process.</p> <p>20 So the five guidances that you asked  21 that we address and then any other guidance, I  22 want to go through those rather quickly if we can</p>	33

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34	<p>1 Inconsistencies among reviewers is 2 another issue that we identify, so having a robust 3 and a quality submission we absolutely agree and 4 support. We also have to have robust processes on 5 the FDA end where there is consistency among 6 reviewers that are reviewing these robust quality 7 submissions.</p> <p>8 Retrospective applications of new 9 criteria that have come into place since the date 10 of the original submission, in some cases years 11 afterwards, are taken into consideration while the 12 ANDA has been sitting at the FDA for a number of 13 months and even years before it's actually picked 14 up, and so that needs to be taken into 15 consideration as well.</p> <p>16 Since the implementation of GDUFA, all 17 informal contact between reviewers and applicants 18 has ceased and has not been replaced with any 19 meaningful alternative, results in major reduction 20 in transparency, and so we would ask the FDA to 21 review comments that we have provided before that 22 was on August 11th for the content and format.</p>	36	<p>1 believes a significant portion of the issues 2 identified during the technical reviews can be 3 classified as Easily Correctable Deficiencies, or 4 ECDs, and communicated to applicants during the 5 review process. Industry is able to respond to 6 ECDs in a very short timeframe, on average 5 7 working days, upon receipt of the ECD, which can 8 facilitate the review process and enhance 9 efficiencies for both the Agency and for industry.</p> <p>10 In the spirit of the goals letter, we 11 request more opportunity to resolve questions via 12 phone and mail, which is a more efficient process 13 for both the Agency and industry resources to 14 ensure timely transparency access to medications. 15 And again I would point the FDA and the panel to 16 the comments that GPhA provided on September 9th 17 regarding this draft guidance.</p> <p>18 Next is prior approval supplements under 19 GDUFA. The draft guidance helps outline the 20 Agency's implementation of GDUFA allowing greater 21 predictability for industry and more timely review 22 of supplements, clarification requested on changes</p>
35	<p>1 There is significant information in there that 2 addresses many of the points and beyond of what 3 I've just addressed.</p> <p>4 And, finally, we would recommend that 5 the Agency and GPhA collaborate to develop a 6 guidance to address common quality issues related 7 to submissions and reviewer consistency.</p> <p>8 Next is controlled correspondence 9 related to the generic drug development. GPhA has 10 significant concerns regarding certain aspects of 11 this draft guidance. To meet our shared aims of 12 reducing the review cycles, FDA should encourage 13 early engagement and feedback in advance of 14 submissions in order to minimize FDA review 15 timeframes and expedite patient access to 16 generics.</p> <p>17 What is the Agency's plan for reviewing 18 and providing a response to controlled 19 correspondence pending an Agency's response prior 20 to Fiscal Year 2015?</p> <p>21 Next is ANDA submissions, amendments, 22 and easily correctable deficiencies. GPhA</p>	37	<p>1 in GDUFA metrics when additions to amendments on 2 PASs is requested, and providing valuable 3 clarification on GMP inspection cycles, and risk- 4 based approach. And again we ask that you refer 5 to the GPhA full comments that were provided on 6 September 9th of this year.</p> <p>7 And then the fifth guidance that was 8 provided in the docket to be addressed in this 9 meeting we're not able to address at this point in 10 time because that draft guidance just came out 11 yesterday, so we're in the process of reading and 12 reviewing rapidly, but we'll save that comment for 13 our follow-up comments to the docket.</p> <p>14 Some additional comments to guidance 15 that we would like to make in addition to the five 16 that were there, and one has already been 17 addressed, but we would like to address it again 18 because it's very important to the entire 19 industry. The Inactive Ingredient Database, or 20 IID, is an important area of need for us. The IID 21 is a critical tool for the generic industry at 22 large. The IID supports ANDAs and should be</p>

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<p style="text-align: right;">38</p> <p>1 complete, accurate, and transparent. The industry 2 should have access to the MDI for all routes of 3 administration. And again we ask that you refer 4 to the GPhA member comments that were provided 5 during the regulatory priorities open session that 6 was in the May timeframe. And as a final note, we 7 believe that providing further investment by the 8 Agency to the IIDs should greatly reduce the 9 number of control correspondences that you are 10 getting currently and are somewhat being addressed 11 in the new draft guidance. 12 Other additional policies. As stated in 13 my opening comments, access is key to public 14 health and an aim of GDUFA. Therefore 15 communications and communications with applicants 16 is important and should be provided, and 17 priorities based on public health needs, target 18 action dates, which have been introduced, and 19 other related actions for ANDAs are not included 20 in the cohort metrics, and we think that they 21 should be. 22 A realistic plan based upon dedicated</p>	<p style="text-align: right;">40</p> <p>1 And then what other GDUFA implementation 2 topics are needed for the guidance. Guidance 3 clarifying QBD, QOS, requirements and expectations 4 we think is an important guidance to review and 5 consider. Industry needs a consistent approach of 6 predictability. 7 To date, guidance documents have focused 8 on processes rather than on what is quality for an 9 ANDA submission for an agency. So as we've talked 10 at different meetings and different time points, 11 we talk about quality submissions, and we 12 absolutely support that premise, but we want to 13 know what is out there to help us define what is a 14 quality submission, we don't think it's there. So 15 again -- and I've said this before, but I think 16 it's worth repeating, GPhA would like to recommend 17 that the FDA collaborate with the industry to 18 develop a guidance to address common quality 19 issues on ANDA submissions. 20 Thank you. 21 MS. NGUYEN: Thank you. 22 (Beginning to clap.)</p>
<p style="text-align: right;">39</p> <p>1 resources to address the enormous backlog of ANDAs 2 and prior approval supplements should be reviewed 3 and addressed. 4 Continued meaningful interactions with 5 industry while planning new guidances before 6 enforcing those draft guidances would be greatly 7 appreciated, and we think that would help both the 8 Agency and the industry as we move forward. 9 Pre-ANDA consultation meetings and 10 communications we believe is an important and a 11 key component to moving forward with GDUFA. 12 Central repository or bulletin board 13 announcements to industry to post-current thinking 14 on ANDA data requirements, webinars, et cetera, so 15 that there are no surprises on either side would 16 be greatly appreciated. 17 Provide specific timeframes, for 18 example, 60 days or similar, of controlled 19 correspondence to answer suitability petitions. 20 And more details, as I said before, will be 21 provided in the open docket in the periods coming 22 up in the next few weeks.</p>	<p style="text-align: right;">41</p> <p>1 MS. NGUYEN: Questions from the panel? 2 MR. FLANAGAN: Someone started to clap. 3 (Laughter.) 4 MR. GAUGH: Just flies, I think they 5 were trying to -- 6 (Laughter.) 7 MR. FLANAGAN: So, Mr. Gaugh, thanks for 8 all the detail, it's very helpful. Lots of 9 potential areas of improvement you identified. 10 MR. GAUGH: Yes. 11 MR. FLANAGAN: When we're thinking 12 through what the most urgent priorities should be 13 and the next tranche of policy improvements that 14 we make, how important is communications 15 transparency? And I have a follow-up question. 16 MR. GAUGH: That would be number one. 17 MR. FLANAGAN: So some of the things 18 that we've contemplated doing to improve 19 communications transparency, sort of a transition 20 management tool as we get into goal dates, are 21 target action dates for pre-Year 3 submissions 22 when we pick one up for review, assigning a target</p>

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42	<p>1 action date, and notifying the applicant with 2 caveats of when we hope to take action on that 3 submission so that folks know when something is 4 under review. 5 In the ECD space, having more real time 6 communications potentially working on pre-CR 7 majors, and for the most commercially significant 8 and most important from a public health 9 perspective, first generics, which we'll discuss 10 in much greater detail this afternoon, possibly 11 offering some sort of -- providing some sort of 12 mid-review status update, would all those things 13 be helpful or any of them not a good idea? 14 MR. GAUGH: So I would answer with a 15 caveat. Absolutely all of those would be helpful, 16 and we do applaud that the FDA is moving in that 17 direction, and there has been a lot of 18 conversation back and forth over many months 19 between GPhA and the FDA about getting to some of 20 these points, and so we greatly appreciate that. 21 I think the thing that concerns us and 22 my colleague who was up here just before talking</p>	44
43	<p>1 about inspections and fees, that's completely 2 understandable where he's coming from, but 3 additionally to that and on the finish-fill dosage 4 side, our companies -- and I hate to say it quite 5 this way, but I'm going to, live and die by when 6 they are going to get their ANDAs approved, and 7 the decisions that they have to make to prepare 8 for that, and that preparation is a bit of a 9 runway. So you can't get approval today and 10 launch tomorrow if you don't know that today is 11 your approval date. So there needs to be some 12 further clarity, and you're providing some of that 13 through what you discussed but with a backlog of 14 over 3,000, probably pushing more towards 3,200, 15 3,300, that's a significant number of products 16 that are very important to the industry as well as 17 to the American public and the health care system. 18 And I know you have a priority review process in 19 mind. We just know that there are products that 20 are going to fall at the bottom end of that 21 priority, and those companies still need clarity 22 on where they are and what they can plan for the</p>	45

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<p style="text-align: right;">46</p> <p>1 MS. NGUYEN: And this vein of 2 discussion, this is more focused on backlog and 3 your one year to application since as we enter 4 Year 3, you will have the clarity that you seek. 5 MR. GAUGH: Absolutely. That's in the 6 metrics, yes. So this is absolutely backlog Year 7 1, Year 2, that we're talking about specifically. 8 MR. FLANAGAN: So actually I have a 9 follow-up question which it may be hard for you 10 to generalize. There may not be a tidy answer. 11 But given the volume of the submissions -- right? 12 -- and our obligation to move the freight along, 13 it's probably not feasible in the immediate short 14 term for each RPM to consult in depth with each 15 applicant concerning the status of each 16 submission, and like discern the best regulatory 17 path forward. It's very resource intensive and 18 requires a lot of experience and sophistication. 19 Right? Are there individual data points that are 20 more helpful than others when your member 21 companies are trying to do the calculus on whether 22 to launch a product? For example, anecdotally</p>	<p style="text-align: right;">48</p> <p>1 MS. NGUYEN: I think we're going to get 2 started in a minute, so if you could please find 3 your seats. 4 Okay, thanks, everyone. During the 5 break, the Acting Director of the Office of 6 Generic Drugs arrived, Cook Uhl. Could you please 7 introduce yourself? 8 DR. UHL: Am I on? 9 MS. NGUYEN: Yep. 10 DR. UHL: There's no color here to tell 11 me I'm on or not. 12 MS. NGUYEN: You're always on. 13 DR. UHL: All right. Good morning. 14 Kathleen Uhl, Acting Director of OGD. Thank you. 15 MS. NGUYEN: Thank you. So we'll just 16 go right into the next set of presentations. Up 17 next is Robert Vincent. Please when you start 18 your presentation state your name and your 19 affiliation. 20 MR. FLANAGAN: Is Marcie next? 21 MS. NGUYEN: Marcie is not going in the 22 morning.</p>
<p style="text-align: right;">47</p> <p>1 we've heard from a lot of people that if the 2 submission is doing well in chemistry, that they 3 feel like that's disproportionately important, and 4 I know it's hard to generalize, but to the extent 5 that you can, could you please? 6 MR. GAUGH: Yes. And so you're right, 7 it is hard to generalize, and I think probably the 8 best option is to say that we have provided some 9 comments to the FDA on communications and on 10 various different example time points that could 11 be used, and we'll add those comments to this 12 docket as well, and we would refer you back to 13 those. 14 MR. FLANAGAN: Very well. Thank you. 15 MR. GAUGH: Thank you. 16 MS. NGUYEN: Thank you. 17 It looks like next we have a 15-minute 18 break. So I have let's reconvene at 10:05. I 19 have 9:49. And as a reminder, the Wi-Fi network 20 is "Guest Net," and the user name and password are 21 "FDA," all caps. 22 (Break.)</p>	<p style="text-align: right;">49</p> <p>1 MR. VINCENT: Okay. Good morning. 2 Thank you. I'm Rob Vincent, with Teva 3 Pharmaceuticals USA. And I thank you for the 4 opportunity to speak this morning and provide 5 comments with regard to the GDUFA implementations. 6 The first thing I thought was important 7 was we should note that there certainly have been 8 already some benefits seen from the movement taken 9 toward GDUFA for the industry. First off, the 10 implementation of the complete response letter or 11 concept has certainly been an improvement. It 12 gives industry a concept of where each of the 13 disciplines is at with regard to their review, how 14 significant the issues may be within each of the 15 disciplines as opposed to getting discipline- 16 specific letters. The chemistry could be further 17 along in biopharmaceutics or compliance or another 18 area further behind depending on the given file, 19 so this gives us a better picture of the overall 20 application review. 21 The issuance of the multiple guidances 22 that have come out regarding providing greater</p>

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50	<p>1 clarity on what the Agency expectation is for the 2 original ANDAs and prior approval supplements 3 certainly is a benefit. Any guidance is better 4 than being left to shoot for a target that we 5 can't see.</p> <p>6 We also have seen more timely response 7 on new post-approval submissions that are being 8 sent to the Agency as well as the backlog 9 submissions has certainly been getting addressed.</p> <p>10 And also the early complete assessment 11 reviews of DMFs certainly helped in terms of 12 knowing that our DMFs are acceptable for review. 13 The issues there have been taken care of, or at 14 least are acceptable for -- excuse me, not taking 15 care of -- they're essentially complete to allow 16 full review, and we are certainly in anticipation 17 of the 3-year metrics at greater clarity to review 18 timing allows us to, as was said earlier, make 19 better business plans with regard to our business 20 of providing drugs to the consumer.</p> <p>21 The challenges that we have had to date. 22 For one, the timing of the guidances has been a</p>	52	<p>1 correspondence guidance expressly states you're 2 not to check on status. Now, I understand when we 3 get to the metric where you're expecting a 4 response in 2 months, you don't want to take up 5 that time in the 2-month period responding to 6 various industries' requests on status, but when 7 it gets beyond the metric date, technically there 8 is nothing in the guidance that would allow you to 9 call in to check status. It could effectively 10 hang out in limbo.</p> <p>11 And also pre-ANDA meeting requests. 12 This is something that requires a very 13 timely feedback from the Agency, and yet they're 14 being excluded from the controlled correspondence 15 metric, which again is not encouraging or it's not 16 helping with regard to the predictability and the 17 review process or timing.</p> <p>18 And then, of course, again just the 19 controlled correspondence guidance, having 20 excluded so many things from consideration under 21 that guidance is causing concern because they were 22 items that would have been considered controlled</p>
51	<p>1 little close to the start of Cohort 3, so there 2 hasn't been a whole lot of time to comment or to 3 prepare comments, although I also understand that 4 this is not a small feat that we're attempting, 5 there is a lot of work to be done, so it's not 6 unexpected, but it's a little difficult to deal 7 with multiple issuance of guidance one on top of 8 the other.</p> <p>9 And while the spirit of GDUFA was 10 intended to increase transparency and 11 predictability in the review process and timing, 12 there have been a few little snags in there. 13 Currently the communications from the PMs 14 regarding applications has been less informative 15 than it was even in the pre-GDUFA days. When you 16 call for a status, any meaningful information is 17 not provided, it's usually something more along 18 the lines of, "It's in review. Call back in 3 19 months." A little difficult to like again make 20 any business decisions based on the limited bit of 21 information on that.</p> <p>22 Another example is the controlled</p>	53	<p>1 correspondence previously.</p> <p>2 Now, my intent here really was not to 3 provide specific comment on the guidances that 4 have been issued so far but more so the questions 5 that were raised by OGD to try to address some of 6 those. So specific comments to the guidances 7 we'll be issuing in writing to the docket.</p> <p>8 But as far as, are there GDUFA 9 implementation issues related to the five 10 guidances that have not been addressed? And again 11 I say that submissions that don't fall into the 12 metric, and I'm of course now drawing a blank for 13 the actual numbers, but say it's, what, 60 percent 14 in the first year, I realize you're targeting as 15 many as you can. Your goal is at least 60. Those 16 that don't make it into the metric, though, there 17 is no time limitation given. And I realize some of 18 them are going to be complicated and take more 19 time, but at some point they can't be allowed to 20 fall into yet another backlog situation or 21 recreate the backlog situation.</p> <p>22 We're also looking for ideas to when the</p>

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54	<p>1 GDUFA guidances themselves are targeted to become 2 official. The hope is that once they are 3 official, they'll become more consistently applied 4 and enforced across all of the application reviews 5 and again gives us a better gauge as to how to 6 predict issues with the Agency. 7       And again I'll stress that just the 8 controlled correspondence guidance just seems to 9 have removed far too many of the topics. The more 10 complicated issues are the ones that really are 11 the ones that we need Agency feedback on and your 12 input, and those seem to be the ones that have 13 been expressly removed from the controlled 14 correspondence guidance. 15       Other GDUFA implementation topics that 16 are in need of guidance, defining again -- and I'm 17 going to hit on the controlled correspondence 18 because that seems to be the one that we've had 19 the biggest issue with, is defining a process and 20 timing for those topics that have been excluded 21 from controlled correspondence. If they are going 22 to remain excluded from the controlled</p>	56	<p>1 help you meet any of the metrics going forward and 2 will allow you to better utilize your resources. 3       There also needs to be clarity with 4 regard to single dose versus maximum daily dose 5 issues with regard to inactive ingredients. We've 6 heard tell that the bar to get an application 7 accepted is, is your formulation acceptable from 8 an inactive ingredients on a single unit that your 9 max daily is a review issue? If your application 10 gets issued -- or excuse me, accepted but then can 11 ultimately become approvable, it kind of defeats 12 the purpose. So not having that information at 13 the time of filing certainly creates an issue for 14 industry, and the addition of that information 15 into the database I think would ease the process 16 on both sides of the -- both for the Agency as 17 well as for industry as well as dosage form 18 interchangeability. 19       Can an ingredient that was used in a 20 buckle formulation be used to justify a sublingual 21 or a transmucosal, likely a topical in a 22 transdermal, can they be interchangeable?</p>
55	<p>1 correspondence, then there needs to be a process 2 by which we can handle these more complex issues, 3 or those may require multiple discipline reviews. 4 Just because they're difficult doesn't mean they 5 should be allowed to be set aside. 6       And then, let's see, are there topics or 7 issues related to generic drug development not 8 directly affected or as a result of GDUFA that 9 need development of guidance? And this one seems 10 to keep coming up, the inactive ingredient 11 database. The accuracy and completeness of the 12 current database is lacking. There have been 13 instances where we believe that ingredients had 14 originally been in the database, had been removed 15 either because the application reference had been 16 withdrawn, but no indication as to whether it was 17 withdrawn for reasons of safety. If it wasn't 18 withdrawn from safety, could it or should it stay 19 within the database? By addressing the issues 20 with the inactive ingredient database, we believe 21 it will actually decrease the number of controlled 22 correspondences coming to the Agency, which will</p>	57	<p>1       Other topics will be, of course, complex 2 drug products, LARs, rings, combination products 3 where a drug and device are closely related or the 4 device is regulating the actual delivery of the 5 drug, not just quantity, but duration, abuse- 6 deterrents, which I know there have been recent 7 discussions with the agency concerning that 8 particular topic. 9       And finally, one which I know is based 10 in law, but Section 1113 of FDASIA was originally 11 aimed to extend the Paragraph 4 applicants period 12 to obtain a timely tentative approval without 13 forfeiting the eligibility for exclusivity, but 14 due to the language of the law, there is an 15 ambiguity as to regarding what this length of 16 period is. Is it 30, 36, or 40 months? 17       So whether it be some sort of guidance 18 with regard to where that particular 19 interpretation may be would certainly be helpful 20 for the industry in determining -- in helping us 21 to determine, are we still eligible? Have we 22 forfeited? And it affects our business decisions</p>

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<p style="text-align: right;">58</p> <p>1 in preparation for launch. 2 So that's the end of my presentation. 3 So thank you. 4 MS. NGUYEN: Thank you. 5 Questions? 6 MR. FLANAGAN: Thank you very much for 7 the specificity. This is not a passive-aggressive 8 request, I'm just really seeking clarity. On the 9 complex drug product and combination drug product 10 issues, have you all submitted comments to the 11 science side of OGD as they formulate their 12 regulatory science agenda? To what extent is this 13 a science issue versus a policy issue? Can you 14 comment on the interplay between science and 15 policy on that bucket of tough issues? 16 MR. VINCENT: Oh, boy. That would be 17 tough to do. You're right. With some of these 18 topics, the complex, the device oriented, there is 19 a very much of an intertwining of both the policy 20 and the science. It's very difficult to separate 21 the two issues. 22 With regard to have there been comments</p>	<p style="text-align: right;">60</p> <p>1 there is -- I respect your opinion of that they're 2 close and they're intertwined, however, if you 3 don't have the scientific basis, it's hard to 4 create the policy in certain circumstances, and it 5 would be helpful for us for you to tease that out 6 in the comments that you submit to the docket 7 because what are the scientific gaps drives the 8 GDUFA research program. What are the policy gaps? 9 So are there particular guidances that you would 10 like some clarity on or would like to see? That's 11 fine. If there's a scientific gap, that's kind of 12 a separate issue. So it's helpful for us to have 13 them nuanced and teased out to assist us because 14 this is multiple components moving forward in the 15 entire program. 16 So to the extent that you could, Teva, 17 or other companies could in their comments to the 18 docket, it would help us tremendously. 19 MR. FLANAGAN: Because we already know 20 that complex drug products are a regulatory 21 challenge for us. 22 DR. UHL: Right.</p>
<p style="text-align: right;">59</p> <p>1 or questions or communications with the science 2 staff within OGD, I believe there have been 3 members, at least within my organization, that 4 have reached out to have some of those 5 discussions. Some of them have been favorable and 6 productive, and others not as much as we would 7 have liked. Certainly, again, any communication 8 is better than radio silence, so we certainly 9 welcome the communication and the opportunity. 10 As far as policy goes, on that one I'm 11 going to have to defer, on that I'm not as 12 familiar with where the company has taken a 13 stance. 14 DR. UHL: Yeah. So can I just expand a 15 little bit on what Keith is saying, and maybe I'll 16 put words in your mouth. I apologize, Keith. 17 It's usually the other way around, that the lawyer 18 puts the words in somebody's mouth, but no worries 19 here. 20 There is a process for regulatory 21 science with GDUFA, there is a regulatory science 22 program with money and grants and research, and</p>	<p style="text-align: right;">61</p> <p>1 MR. FLANAGAN: The issue is which 2 subissues and which types of products should we 3 focus our regulatory -- your regulatory resources 4 on. 5 DR. UHL: Right. Right. It will help 6 us in a prioritization scheme because there are 7 limitless numbers -- well, maybe not limitless 8 numbers, but we do know there are a number of 9 products for which there are no generics. There 10 is a finite amount of resources that we have to 11 create either the science base or the policy base 12 for those. So it would be helpful to get that 13 kind of input. 14 So can I follow up with a second type of 15 question? Thank you. 16 Controlled correspondence, you used a 17 considerable amount of your time talking about 18 that. Could you expand, and if you don't feel 19 comfortable now, but if you could in the docket, 20 on what specific areas you feel were removed that 21 should be added back in, and in addition, the 22 aspect of a process to handle more complex issues.</p>



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<p style="text-align: right;">62</p> <p>1 Can you expand on what that process could be, 2 should be? What would that look like? 3 MR. VINCENT: I'll take the second part. 4 Actually the second part may actually be a little 5 easier only because it's proposals or ideas of 6 ways you could potentially approach that topic. 7 The complex issues, complex products, or 8 combination products, require more in-depth 9 knowledge of the product and the process, 10 something that you've got a handful of people in 11 the industry perhaps that know of that technology. 12 Some may or may not reside within the Agency. The 13 only way to get that information is to have more 14 open dialogue between industry and the Agency, 15 perhaps as -- well, actually you've already 16 started doing some of it with the abuse-deterrents 17 recently, there have been some communications 18 there. There are networks on the branded side, 19 possibly a little easier than it does on the 20 generic side. It's a little difficult for us to 21 get together in a room with all of our -- you 22 know, all of the generic industry and start</p>	<p style="text-align: right;">64</p> <p>1 perspective, you've got multiple generic companies 2 potentially targeting a specific branded product. 3 And we're all trying to find ways of developing a 4 product that is the same but depending on given 5 development requirements, it may have to be just a 6 little different for legal purposes. So we're all 7 finding different ways of making it that little 8 different, and we're certainly not wanting to 9 share that information with our direct 10 competitors. 11 MS. NGUYEN: That's helpful. thank you. 12 I had another question. You had mentioned that 13 status checks are not permitted. You talked about 14 this in the context of the controlled 15 correspondence guidance and suggested that status 16 checks after a metric had passed might be 17 appropriate. 18 MR. VINCENT: Right. 19 MS. NGUYEN: Was that comment intended 20 for just the controls metrics or all metrics? 21 MR. VINCENT: Certainly it would be nice 22 for all metrics. I understand that it would be</p>
<p style="text-align: right;">63</p> <p>1 talking about areas of science because some of it 2 gets into what's proprietary and what's our 3 business edge. So it's a little difficult to be 4 forthcoming in a more public environment. There 5 are perhaps an opportunity for more one-on-one 6 meetings between select members of the industry 7 and members of OGD. It would be helpful and it 8 would allow that exchange of science information 9 that wouldn't be as accessible in a public forum. 10 I realize that's a little more resource intensive 11 for the Agency, having to meet individually, but 12 otherwise I don't know that you would be able to 13 get that free flow of ideas on the science. 14 MS. NGUYEN: Does that answer all the 15 questions? 16 (No audible response.) 17 MS. NGUYEN: Could you comment on why 18 the flow of information challenges exist more in 19 the generic sector than in the brand sector? 20 MR. VINCENT: Well, that's my 21 assumption. I've never worked in the branded side, 22 I'll say that right off the bat, but from my</p>	<p style="text-align: right;">65</p> <p>1 better if the Agency's resources were spent 2 reviewing instead of answering calls from 3 industry, but whether it be an application, a 4 controlled correspondence, a prior approval 5 supplement, you've exceeded your goal date and 6 you've not gotten your letter, so you're not going 7 to be one of the applications or the supplements 8 that make it within the GDUFA metric date. 9 Granted, industry has not been 10 prohibited from getting a status check, but like I 11 said earlier, the status checks that we've been 12 getting haven't been exactly meaningful in helping 13 us have any kind of business intelligence with 14 regard to the review of those submissions. So if 15 those applications or those supplements or those 16 controlled correspondences that have not met the 17 metric or the action date, if we could get a more 18 meaningful correspondence on that, that might be a 19 middle ground to work with. It's certainly one 20 idea. 21 MS. NGUYEN: And by status check, you 22 mean when we'll get you the answer, or what more</p>

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<p style="text-align: right;">66</p> <p>1 information would you like? 2 MR. VINCENT: Timing would be helpful 3 certainly. If there is any indication as to -- 4 well, I'll go back several years when, you know, 5 you might be able to get the comment that 6 chemistry review is just wrapping up, we should 7 have those -- we're hoping to have those questions 8 issued within the next 2 weeks. Bioreview is 9 done, they found it acceptable. That's something I 10 didn't know before. So that gives me a better 11 gauge as to how far my application is in the 12 review process. 13 So it can be timing. It can be somewhat 14 -- I realize you can't necessarily give the 15 content of the comments, but even if there is a 16 gauge as to whether it's major or minor ECD would 17 certainly be helpful. 18 MS. NGUYEN: So at the start of your 19 presentation, you were highlighting the benefit of 20 receiving complete response letters -- 21 MR. VINCENT: Right. 22 MS. NGUYEN: -- that gave you</p>	<p style="text-align: right;">68</p> <p>1 Larry? 2 MR. FLANAGAN: It's an easy question. 3 Don't worry. 4 UNIDENTIFIED MALE SPEAKER: Okay. Whew. 5 (Laughter.) 6 MR. FLANAGAN: So one of the challenges 7 we have is the commitment letter only gives us 8 credit towards a GDUFA action if it's a complete 9 response; right? So that means the commitment 10 letter calls for us to have all the reviews 11 completed and to have inspections done and 12 compliance status determination and everything you 13 would want to know wrapped up in one package, and 14 there's the benefit of getting a complete 15 response, which you highlight. However, the 16 downside is it involves delay as you wait for all 17 the pieces to come together. Right? 18 MR. VINCENT: Right. 19 MR. FLANAGAN: We are thinking, as I had 20 an exchange with Mr. Gaugh, we're thinking about 21 ways that we can show some flexibility because of 22 the downside of that commitment letter</p>
<p style="text-align: right;">67</p> <p>1 information on the different disciplines and the 2 application status with respect to those reviews. 3 Could you, following on your comments, tell us 4 about the benefit, if any, of having information 5 about pre-CR majors? Which would be not a 6 complete response. 7 MR. VINCENT: Right. Uh -- 8 MS. NGUYEN: Is this something you want 9 us to work on? 10 MR. VINCENT: Right. Having information 11 pre-CR majors. Good question. That one requires 12 some thought. 13 MR. FLANAGAN: Is the answer that you 14 get significant deficiencies more rapidly so you 15 can start to attack them and move your submission 16 forward more rapidly than you otherwise would have 17 if you had to wait for the CR? 18 MR. VINCENT: Wait for the response, 19 right. 20 MR. FLANAGAN: Can I ask a related -- 21 we're over time, but -- 22 MS. NGUYEN: May we have more time,</p>	<p style="text-align: right;">69</p> <p>1 requirement. If we were doing things like issuing 2 pre-CR majors and on occasion if the scientific 3 and technical review is complete and we didn't 4 have the inspection, how supportive do you think 5 industry would be about giving us wiggle room on 6 that because every time that we do something to 7 try to be helpful, like I just described, it hurts 8 us from a GDUFA perspective. We cannot take 9 credit for that action. 10 What are your thoughts on that? 11 MS. NGUYEN: That was not a short 12 question. 13 MR. FLANAGAN: It was pretty easy. It 14 was like a softball question that you're supposed 15 to say -- 16 (Laughter.) 17 MR. VINCENT: Okay. To that, I'll ask 18 the first part of the question: Would getting 19 that forewarning of some of those major issues 20 ahead of the CR major be helpful? Absolutely. 21 And depending -- I'm sure there are certain 22 circumstances where if the issue is major enough,</p>

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<p style="text-align: right;">70</p> <p>1 a company could decide, you know what? I almost 2 have to go back and redevelop the product to 3 potentially do new studies. I don't have the 4 resources to do that, and they could withdraw the 5 application at that point, thereby not consuming 6 your resources, continuing on in the reviews. 7 So when issues are major enough, I would 8 support -- I would think that would certainly give 9 industry a leg up, it gives us more time to 10 respond, we'll be able to respond to the major 11 when it comes in, in a more timely manner, and 12 keep the whole review process going much better. 13 So to that, I don't know that anyone would argue 14 with getting information early, especially if it's 15 major to the development. 16 The other one -- the other part of the 17 question actually, I don't know, it's somewhat of 18 the softball part of the question in that, how do 19 you do it in such a way that you can relay that 20 information and still get some sort of credit? 21 Because it leads into the ultimate -- your credit 22 only comes in at the complete response. Should</p>	<p style="text-align: right;">72</p> <p>1 more appropriate to be submitted to that docket, 2 please do so or submit comments to both dockets. 3 That way, we and the right folks can consider them 4 as we develop our priorities for the coming year. 5 Thank you. 6 Next up is Marcie McClintic Coates, from 7 Mylan. 8 MR. FLANAGAN: No. 9 MS. NGUYEN: No. 10 MR. FLANAGAN: It's Good Keith. 11 MS. NGUYEN: Good Keith. Oh, I'm sorry. 12 I'm out of order. Did I just say "Good Keith" on 13 the microphone? 14 (Laughter.) 15 MS. NGUYEN: Keith Webber. I'm sorry, I 16 don't have my correct papers in front of me. So 17 could you please state your affiliation? 18 DR. WEBBER: Yes. Keith Webber. I am 19 affiliated with the generics industry in general, 20 with Perrigo Company specifically. And I first 21 want to start out with thanking the FDA for 22 providing this venue for us to provide comments</p>
<p style="text-align: right;">71</p> <p>1 there be consideration for that? Absolutely, 2 especially when it runs into a situation where the 3 application may eventually get withdrawn. There 4 will be no issuance of a major letter, yet you've 5 consumed some of your resources in identifying 6 some of these issues. So my guess is you're going 7 to have to go back in and look at the policy and 8 potentially within GDUFA2 structure something in 9 there that would allow for that communication 10 during that initial review period, but it's 11 something I think overall industry would certainly 12 welcome. 13 MS. NGUYEN: Thank you. Any other 14 comments from the panel? 15 (No audible response.) 16 MS. NGUYEN: So this is a general 17 comment. You know, we've asked a couple of 18 questions of you and of the room. If folks have 19 comments, please submit them to the docket. The 20 docket number for today is FDA-2014-N-1168. You 21 may know that we had a regulatory science public 22 hearing earlier this year. If your comments are</p>	<p style="text-align: right;">73</p> <p>1 regarding recent GDUFA guidance documents as well 2 as other topics which could use guidance. 3 And I want to start out, let's see, with 4 figuring out how to use this. There we go. 5 I need to start out with some 6 disclaimers. Number one, my comments at this 7 public hearing are not meant to be a specific 8 benefit to my company, Perrigo, but they are 9 really intended to improve the general 10 collaborative effort between the generic drug 11 industry and the FDA to accelerate the development 12 and approval of generic alternatives to brand name 13 pharmaceuticals. And finally, I haven't received 14 any specific compensation for this presentation. 15 Next on the agenda, I would like to say 16 thanks to the FDA for the GDUFA invitation 17 activities that you've gone through so far. 18 Quarterly meetings with industry, representatives 19 through GPhA, and other venues at the FDA we have 20 greatly appreciated. Our publication of the FDA 21 processes and procedures in your maps online is 22 very helpful for us to understand how the FDA</p>

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<p style="text-align: right;">74</p> <p>1 addresses issues and deals with applications. The 2 publication of guidance for industry that we're 3 talking about today I think has been very helpful 4 to the industry. 5       The meeting with industry via the small 6 business and industry assistance process I think 7 has been appreciated by many as well. And then 8 you've also held webinars to provide information 9 to the Agency with regard to GDUFA implementation 10 and other topics. 11       Today you presented us in a Federal 12 Register Notice with two basic areas, one is on 13 the draft guidances and other GDUFA issues that 14 are related to the draft guidances, and then other 15 topics that need guidance addressed. That's the 16 main area I'm going to speak about. I have one 17 slide which covers the afternoon on 180-day 18 exclusivity. I'll probably throw that in this 19 morning if I can, but will not speak this 20 afternoon on that topic since it's really not the 21 main thrust of my presentation. 22       Let me start out to say many of the</p>	<p style="text-align: right;">76</p> <p>1 complexity of policy development. I think we do 2 have some concerns about how broadly that might be 3 applied, not to have it be sort of a pat answer, 4 "Oh, this is policy development, we're going to 5 get out, we won't answer that." 6       So what falls under policy development, 7 further guidance in that would be helpful. And 8 requests that will not be considered controlled 9 correspondence, bioequivalent study design 10 requests, clinical protocol design requests. I 11 understand those are fairly complicated or can be. 12 But as was brought up by another speaker, what is 13 the alternative there? If we can get meetings with 14 OGD to discuss those issues in a timely manner, 15 that I think would be sufficient and perhaps 16 preferable to a controlled correspondence, but 17 that depends on being able to get those meetings. 18       Let's see. Next, Number 3, inactive 19 ingredients can be addressed in one controlled 20 correspondence. Given the timelines, I can 21 understand that. To some extent, however, it's 22 likely to increase the number of controlled</p>
<p style="text-align: right;">75</p> <p>1 comments I have in my presentation are much more 2 specific than you've heard so far, and I hope 3 that's appreciated. We will be submitting comments 4 to the docket as well, but I thought that to hit 5 on some really focused concepts with regard to or 6 focused areas within the guidance document would 7 be helpful. 8       Thumbs-up mean good, we like it. In the 9 controlled correspondence related to generic drug 10 development guidance document, the citizens 11 petition is being preempted by controlled 12 correspondence -- or preempting controlled 13 correspondence, I said it wrong -- is understood. 14 I mean, there are different requirements, 15 different regulatory issues there. 16       I think generally the out-of-scope 17 topics and out-of-scope entities that are 18 described in that guidance document are presented 19 with sufficient clarity, although there are some 20 questions that we have in that regard. Number 21 one, CC questions requiring policy development 22 will not be answered. I can understand the</p>	<p style="text-align: right;">77</p> <p>1 correspondence you receive. There is no reason 2 that a manufacturer can't submit two controlled 3 correspondence, one with three, one with one, if 4 they have four questions. So it's not really 5 going to do I think much in terms of workload 6 other than increase it in terms of tracking those 7 documents, getting responses sent out on those, et 8 cetera. So that might be something to consider 9 changing. 10       The FDA does not review proposed 11 formulations that are not required to be Q1/Q2 12 equivalent. I know this has been a policy before. 13 It does create some difficulties for the industry 14 in that if a biowaiver is needed or dependent upon 15 a Q1/Q2 formulation, then we really should be able 16 to get an answer on those because that could 17 result in a Refuse- to-receive, and a Q1/Q2 may 18 not be required for approval, but if it's required 19 for getting in the door, then we need to know 20 that. 21       The FDA will not respond to status 22 requests regarding pending controlled</p>

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78	<p>1 correspondences. I think if the GDUFA guideline 2 deadline has passed, then we should be able to 3 request a status update on that controlled 4 correspondence because oftentimes things that are 5 submitted in controlled correspondence are 6 critical to decision in terms of product 7 development. 8       This slide here addresses the RTR 9 guidance which was actually just finalized 10 yesterday, so I won't go into much more detail in 11 this other than to say my first comment there 12 regarding the five-day response time for filing 13 deficiencies we felt was too short, but we do 14 notice that that was up to 7 days, not quite the 15 10 we hoped for, but that's a good move in the 16 right direction. 17       Now I'll move on to the ANDA content and 18 format guidance. This is a thumbs-up. It's a 19 very valuable and appreciated guidance document by 20 industry. It provides a lot of good information. 21 There are some very specific comments related to 22 that document. First off, in Module 1,</p>	80
79	<p>1 information is asked to demonstrate sameness to 2 the RLD for inactive ingredients and that they 3 don't impact safety and efficacy. It seems like 4 in Module 1 it's asking for depth in detail of 5 information that really I think would be better 6 put into Module 2 and 3. So if that's not your 7 intent, maybe further guidance in that area would 8 be helpful. 9       In Module 2, the CTD summaries, thumbs- 10 up. Question-based review I think is something 11 that's been very successful and helpful. 12       Let's see. Now moving on to Module 3, 13 drug substance section. Information on drug 14 substance manufacturers ask for three different 15 numbers, a Central File Number, the Facility 16 Identifier Number, and the Data Universal 17 Numbering System number. It seems like there are 18 an awful lot of numbers there. Probably the FEI 19 number and a DUNS number would be sufficient. We 20 would request or suggest that some of the GDUFA IT 21 funds be funneled toward developing electronic 22 cross-referencing system that would eliminate some</p>	81

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82	<p>1 Moving on to the guidance on ANDA 2 amendments and ECDs, Easily Correctable 3 Deficiencies. This was one of the major comments 4 we had, was regarding major amendments. It says 5 that a request by the Agency for full-term 6 stability data would be a major amendment. We find 7 this to be problematic in that if full-term 8 stability is needed, it may in and of itself 9 require a 12-plus-month delay in getting that 10 response to the Agency if that data has to be 11 generated, which it would have to be generated. 12 So adding 10 months to the review rather than a 13 standard 3 months doesn't seem to be really 14 justified by the length of time it takes to review 15 stability data, it doesn't take that much extra 16 time, and so it's an additional burden of up to 22 17 months to the Agency -- to the industry. 18 Moving to the guidance on prior approval 19 supplements, we appreciate the documentation. 20 CGMP inspection cycle for the different types of 21 facilities. That's very good. And the acceptance 22 of comparability protocols in lieu of multiple</p>	84	<p>1 with written responses doesn't, we think, meet the 2 GDUFA goal of interacting with the applicant, as 3 we agreed to in the GDUFA goals letter. 4 Some other topics, very specific ones. 5 Setting specifications, how that's done, we see 6 variability there. Sampling plans are another 7 area where we could use additional guidance, and 8 safety of inactive ingredients. So specifically 9 with setting specifications, we get comments, the 10 specs are too wide, set them to the RLD data. If 11 we set specs to the RLD, we go to (inaudible), 12 test it, tighten it to match the process results. 13 We matched ICH. Maybe we are asked to tighten to 14 match the process. I think there is some focus on 15 developing specifications that are clinically 16 meaningful, and so this is an area where I think 17 we really need to get better guidance. 18 Sampling plans, we've gotten variable 19 questions from the Agency with regard to sampling 20 plans, 3 samples per batch, 10 samples per batch, 21 5 samples per batch. There doesn't seem to be a 22 clear policy there in terms of sampling plans.</p>
83	<p>1 prior approval supplements is very much 2 appreciated and is something we would like to see 3 more of in the industry. 4 We could use more clarity on what types 5 of changes can be bundled into a single prior 6 approval supplement and which cannot. For 7 example, if you're adding multiple API sources, is 8 that okay? So we would like to know. 9 Other GDUFA implementation topics that 10 need guidances. With regard to the post-complete 11 response letter teleconferences that are part of 12 the GDUFA goals letter, our experience has shown 13 that interactive T-cons are usually not scheduled. 14 Generally, written responses are issued to the 15 industry. We do appreciate that we get clear 16 timelines of when those responses will come, 17 that's very helpful, however, the clarity of 18 direct conversation is really lost in that 19 process, and the written responses don't 20 necessarily address the breadth and depth of the 21 applicants' questions. 22 Finally, responding to a T-con request</p>	85	<p>1 And then finally the safety of inactive 2 ingredients. We would recommend that you consider 3 a FDA approach and accept food standards for 4 inactive ingredients in drugs. We've gotten 5 comments that a component which is safe in foods 6 at quite high levels is not acceptable in a drug, 7 and that just doesn't quite make sense to the 8 industry in general from a safety perspective. 9 And as was said before, revising the IID to give 10 maximum daily intake by route of administration 11 would be very helpful. I won't go into any more 12 details there. 13 With regard to this afternoon's session, 14 I'll just say very quickly I'm sure the FDA will 15 consider -- consideration of eligibility for 180- 16 day exclusivity for specific products be published 17 process. We think the process works well now, 18 don't recommend any changes there. Disclosure of 19 which companies are vying for exclusivity could 20 well put companies at severe commercial 21 disadvantage. That's one comment we have. 22 And again with what legal or regulatory</p>

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86	<p>1 mechanisms could facilitate resolving of 180-day 2 exclusivities. The current criteria for 3 identifying first generics seem to be sufficient, 4 so we're okay with those. That's for my afternoon 5 session. 6 And I thank you again very much for 7 providing this venue and I'll take any questions 8 you have. 9 MS. NGUYEN: Thank you, Keith. 10 Questions. 11 MR. YOUNG: Keith, I have several 12 questions focused on what seems to be the topic of 13 the morning, the IID. So one of the points that 14 you cover in your presentation, I don't recall if 15 you verbalized it or not, but it is on a slide, 16 has to do with the suggestion that because the IID 17 is in need of repair, that essentially levels of 18 inactive ingredients not be considered for filing 19 purposes. Is there an alternative suggestion that 20 would be used in lieu of that? 21 DR. WEBBER: I think that in lieu of 22 that, it would be valuable to move that into a</p>	88	<p>1 to a differential between single dose or short- 2 term acute treatment drugs versus chronic 3 administered drugs that might be given for a 4 lifetime. 5 MR. YOUNG: And my final question. When 6 it's suggested that food levels or a food level 7 statement could be used in lieu of a particular ID 8 level for justification purposes, is there 9 consideration being given to whether or not the 10 length of administration is playing into that sort 11 of suggestion; in other words, acute versus 12 chronic use? 13 DR. WEBBER: Well, most foods are 14 administered chronically. 15 (Laughter.) 16 DR. WEBBER: So I've really given a lot 17 of thought to that, whereas drugs are generally 18 given for less time, usually until the issue 19 resolves or the illness resolves, and so I think 20 using the food safety standards for food additives 21 would be a worst case scenario compared to drugs. 22 MR. YOUNG: Thank you.</p>
87	<p>1 review issue and look at what documentation the 2 company provides to justify the level of the 3 inactive ingredient in their product and also to 4 go back, as part of the review process, and ensure 5 that the levels that are in the generic product 6 are actually not in compliance with the levels 7 that are currently in either foods, I would say, 8 or in other drugs, because the IID, it's not 9 always up to speed, and it also gives you numbers 10 in percentages, which are hard to convert into 11 maximum daily doses. 12 MR. YOUNG: And as a follow-up to that, 13 with respect to -- and I've heard it mentioned 14 several other times this morning, again with 15 regard to the IID, it seems that having the MDI as 16 a listing would be helpful. Are there other types 17 of categories of information that industry feel 18 would be useful to be incorporated into the IID 19 where possible? 20 DR. WEBBER: If possible, I think it 21 might be valuable to have, in addition to the 22 maximum daily dosage, some information with regard</p>	89	<p>1 DR. WEBBER: Thank you. 2 MS. NGUYEN: Go ahead. 3 MS. GIAQUINTO: I believe you gave QBR a 4 thumbs-up in your presentation. Is there anything 5 we can be doing to improve how widely used QBR is 6 in applications currently submitted? Are there 7 other examples we should be putting up on our 8 website or QOS model summaries? 9 DR. WEBBER: I'm not really sure about 10 that. I think that the Agency has done a fairly 11 good job of providing guidance on use of QBR. I 12 know there is a revised list of questions that are 13 out for consideration, not for implementation as 14 yet. I think that it's not clear, I think, to 15 many in the industry how much the QOS is actually 16 used as part of the review process, so that might 17 be something that would be worth perhaps open 18 public discussion as well. 19 MS. GIAQUINTO: Thank you. 20 DR. UHL: Thanks, Keith. I wonder if 21 you could just give a little bit more 22 clarification on the issue related to the Q1/Q2</p>

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<p style="text-align: right;">90</p> <p>1 and biowaivers. 2 DR. WEBBER: Sure. 3 DR. UHL: So is it that industry wants 4 to be able to submit those as controls, so they 5 basically get a response that blesses the 6 application for filing, or what exactly is the 7 ask? 8 DR. WEBBER: Yes. I think the ask is 9 that if Q1/Q2 is required to get a biowaiver for a 10 particular product, then we have the confidence 11 and assurance that if we submit an application 12 that is Q1/Q2 and we submit a biowaiver, that we 13 would not be refused to file because we hadn't 14 done a biostudy. 15 DR. UHL: Okay. Thanks. 16 MS. NGUYEN: I have a few detailed 17 questions. You had mentioned in the ANDA content 18 and format guidance that there were a couple of 19 areas of possible redundancy. 20 DR. WEBBER: Mm-hmm. 21 MS. NGUYEN: Did you have for the three 22 -- or for the two that you flagged, did you have a</p>	<p style="text-align: right;">92</p> <p>1 DR. WEBBER: Mm-hmm. 2 MS. NGUYEN: Should that go into P2 or 3 S404 or any of the other ones? It looks like P2 4 might capture in one place information that is 5 asked for in several other sections, so the CTD. 6 DR. WEBBER: Yes. And I would say that 7 the certificates of analysis should probably go 8 not in the P2 section, that's my own belief, that 9 the P2 is more of an overview summary of the 10 product development, not really delving into as 11 much detail and specifics as perhaps a certificate 12 of analysis would. 13 MS. NGUYEN: Okay. Thank you. And I 14 had a clarifying question. It's actually three 15 slides from that one, my slide 14, but on the 16 post-CR letter teleconference. 17 DR. WEBBER: Mm-hmm. 18 MS. NGUYEN: So right now we give you 19 the opportunity to request a teleconference. 20 Could you tell me what happens so that it ends up 21 that we don't have one getting scheduled? 22 DR. WEBBER: Well, generally we follow</p>
<p style="text-align: right;">91</p> <p>1 recommendation as to whether the information on 2 drug product manufacturers should go in 32P3 or 3 32P52? 4 DR. WEBBER: Let's see, let me go back 5 to that one real quick if I can. Is this a slide? 6 MS. NGUYEN: No. It starts with 7 "Specific Comments Continued." That one. 8 DR. WEBBER: This one. 9 MS. NGUYEN: No. I'm sorry. It's the 10 next one right after that. 11 DR. WEBBER: Okay. Testing description. 12 I think that -- I haven't really given a lot of 13 thought to where it should go. I would suggest 14 that it perhaps go in the earlier section, which 15 is P3 and then -- because that's focused more on 16 the description of the facilities that are 17 performing new tests and put the actual tests and 18 description of tests themselves into the other 19 sections, just off the top of my head, that's what 20 I would do. 21 MS. NGUYEN: Okay. Thank you. On the 22 next slide, information on components.</p>	<p style="text-align: right;">93</p> <p>1 out a procedure of submitting a request for a 2 post-complete response teleconference and provide 3 the information that we are looking for answers 4 to. It's a learning experience for all in 5 industry of how to do this. So in some cases we 6 provide a very abbreviated description of what we 7 need information on, and without going into huge 8 detail, if we get a response back that, well, 9 we're not going to have a meeting, but we will 10 send you written responses, then the written 11 responses may only address superficially what we 12 were requesting information about without really 13 delving into the information that we would provide 14 in a meeting and a discussion that would occur in 15 a meeting. Then we get a response back from the 16 Agency that says we're going to send written 17 responses and we're going to do it by this date, 18 which is, like I said, very nice to get a specific 19 date for those. And then usually we get the 20 responses by that date and we move forward from 21 there with our best guess of what we should do 22 based on that information.</p>



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<p style="text-align: right;">94</p> <p>1 MS. NGUYEN: But you would like more 2 often to have a conversation about the 3 deficiencies, not just the questions that you 4 identify as needing clarity. 5 DR. WEBBER: No, well, not generally 6 about the deficiencies, but we would like to delve 7 more deeply into the reasoning and thought 8 processes that the Agency had with asking that 9 question and then be able to discuss with the 10 Agency our reasoning for why this may be -- how it 11 should be addressed, for instance, what 12 information we might have that would address it in 13 a particular way and not just generally to meet 14 and discuss about the overall deficiencies, but we 15 still continue to be very specific. 16 The result of that I think is going to 17 be that there will be -- if we continue to not get 18 meetings, the meeting requests are going to get 19 much, much more detailed, asking very, very 20 specific questions, get very long and become 21 actually a review document in and of themselves. 22 MR. FLANAGAN: So it's just the</p>	<p style="text-align: right;">96</p> <p>1 believe they could be 30-minute teleconferences, 2 but I think that the face-to-face interaction, not 3 face-to-face, but telephone-to-telephone 4 interaction, with the Agency is much more 5 productive to talk with the scientists directly 6 than it is to just throw something in terms of 7 questions to the Agency, they throw back answers, 8 and we move on from there. 9 DR. UHL: Okay. Thanks. 10 MS. NGUYEN: I don't know if you can 11 give a general answer to this question, but in 12 this teleconference, do you find that there are 13 times when FDA has misunderstood the content of 14 the information provided in the application and 15 you would like to use the teleconference as an 16 opportunity to clarify as opposed to seek more 17 information on how to respond to the deficiency? 18 DR. WEBBER: Well -- 19 MS. NGUYEN: Are you seeking to change 20 our mind? 21 (Laughter.) 22 DR. WEBBER: In some cases, yes. In</p>
<p style="text-align: right;">95</p> <p>1 substantive issues, you would also seek or 2 recommend additional clarity regarding the process 3 there; right? 4 DR. WEBBER: You mean in this particular 5 venue or in -- 6 MR. FLANAGAN: Well, on how the process 7 will unfold post-CR. 8 DR. WEBBER: What I really am looking 9 for is that we would have -- more often than not, 10 we would have a meeting with the Agency to discuss 11 the post -- teleconference with the Agency to 12 discuss the post-CRL questions rather than getting 13 written responses. 14 MR. FLANAGAN: Okay. 15 DR. UHL: And, Keith, to clarify on that 16 because it sounds to me like what you're saying is 17 you really want to have an in-depth discussion and 18 conversation. So can you expand on that or 19 elaborate on that given the context of the 20 commitment letter that refers to these post-CR 21 meetings as 30-minute teleconferences? 22 DR. WEBBER: I think that we still</p>	<p style="text-align: right;">97</p> <p>1 some cases, yes. There have been instances where 2 we have questioned a CR comment and the Agency has 3 gone back, looked at it, and said, "You're right, 4 we're going to take that out of the letter." And 5 so sometimes we're successful at changing the 6 mind. Sometimes it is just a matter of 7 determining or finding out how we should address 8 that question. If there is a particular issue 9 related to a tox study, let's say, we could 10 provide within our request a description of the 11 tox study we plan to do. We could have a 30- 12 minute teleconference that says, okay, the Agency 13 says, yeah, we like this, we like that, we don't 14 like this, and getting that type of response, 15 which requires really an interaction in a single 16 response from the Agency really isn't sufficient 17 to efficiently and quickly resolve the issue and 18 move us toward product on the market. 19 MS. NGUYEN: Thank you. Are there other 20 questions from the panel? 21 DR. UHL: So just for my clarification 22 on this then. So essentially these post-CR</p>

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98	<p>1 meetings are you looking for something that's 2 more than just a teleconference to discuss the 3 content of the CR letter. 4 DR. WEBBER: We're looking for a 5 teleconference to discuss specific questions that 6 are in the CR letter and get clear direction and 7 understanding of how to move forward with our 8 responses. 9 DR. UHL: Okay. Thank you. 10 MS. NGUYEN: Thank you. Other 11 questions? 12 (No audible response.) 13 MS. NGUYEN: Okay. Thank you. 14 DR. WEBBER: Thank you very much. 15 MS. NGUYEN: I think that concludes the 16 morning presentations, so we will now move into 17 the open comment session. I think, is it just 18 three? We have three presenters, so I think there 19 is time to allow each commenter to speak for 10 20 minutes. 21 Our first commenter is Candis Edwards. 22 MS. EDWARDS: Good morning. Candis</p>	100
99	<p>1 Edwards from Amneal Pharmaceuticals. I didn't 2 know I had 10 minutes, so I can slow down a little 3 bit, I won't talk as fast. 4 MS. NGUYEN: Or we can ask you more 5 questions. 6 MS. EDWARDS: Yeah. Absolutely. 7 So I wanted to address a couple of 8 issues since I had a short period of time. We 9 will provide more detailed comments to the docket, 10 but I wanted to address controlled correspondences 11 specifically. The recent practices in OGD's 12 modernization of the controlled correspondence 13 system has resulted in controlled correspondences 14 being closed at the Agency's discretion without 15 providing an answer to the questions posed since 16 the ANDA itself was already submitted, and what 17 was happening was that the CC was pending in the 18 queue for an extended period of time which 19 actually surpassed the development of the ANDA 20 from the firm's perspective, so the ANDA was 21 filed. And this results in an at-risk filing for 22 the ANDA holder because we don't have the answer.</p>	101

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102	<p>1 the appropriate filing mechanism was. So it seems  2 that we're sort of taking that same approach with  3 ECDs. And Amneal recommends that there also be a  4 possibility that OGD can base a classification of  5 a deficiency as an ECD on a sponsor's ability to  6 respond to the deficiency with some predetermined  7 time period, for example, 10 days, because I think  8 the key, the real key, is once you identified a  9 deficiency, how long is it going to take for the  10 sponsor to get information back to you as opposed  11 to which actual category it falls in. So that  12 would be a recommendation, to include that.  13 I also would recommend that OGD adapt  14 practices which are utilized during NDA review  15 whereby a project manager is authorized to engage  16 in a telephone discussion with a sponsor in order  17 to obtain rapid clarification on uncomplicated  18 review questions, which if resolved, are then  19 usually followed up by some formal correspondence  20 to that, and the file within some agreed upon  21 timeframe. That might also move the process along  22 a little quicker.</p>	104
103	<p>1 My last comment, it deals with a  2 definition of first generics. I know that this is  3 a topic that will be addressed in the afternoon,  4 but I'll still take this opportunity, unless you  5 prefer me to hold this till the afternoon because  6 I didn't realize they were separated out.  7 MS. NGUYEN: If you could hold it till  8 the afternoon, we'll have a different panel --  9 MS. EDWARDS: Okay. Just sign up and  10 then I'll come back up again.  11 MS. NGUYEN: Please. We'll have a  12 separate panel that will --  13 MS. EDWARDS: Okay. So I'll hold off on  14 the last comment.  15 MS. NGUYEN: Thank you.  16 MR. FLANAGAN: You wanted to leave,  17 didn't you?  18 MS. EDWARDS: Pardon me?  19 MR. FLANAGAN: You wanted to leave us.  20 (Laughter.)  21 MS. EDWARDS: No, I'm here for the day.  22 This is my lifeblood. So those are the two</p>	105

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<p style="text-align: right;">106</p> <p>1 to use examples, it's hard to do this without 2 examples, but the answer might have been your 3 proposal is not acceptable. Well, if I knew that 4 was the answer, I would not have proceeded in that 5 direction in my development, and I would not have 6 filed the ANDA, then I would have taken an 7 alternative approach that would have been 8 acceptable. So it's the value -- I think the 9 whole concept here is the value of getting the 10 answers up front. The more that we can get 11 clarification and get our answers up front to our 12 issues, the less resources are going to be 13 utilized by OGD, and these applications are going 14 to start to sail through the system, and I think 15 that's really what I'm going to. 16 DR. UHL: So you would say that if you 17 had a control that wasn't answered and you took 18 the risk essentially -- right? 19 MS. EDWARDS: Right. 20 DR. UHL: -- of submitting an 21 application, and somewhere during that -- so we're 22 assuming you would submit after October 1, and</p>	<p style="text-align: right;">108</p> <p>1 correspondence, I think these situations will go 2 away because the company won't have to wait 9 3 months or a year for an answer. So really what 4 we're probably having this (inaudible) situation, 5 because of the backlog, because of backlog in 6 applications, as well as backlog in controlled 7 correspondences, so that is also contributing. 8 So I guess what I'm saying is at least 9 that there would be a dialogue before it was 10 arbitrarily closed out to speak with the sponsors 11 and say, "Hey, would it be beneficial to answer 12 this? I know you filed." You know, there is 13 another situation where the ANDA may be open- 14 ended, maybe a controlled correspondence in 15 response to a complete response. So there are a 16 couple of situations, but again it's just been 17 arbitrarily closed with no interaction or 18 discussion. I think that's the main point. 19 DR. UHL: So I'm just trying to seek 20 clarification because in my mind I'm hearing 21 mixed, this is kind of pre-GDUFA without goal 22 dates, which was past practice, this is --</p>
<p style="text-align: right;">107</p> <p>1 there would be GDUFA goal dates, so sometime in 2 there you would get a response to that control. 3 MS. EDWARDS: Mm-hmm. 4 DR. UHL: The applicant would make a 5 decision potentially to withdraw that application. 6 MS. EDWARDS: Right, potentially. 7 DR. UHL: So I would posit the argument, 8 though, that once the application comes in, we're 9 investing resources, the whole time to be moving 10 that through the GDUFA chain. 11 MS. EDWARDS: Right. 12 DR. UHL: We would answer the control in 13 the context of the filing review, the scientific 14 review, et cetera. You're -- I'm just getting -- 15 MS. EDWARDS: Right. 16 DR. UHL: You don't want it then. 17 MS. EDWARDS: The only thing is that the 18 resources that you're going to use in the review 19 process are much more intensive than the resources 20 you're going to use in the controlled 21 correspondence. And I think that once we start to 22 approach goal dates for responses to control</p>	<p style="text-align: right;">109</p> <p>1 MS. EDWARDS: Yeah. Right. 2 DR. UHL: So you're still making the 3 recommendation that effective October 1, when 4 controls come in with goal dates and there are 5 applications, your recommendation is all those 6 controls get closed out with a response 7 irrespective of whether or not an application has 8 been submitted related to that issue. 9 MS. EDWARDS: Yes. You're talking post- 10 goal date. I think the question is -- 11 DR. UHL: We're only 14 days to goal 12 date -- 13 MS. EDWARDS: I know. 14 (Laughter.) 15 DR. UHL: -- so unless you're submitting 16 a whole bunch today -- 17 MS. EDWARDS: No. 18 DR. UHL: -- we're really darn close to 19 that. 20 MS. EDWARDS: What I'm saying is you're 21 asking me to draw this line in the sand. It's 22 probably hard now because I think the situation</p>

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110	<p>1 I'm describing is relevant because there are a lot 2 of controlled correspondences in the queue that 3 have been there for a long time. It will improve. 4 This is only the first year that you're going to 5 have to face your metrics and achieve your goals. 6 As you progress, it will improve, and this 7 situation will probably not exist. 8 DR. UHL: Okay. Thanks for that 9 clarity. 10 MS. EDWARDS: Okay. 11 MS. NGUYEN: I just have a quick 12 question. Could you -- you had mentioned that we - 13 - in the current amendments guidance, we have 14 provided a list of examples of Easily Correctible 15 Deficiencies, and you suggest that we classify 16 those based on the time it would take for a 17 company to respond to those deficiencies. I think 18 we heard in other presentations today that there 19 is significant variation in financial resources 20 among companies. Could you pose a timeframe that 21 would be equitable for small companies and large? 22 MS. EDWARDS: Okay. I'm not going to do</p>	112	<p>1 get feedback from FDA. And I just want to take 2 some specific examples. These are based on our 3 experiences at InnoPharma. The first one I want 4 to talk about is like CBE-30. So CBE-30, you 5 know, there is a timeline defined by the 6 nomenclature itself that you need to get some kind 7 of feedback from FDA possibly within 30 days. So 8 there have been instances where we have one 9 instance where we filed a CBE-30 and we didn't get 10 a response within the 30 days, but we met all the 11 CBE-30 requirements, but then after 9 months we 12 got rejection of the CBE-30 and the conversion of 13 a CBE-30 to a PAS. So I think from a business 14 perspective, I mean, that can be disastrous 15 because you're following the guidelines and it 16 says CBE-30, and then if you don't get a response 17 in 30 days, you say go ahead and market the 18 product. 19 So I think that's something that again 20 is just a comment. I don't know how it needs to 21 be addressed, but definitely if there is an issue 22 with a CBE-30 submission, then we should get</p>
111	<p>1 that here, but I will do that in my written 2 comments. 3 MS. NGUYEN: Thank you. 4 MS. EDWARDS: That's a good point and 5 it's something that I did think about, so since I 6 only had 5 minutes, I will do it myself. 7 MS. NGUYEN: Thank you very much. 8 MS. EDWARDS: Okay. 9 MS. NGUYEN: Other questions? I think 10 we're over time. 11 MS. EDWARDS: Okay. Thank you. 12 MS. NGUYEN: Thank you, Candis. 13 Next up we have Satish. 14 MR. PEJAVER: My questions are related 15 more -- 16 MS. NGUYEN: I'm sorry. Could you state 17 your name and affiliation? 18 MR. PEJAVER: Yes. Satish Pejaver, from 19 InnoPharma. 20 MS. NGUYEN: Thank you. 21 MR. PEJAVER: Again, my questions are 22 related more towards timelines in terms of how we</p>	113	<p>1 feedback, "Hold," or, "We are reviewing it," or, 2 "It's fine." So some kind of feedback. I think 3 that puts us in jeopardy in terms of how we 4 operate as a company. 5 The other timely aspect -- and I think 6 many people in this room will have the same 7 comment -- is about acceptance of the ANDA. I 8 mean, before the GDUFA, we had some sense on when 9 we would get an acceptance, and it's typically in 10 a 2-month timeframe. Now it varies all over the 11 place. I mean, I do understand we're going 12 through a transition scenario, but the timelines 13 are very -- I mean, it can vary. We have one 14 which is we haven't gotten a response for 18 15 months. So it's very difficult again from a 16 business perspective, and we find quality and we 17 don't get a response for 18 months, and there is 18 no open communication in terms of what's 19 happening. 20 So I think, again, my question or 21 comment is, is there metrics for acceptance of 22 ANDAs? And I think there should be. And it's</p>

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114	<p>1 something that we are battling with right now. I 2 would like to get some feedback on that if 3 possible today. 4       The other thing is on controlled 5 correspondence right now, post-October 1st, we 6 have 70-percent response within 4 months. So I 7 think the clarification there that we're looking 8 for is, what is a 70-percent comprised of? Like 9 how is 70-percent defined? Is there some kind of 10 Tier 1/Tier 2 criteria which would fall under the 11 70 percent? And I think some of the simpler 12 things, again, with, let's say, Q1/Q2, people have 13 raised that question before. So Q1/Q2, I think it 14 can be easy to respond before the timeline. 15 Before the pre-GDUFA days it was 6 months, not 6 16 months, actually 2 months, and now I don't get a 17 feel for when we'll get a response on that. It 18 again varies. It's never within 2 months, but it 19 varies quite a bit. So some kind of clarification 20 on that, as particularly Q1/Q2, because that 21 defines how we are going through our development 22 process and how we need to develop the product</p>	116	<p>1 the metrics. So that actually doesn't jive. 2       The other comment I have is on stability 3 guidelines and the Q1A-E document, which is final. 4 There are some clarifications that are required, 5 you know, especially for sterile injection, 6 injectables, secondary packaging of injectables, 7 powder fills. So again some clarification on 8 these pieces of information we can definitely put 9 into the docket. How is that typically handled by 10 FDA? 11       So this is a list of comments that I 12 had, and I guess if you need any more 13 clarification, I can definitely provide that. 14       MR. FLANAGAN: Thank you very much for 15 all those comments. My colleagues are going to 16 remind me that I'm not really supposed to answer 17 questions. Right? You raised a laundry list of 18 comments. Please do submit all of those to the 19 docket because I was writing furiously, but you 20 had a significant volume of them. 21       MR. PEJAVER: Sure. 22       MR. FLANAGAN: I do have a couple</p>
115	<p>1 there, so it's very, very important criteria from 2 a business perspective as well. 3       So the other question on controlled 4 correspondence also in the pending controlled 5 correspondence is, how are they going to be 6 handled post-October 1st? So anything that's 7 submitted October 1st falls into the 70-percent 8 metrics and the 4-month metrics, but what about 9 the pending controlled correspondence? Is there 10 some clarification, some guidance, on how that's 11 going to be handled? 12       A couple of other comments that I have, 13 new controlled correspondence guidance conflicts 14 with the commitment letter from FDA. Just one 15 example would be -- 16       MR. FLANAGAN: Conflicts with what? 17       MR. PEJAVER: With the commitment 18 letter. So, for example, the commitment for 19 clinical division feedback said you require one 20 additional month for that feedback to come in. As 21 for the new controlled correspondence guidance, 22 anything enrolled in clinical does not fall into</p>	117	<p>1 comments, although my colleagues may join me. The 2 first thing you raised was CBE-30s and the delayed 3 response. I was a co-presenter yesterday at an 4 FDA PQRI conference with Lawrence Yu, who is the 5 Acting Director of OPS, and Susan Rosencrance, who 6 is a senior leader in the CMC organization, and 7 they presented a lot of data concerning CMC's 8 aggressive attack on the supplement backlog, which 9 I think actually Dr. Webber mentioned as well. So 10 we're aware of the significant volume of work we 11 have in that space and are making good progress 12 attacking it. I would also note that only PASs 13 have metric goals pursuant to GDUFA, but we still 14 want to attack the CBEs. 15       MR. PEJAVER: Mm-hmm. 16       MR. FLANAGAN: On the filing issues -- 17 and Johnny may wish to supplement or correct my 18 remarks -- but we're aware of those issues as 19 well. Pursuant to GDUFA, the clock starts to tick 20 at submission, not when we figure out what we want 21 to do with the submission, and we issued the 22 finalized RTR guidance yesterday and concurrently</p>

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118	<p>1 issued a draft guidance concerning RTR for 2 basically failure to explain, failure to how -- 3 MS. NGUYEN: Provide information on 4 purities. 5 MR. FLANAGAN: Thank you. And that's 6 going to be the -- that's maybe the first in a 7 series of draft guidances because there are 8 recurring discipline-specific filing rather than 9 review issues that we should RTR for when people 10 send us stuff that we shouldn't accept that 11 penalizes everyone else who is sending in a 12 quality submission, and we should be making 13 improvements to RTR over time, it's just that we 14 want to do it in a manner consistent with our 15 procedural obligations and in a way that it's 16 transparent and gives industry an opportunity to 17 comment. 18 And the last thing that I would touch on 19 is a common question. You asked, okay, so assume 20 that the metric for Year 3 for controls is 70 21 percent within 4 months. How do you decide which 22 goes in the 70 percent and which goes in the 30</p>	120	<p>1 clarity from Keith. 2 I would like a bit of clarification on 3 one of the things that you mentioned, was the 4 acceptance criteria. You're talking about a 5 filing decision or an approval decision? 6 MR. PEJAVER: A filing decision. 7 DR. UHL: A filing decision. 8 MR. PEJAVER: Yeah. 9 DR. UHL: Thank you. I just wanted to 10 be clear that that's what you were meaning. Thank 11 you. 12 MR. PEJAVER: Just one last comment 13 again on ANDAs that have been submitted and have 14 not been accepted yet, and some clarification on 15 how those ANDAs are going to be handled because 16 they don't fall under the GDUFA metrics. That's 17 what I understand. So some clarification on that 18 would be great as well. 19 Thank you very much. 20 MS. NGUYEN: I have a question for you. 21 Thank you for your comments. You had mentioned -- 22 you started your comments with the discussion</p>
119	<p>1 percent? We don't have like a clever master plan 2 to divide them into buckets we're going to try and 3 hit and buckets we're on purpose going to miss. 4 We're going to try to get 100 percent. 5 MR. PEJAVER: Sure. 6 MR. FLANAGAN: So that's the answer. 7 DR. UHL: So I appreciate your request 8 of us that you get feedback today and leave here. 9 I want to kind of jump in where Keith was because 10 I'm thinking that Part 15 hearings are not 11 something that the generic industry is necessarily 12 very familiar with or something that they engage 13 the Agency with frequently, and so the purpose of 14 a Part 15 hearing is for us to hear, to listen, 15 and to ask stakeholders for clarification on 16 particular issues. And we've had several of these 17 and we will continue to have public hearings and 18 Part 15 hearings to allow us to get feedback from 19 our stakeholders to clarify what we are doing 20 internally. Okay. So I understand your need. I 21 just want to set your expectations that that's not 22 the purpose of today. And I'm sure you got some</p>	121	<p>1 about the CBE-30s that were denied to a prior 2 approval supplement 9 months later. Do you have 3 the clarity that you need to know whether to 4 submit a prior approval supplement or a CBE-30? 5 MR. PEJAVER: There are guidelines for 6 CBE-30. In some cases, there are some grey areas, 7 but when it's somewhat clear-cut as for the 8 guidelines, we assume that if FDA does not come 9 back in 30 days, that it meets the requirements. 10 It would be great to get feedback within the 30 11 days no matter what because in some cases there 12 are some grey areas where FDA may decide to be 13 more conservative or they understand the position 14 of the industry and they grant the CBE-30, but 15 without any dialogue, it's very difficult. 16 In this particular case, we followed the 17 guidelines. So I think the haziness on the 18 submission was somewhat limited, was pretty clear- 19 cut, so it was a surprise to get the feedback 9 20 months later. 21 MS. NGUYEN: I would like, if you're 22 able to submit comments to the docket, more</p>

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122	<p>1 information on some of those gray areas. We would  2 like fewer gray areas over time so that there was  3 more clarity as to how you should proceed with  4 change.  5 MR. PEJAVER: Okay.  6 MS. NGUYEN: Thank you.  7 MR. PEJAVER: Okay. Thank you.  8 MS. NGUYEN: Anything else from the  9 panel members?  10 (No audible response.)  11 MS. NGUYEN: And our last commenter for  12 this morning?  13 MR. ROTH: Hi. I'm Gil Roth, the  14 President of the Pharma and BioPharma Outsourcing  15 Association. I want to thank you for the  16 opportunity to speak today. I founded the  17 association earlier this year to help organize and  18 represent contract manufacturers and contract  19 development manufacturing organizations, we'll  20 call them CMOs for the sake of this comment  21 session. This came after 14 years of covering the  22 industry as the editor of Contract Pharma</p>	124	<p>1 being transferred, and it's a very anecdotal  2 industry, but I have anecdotes of companies that  3 have told me they're essentially looking to get  4 out of manufacturing generics because these fees  5 make it unprofitable for them as well as for the  6 client company they're working with.  7 Now, one of our members has helped --  8 well, a congressman, Representative Robert Hurt,  9 Republican in Virginia, he and Phil Roe in  10 Tennessee have introduced HR-3631, a Small  11 Manufacturer Protection Act, which empowers the  12 Secretary at FDA to issue small business  13 exemptions when GDUFA might create barriers to  14 entry. I believe the threshold for that is  15 companies that are \$20 million and smaller, and  16 that bill is currently sitting in the Health  17 Committee.  18 I'm here because this is our coming out  19 party in a sense. This is the first public  20 appearance the association has made.  21 MS. NGUYEN: Congratulations.  22 MR. ROTH: Thank you very much. We're</p>
123	<p>1 Magazine.  2 And our main area of interest at this  3 hearing is facility fees for final dosage for  4 manufacturers. I was gratified to hear Mr.  5 Pressman's presentation earlier about the small  6 business issues related to those fees, and we're  7 coming from somewhat different directions, but I  8 think we have some of the same goals. Several of  9 our members are interested in a small business  10 exemption under GDUFA as well as perhaps a tiered  11 structure for CMOs as opposed to companies that  12 are manufacturing generics for themselves. It's a  13 very different business being a contract  14 manufacturer than being a pharma company or a  15 generic company operating under much different  16 margins.  17 Within the field, we have some companies  18 that might have a single generic client that they  19 do one week of work for per year, and yet they  20 face the same facility fee that a major, major  21 generic facility is going to pay. Not all  22 contracts are made to accommodate that sort of fee</p>	125	<p>1 interested in reaching out to FDA in helping to  2 inform them a bit more about how the CMO industry  3 differs from the branded pharma industry, from the  4 generics industry. Like I said, they operate on  5 very different margins. Some of them are carved  6 out of existing pharma companies. In this case,  7 some of them have generic products of their own  8 through other businesses. I should note that the  9 interest in GDUFA does not reflect the entirety of  10 the membership of the PBOA. Some of these  11 companies don't handle generics at all, some are  12 biologics focused, but still they're contract  13 manufacturers and they don't seem to be  14 represented in the way GDUFA was structured in its  15 initial incarnation. We're hoping going forward  16 with the renewal that we can have some effect and  17 help negotiate some way of differentiating CMOs  18 from pure generic companies under the facility  19 fees going forward, particularly for final dosage  20 form.  21 And that is essentially all I have to  22 say. We are planning on submitting comments to the</p>



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126	<p>1 docket in the weeks ahead to again try and pave 2 the road here, but if you have any questions, I 3 would love to start a conversation. 4 MS. NGUYEN: Thank you. 5 MR. FLANAGAN: Welcome to the excitement 6 of GDUFA. 7 MR. ROTH: Thank you very much. 8 (Laughter.) 9 MS. NGUYEN: It's always a party. 10 MR. ROTH: Well, this all began because 11 I was reporting on GDUFA for Contract Pharma 12 Magazine, where I was the editor, and the number 13 of contract manufacturers who said to me, "We 14 don't know what we're doing under this. We can't 15 pass these fees along to our clients," they were, 16 I don't want to say blindsided, we knew fees were 17 coming. I don't think they knew exactly how it 18 would be structured and how they would be 19 implemented. We want to be part of the party, I 20 guess. 21 MS. NGUYEN: Do you have -- can you give 22 me a ballpark estimate on how many players would</p>	128	<p>1 also -- if you like what we currently do in PDUFA 2 and whether that would be acceptable. 3 MR. ROTH: And that's what I was 4 wondering. Under PDUFA, there is both a small 5 business exemption and facility fees are applied 6 directly to the drug filers, not to the individual 7 manufacturing sites. Both of those did not carry 8 through to GDUFA. So we want to see about how 9 that can be implemented. 10 One of the ideas we had was simply a 11 checkbox of sorts under the self-identified 12 facilities list to ask companies, do you or any of 13 your subsidiaries own any NDAs of your own? If 14 they don't, it's a contract manufacturer, it's not 15 a generic company, and that might be a good way of 16 splitting the pie to separate final dosage form 17 into companies making them for themselves versus 18 ones that are making them for clients. 19 MS. NGUYEN: Thank you. 20 Other questions from the panel? 21 DR. UHL: I was just wondering if you 22 could elaborate on your choice of the \$20 million.</p>
127	<p>1 fit into the under \$20 million exemption? 2 MR. ROTH: Not entirely. It's an 3 industry that's dominated by a few very, very 4 large companies and a very large number of small 5 companies, and some of those come and go. If 6 anything, when I was building the membership list 7 for this, I looked over the self-identified 8 facilities list under GDUFA to see which companies 9 I knew which companies didn't appear to be generic 10 firms of their own, and start figuring out who was 11 a small CMO, who I don't want to say get caught in 12 the net, but showed up as a self-identified 13 manufacturer of generics. 14 MS. NGUYEN: So was it a lot? 15 MR. ROTH: There's a bunch. I will try 16 and get that information for you. 17 MS. NGUYEN: Yeah. I just want a feel 18 for what would happen if we were to work on an 19 exemption. I think a presenter earlier had talked 20 about a sliding scale fee structure. You're 21 talking about an exemption which would be 22 something different. I don't know if you would</p>	129	<p>1 MR. ROTH: Oh, that's not my choice. 2 That's in the small business -- that's in HR-3631. 3 DR. UHL: Okay. Even that, how was that 4 put? I mean, do you have any knowledge of that, 5 that selection? 6 MR. ROTH: I don't know how that number 7 was settled on, but it might be something that's 8 come up in small business waivers in the past, but 9 I'm afraid I don't know how they settled on the 10 number. 11 DR. UHL: Okay. Thank you. 12 MS. NGUYEN: Other questions? 13 (No audible response.) 14 MS. NGUYEN: We'll look forward to 15 seeing your comments in the docket. 16 MR. ROTH: Thank you very much. 17 MS. NGUYEN: So that concludes the 18 morning session. We are at 11:47. Let's 19 reconvene at 1:05. So we'll follow the agenda and 20 just meet back here in an hour and 15. Thank you. 21 (Lunch.) 22 MS. TOUFANIAN: Good afternoon. We'll</p>

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130	<p>1 go ahead and get started. My name is Maryll 2 Toufanian. I am an Acting Division Director within 3 the Office of Generic Drug Policy. First, we 4 would like to thank everybody for their 5 participation this morning. We thought it was a 6 really informative and helpful discussion. 7 This afternoon we'll be shifting gears a 8 bit. I'll relay that the process is similar to 9 this morning in that we have two speakers who have 10 prepared remarks, and then we'll give an 11 opportunity for folks who would like to comment on 12 the issues that we'll be discussing, some of whom 13 I believe have registered earlier today whose 14 names will be projected on the list, and then if 15 we have any additional time, we'll go ahead and 16 permit additional comments. 17 This afternoon's policy discussion 18 concerns two topics of GDUFA implementation that 19 are informed by the unique incentives for generic 20 drug manufacturers embedded into the Hatch-Waxman 21 amendments. All of us are familiar with the 180- 22 day exclusivity, so I won't get into the nuances</p>	132	<p>1 we really look forward to getting comments from 2 stakeholders involved in GDUFA implementation. 3 The first concerns, what is actually a 4 criterion for Agency prioritization set forth in 5 the commitment letter, the notion of a category of 6 a first generic who will be receiving priority 7 review, and what we have discovered based on 8 informal comments is that description and 9 categorization set forth in the commitment letter 10 is not as clear as we would like, or it's not as 11 easily defined as we thought. We have received 12 differing definitions. Is a first generic a first 13 ANDA that is submitted for a particular RLD? Is 14 it a first-to-file ANDA that contains a Paragraph 15 4 challenging patents with a brand drug? Is it 16 the first generic that's approved, that is 17 approvable, the first generic that is marketed or 18 marketable, and/or is it the most important number 19 one priority for a specific company? 20 Having received these informal and 21 somewhat differing or diverging understandings of 22 what a first generic is, we thought it was</p>
131	<p>1 of that, but before we discuss our criteria -- or, 2 excuse me, our topics of discussion today, I would 3 like to give the new panel -- you'll see some 4 fresh faces up here -- an opportunity to introduce 5 themselves. These are folks that are on the front 6 line of considering the issues we'll be discussing 7 today, many of whom will be familiar to the folks 8 in the room. 9 MR. FLANAGAN: I'm Keith Flanagan. I'm 10 the Transition Lead for Policy in OGD. 11 MR. REED: Dave Reed, Regulatory Counsel 12 in OGD. 13 MS. DETTELBACH: I'm Kim Dettelbach. 14 I'm Senior Counsel in the Office of Chief Counsel. 15 MR. SHIMER: Martin Shimer. I'm the 16 Deputy Director of the Division working with 17 Maryll. 18 DR. UHL: And good afternoon. I'm 19 Kathleen Uhl, the Acting Director of the Office of 20 Generic Drugs at CDER. 21 MS. TOUFANIAN: Thank you. So as I 22 indicated, we have identified two topics on which</p>	133	<p>1 essential to invite stakeholder comment on what is 2 the appropriate definition of a first generic for 3 the purposes of agency prioritization of ANDA 4 review. 5 And the second topic we'll be receiving 6 comments on is the Agency's consideration of 180- 7 day exclusivity. I think everyone is well aware 8 of what that is and that the Agency's 9 consideration in decisions with respect to 180-day 10 exclusivity are complex, fact-specific, ever 11 shifting, almost always occurring prior to 12 approval and almost always involving confidential 13 commercial information, and that being said, we 14 have received again a number of informal comments 15 from a variety of stakeholders asking whether 16 there is a way to make that process more 17 transparent and potentially open to public 18 participation. 19 As I indicated, many of these decisions 20 are fact specific, but they deal with issues that 21 recur for a variety of applications and for a 22 variety of products. So we are soliciting</p>

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134	<p>1 comments on if there are mechanisms mindful of the 2 confidential nature of some of these 3 determinations, are there mechanisms to make part 4 or all of those considerations public? 5       The folks in the room are the folks that 6 deal with these issues on a daily basis, and we 7 thought it would be very helpful to get comments 8 on those as well. 9       In addition, we're welcoming comments on 10 other elements with respect to the sort of non -- 11 I don't want to say non-scientific, but the more 12 policy or legal elements of GDUFA implementation 13 where additional guidance or additional clarity 14 from the Agency would be beneficial. 15       So with that, we'll go ahead and start. 16 I believe Robert is -- no? You're all set? 17       MR. VINCENT: I'm (off mike). 18       MS. TOUFANIAN: Okay. I'm sorry. Then, 19 Marcie, if you would like to go ahead and join us. 20 Please go ahead and just introduce yourself and 21 identify your affiliation. 22       MS. McCLINTIC COATES: Sure. Well, good</p>	136	<p>1 in a way that's consistent with the key aims that 2 we sought for in the negotiations of the three 3 public health aims of improved safety, access, and 4 transparency, and certainly consistent with the 5 key underpinnings that make our industry so 6 unique, the Hatch-Waxman system that we have. 7       GDUFA was one of the most significant 8 pieces of legislation impacting the generic drug 9 industry since the Drug Price Competition and 10 Patent Term Restoration Act of 1984, commonly 11 known as Hatch- Waxman, which essentially created 12 the generic drug industry as we know it today and 13 interestingly next week will celebrate its 30-year 14 anniversary. 15       Since the passage of this act, generics 16 have played an increasingly vital role in the 17 nation's public health, as FDA has approved more 18 than 8,000 generic equivalents to brand name 19 drugs, resulting in 85 percent generic utilization 20 in the U.S. and saving the country over a trillion 21 and a half dollars in just the last decade. 22       Now, much of that success has come</p>
135	<p>1 afternoon and thank you. My name is Marcie 2 McClintic Coates, and I serve as Mylan's Vice 3 President and Head of Global Regulatory Affairs 4 and also as a former member of the GPhA GDUFA 5 Negotiating Team. 6       Mylan has a 53-year history of working 7 closely with FDA, and we appreciate the 8 opportunity to provide comments today, 9 particularly given a lot of involvement in the 10 development on negotiating of the GDUFA program 11 along with our industry colleagues. 12       We look forward to supplementing the 13 docket today with additional detail regarding all 14 of the questions that have been published in the 15 Federal Register Notice, and we thank the Agency 16 for creating this forum today. I think it's well 17 served and a continuation of having these goes a 18 long way for both industry and FDA, so thank you. 19       For today, I will share some general but 20 important considerations that really should shape 21 our thinking as we implement GDUFA to ensure that 22 the true intent of the program is operationalized</p>	137	<p>1 directly from the very unique Hatch-Waxman 2 framework that Congress put in place to expedite 3 generic competition to give patients faster access 4 to more affordable medicine on the very earliest 5 possible date that no legal barrier approval 6 exists. 7       Now, exactly 4 years ago today on 8 September 10, 2010, FDA had a very similar public 9 forum as this welcoming dialogue on what a generic 10 user fee program ought to look like, and what did 11 industry think about? So I went back and 12 revisited our comments then and comments that many 13 of our colleagues have put forth as we started to 14 really look at the need for a program, and one of 15 the comments that we shared, Mylan's CEO shared, 16 at the time that I think is still relevant is 17 while it's widely recognized that Hatch-Waxman has 18 successfully delivered significant savings to 19 consumers, no one could have predicted in 1984 20 that that framework would over time tax the FDA 21 system due to the complexity of the global 22 marketplace. Today's reality means we must</p>

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138	<p>1 address the issue through a holistic user fee  2 approach, one that supports the mission and true  3 intent of Hatch-Waxman at the same time generating  4 much needed funding for the FDA and assurance for  5 product safety amidst the globalizing industry  6 that the Agency regulates.  7       Now, over the time period leading up to  8 GDUFA, median review times had hit 31 months, they  9 had doubled over the last decade, and, quite  10 frankly, as we all know, the Agency's resources  11 had just not kept up with that demand nor the  12 ability to inspect facilities located in the U.S.  13 and outside the U.S. at the same frequency and  14 occurrence and thus contributing to these delays  15 because a recent inspection history is, of course,  16 needed before you can get approval.  17       Now, what was happening prior to then,  18 as we know, we were inadvertently forfeiting  19 exclusivity as an industry. As you know, the  20 generic drug industry has 180-day exclusivity,  21 it's the sole exclusivity that exists for  22 generics, and in 2003, the Medicare Modernization</p>	140	<p>1 predictability, increasing timeliness in the  2 review, improved transparency by improving FDA  3 communications and feedback within industry in  4 order to expedite product access, and improved  5 safety by ensuring that both foreign and domestic  6 industry participants in the U.S. are held to  7 consistent high quality standards and inspected  8 biannually using a risk-based approach.  9       Now, as FDA is now operationalizing  10 GDUFA and coming up with new policy development  11 activities training within the Agency, these three  12 overarching stated purposes of improved safety,  13 access, and transparency should really serve as  14 the guiding principles on all of the  15 implementation efforts, and these are complemented  16 by two longstanding and bedrock principles that  17 have historically made the U.S. generic drug system  18 the most successful in the world. Number one, FDA's  19 relentless passion and commitment, sense of urgency,  20 to carry out the unique Hatch-Waxman framework  21 of getting drugs approved and into the hands of  22 patients on the very earliest date that no legal</p>
139	<p>1 Act updated those Hatch-Waxman amendments and  2 provided forfeiture provisions finding that if a  3 company fails to get a tentative approval within  4 30 months, you will lose your 180, and as that  5 number -- in 2003, when that was created, it took  6 16 months median review time to get a tentative  7 approval at FDA. And now that we're at 30, 31  8 months prior to the start of GDUFA, companies were  9 inadvertently forfeiting through no fault of their  10 own and thus threatening this important  11 exclusivity that Congress had put in place to  12 incentivize companies to take on the expensive --  13 the extensive legal risk involved to challenge  14 patents and at the end of the day get products  15 into the hands of consumers faster.  16       So it was with all those pieces in mind,  17 with Hatch-Waxman being at that point a century  18 old, that industry came up with, with FDA a  19 comprehensive user fee program that was focused on  20 three public health stated aims of GDUFA:  21 improved access by expediting the availability of  22 low cost medicine by bringing greater</p>	141	<p>1 barrier exists as well as, two, FDA's strong  2 reliance on good science to continuously improve  3 and evolve Agency thinking.  4       So thus GDUFA was intended to provide  5 FDA with additional resources to essentially  6 achieve the ultimate purpose of Hatch-Waxman that  7 had become really strained with the growth of the  8 industry and the number of facilities and players  9 involved and the lack of resources at the Agency  10 for generic drugs. And both Congress and the  11 courts have found that Hatch-Waxman's central  12 purpose is to implement the policy objective of  13 getting safe and effective generics into the  14 market as quickly as possible after patent  15 expiration or earlier where companies are able to  16 do so by challenging patents.  17       Now, the GDUFA goals letter identifies  18 improved access as a key public health aim of  19 GDUFA, and leading up to GDUFA, as we mentioned,  20 the generic approval had increased to 31 months in  21 2011. Now, a significant amount of progress has  22 been made to date implementing GDUFA, and we will</p>

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142	<p>1 outline more of those as well because they are  2 worth noting and they're important, toward the  3 inspection disparities, many of them, and we were  4 having conversations at lunch with several  5 colleagues about the improvements that have  6 occurred, but one area that we both continue to  7 struggle in is on the median approval times on  8 that purpose of access. So while much has been  9 made to hire and train and set up the  10 infrastructure to get the generic review system a  11 more predictable footing from the start of GDUFA,  12 the median time for generic approval has increased  13 to 36 months in 2013, and it's projected to be at  14 around 43 months in 2014, although not all full  15 data is out yet, but from the sampling that we  16 have been able to see. And in the last year, the  17 U.S. health care system has lost an estimated --  18 over a billion dollars in savings due to delays in  19 first generic approvals missing getting approval  20 in that earliest stage that no legal barrier exists  21 for approval. And we, as an industry, continue to  22 have inadvertent forfeitures for failing to get</p>	144	<p>1 for approval is tied to the Hatch-Waxman  2 amendments, which link the patent dispute process  3 with the generic drug approval process and  4 requires FDA to make approval determinations on  5 applications within 180 days. And in proposing  6 and negotiating that framework, much time was  7 spent identifying the unique Hatch-Waxman  8 framework that differentiates our program from  9 following a rubber stamp, mirror image of PDUFA.  10 And as shared during several previous public  11 meetings as we talked through this, if the generic  12 drug user fee program is tied solely to the  13 certainty of an artificial timeframe alone without  14 regard to the Hatch-Waxman framework, that  15 encourages the earliest entry of generic  16 competition, this would be flawed because not all  17 applications can or should be treated equally.  18 FDA should not simply create a cookie-cutter  19 approach that treats all applications alike and  20 fails to recognize the legal distinctions between  21 each application, such as first-to-file ANDAs,  22 subsequent ANDAs, and/or significance of a</p>
143	<p>1 that timely approval. On top of that, of course,  2 the Agency has received a record number of  3 applications just in June alone, so the workload  4 has not gone away either.  5       We are encouraged by the new  6 Prioritization Map that has come out with FDA to  7 try to address these challenges and to make sure  8 that we're not losing sight of those critical  9 products, applications that are opening the market  10 and getting more affordable access to patients.  11 We would urge FDA to ensure that the key  12 principles are carried out through the  13 prioritization of both the application submitted  14 before October 1, 2014, as well as those that come  15 after this date. And this is a very important  16 point as we look at this framework and we have as  17 a sister model to look at, is PDUFA, but I think  18 this is really helpful to underscore this  19 distinction.  20       While much of GDUFA is modeled after  21 PDUFA, GDUFA is particularly distinguishable from  22 PDUFA because GDUFA's goal of decreasing the time</p>	145	<p>1 particular product, like one that treats an unmet  2 medical need or otherwise a first generic or an  3 orphan drug or some other significant public  4 health impacting application.  5       Mylan recommends that FDA clarify its  6 recent Prioritization Map with associated target  7 action dates to prioritize those applications that  8 have the most significant impact on the public  9 health so that more timely approvals can be  10 achieved. These include the availability of new  11 first generic medicines, medicines that lack  12 significant generic competition, including second-  13 to-file as well as any other applications that  14 particularly play an important role in the public  15 health in addition to PEPFAR and drug shortage  16 applications.  17       First generics should include those  18 applications for which no other generic version of  19 the same reference listed drug has yet been  20 brought to the market under an approved ANDA.  21 Consistent with the purposes of Hatch-Waxman, FDA  22 should aim to approve applications immediately</p>

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146	<p>1 upon patent expiration, exclusivity expiration, 2 expiration of a 30-month stay, commencement of a 3 patent license date, or the earliest date that no 4 other legal barrier to approval exists; for 5 example, for a late statement or a forfeiture by 6 the first applicant. FDA should prioritize any 7 other application for which the applicants can 8 sufficiently demonstrate a significant and 9 compelling public health need taking into 10 consideration factors such as whether the product 11 will fulfill an unmet medical need or satisfy an 12 undue economic hardship.</p> <p>13       As the Agency assigns appropriate action 14 dates and time to allow for a final and tentative 15 approval, that should be aligned with the relevant 16 Hatch-Waxman dates, and once that has been 17 identified, these dates should have the ability to 18 change to an earlier date just given the 19 constantly changing dynamic nature of the Hatch- 20 Waxman framework if it's needed. If an 21 application has now entered into a settlement 22 agreement, then gives the opportunity for an</p>	148	<p>1 Thus, FDA should aspire to meeting approval times 2 of no more than 30 months of applications 3 submitted before October 1, 2014, that are not 4 prioritized. So the backlog is moving through 5 toward approval.</p> <p>6       In keeping with GDUFA's third core 7 purpose of improving transparency and feedback 8 with industry, we respectfully urge FDA to clarify 9 issues relating to determining the status of 10 pending ANDAs and approval timing so that 11 applicants are prepared to launch immediately upon 12 FDA approval to allow enough time to secure raw 13 materials, plan production schedules, manufacture 14 and coordinate distribution among many of the 15 other pre-launch activities necessary so that 16 industry can be prepared to provide more 17 affordable products on Day 1.</p> <p>18       Industry cannot plan appropriately 19 without better predictability and potential 20 approval times and Agency action dates. When too 21 much is made or there are significant delays in 22 launch, expired drug must be disposed, resulting</p>
147	<p>1 application to be approved earlier, that target 2 action date should have that ability to respond to 3 that dynamic and nimble nature that Congress 4 intended to drive competition.</p> <p>5       Additionally, all divisions within FDA 6 that can impact the approvability of an 7 application should be held accountable to that 8 date. So it's not just CMC and bioequivalence and 9 the traditional OGD review, but if something 10 entails a consult or a citizen petition review or 11 a review by Office of Chief Counsel, we would 12 suggest that all of those should be -- or of 13 wrapping up an inspection or closing out an 14 inspection -- included here.</p> <p>15       And with respect to submissions that are 16 impending with FDA submitted anytime before 17 October 1st of 2014 when the Year 3 metrics kick 18 in, FDA should strive to maintain a level of 19 productivity at least similar to the pre-GDUFA 20 levels as provided in the goals letter, which says 21 FDA will aspire to maintain pre-GDUFA level 22 productivity as the Agency ramps up the program.</p>	149	<p>1 in unnecessary waste. Additionally, when there 2 isn't enough visibility to know when to expect 3 approval, production delays are incurred counter 4 to the purposes of Hatch-Waxman of being there on 5 the earliest possible date.</p> <p>6       We urge FDA to revise its internal 7 communication policy to align the purposes of 8 GDUFA and to improve communication and 9 transparency with industry with particular 10 emphasis on applications that are within at least 11 that 6-month time period for which no legal 12 barriers exist that would allow them to be 13 eligible for final or tentative approval.</p> <p>14       In conclusion, we appreciate the 15 opportunity to share some of these general 16 comments and considerations that shape the 17 Agency's thinking around implementation as a 18 whole. It's these collective principles of 19 safety, access, and transparency, the Hatch-Waxman 20 program, and the strong focus on science that have 21 been the fundamental underpinning of the industry 22 for the last 30 years and have allowed us to get</p>

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<p style="text-align: right;">150</p> <p>1 to the savings that we're able to offer to 2 patients, and we look forward to continuing to 3 partner with you to navigate through 4 implementation to ensure that GDUFA is implemented 5 as intended to get faster medication to patients. 6 So thank you. 7 MS. TOUFANIAN: Thank you very much. 8 Questions from the panel? 9 MR. FLANAGAN: Thank you for your 10 comments. 11 So I'm curious about the \$1 billion 12 number you cited. 13 MS. McCLINTIC COATES: Yeah. 14 MR. FLANAGAN: Are those submissions 15 where there are no scientific and technical review 16 issues outstanding inspection or compliance issues 17 outstanding, and no outstanding Hatch-Waxman 18 patent, legal, or related issues outstanding? 19 MS. McCLINTIC COATES: Yeah. It's a 20 good question. So of what was estimated in known 21 delays for first generics, it's a variety, and 22 candidly I would say that some of those, I</p>	<p style="text-align: right;">152</p> <p>1 there is a billion dollars in lost cost savings 2 due to FDA dropping the ball, and my perspective 3 is that if the submission has quality challenges 4 and is not approvable or if there are outstanding 5 patent exclusivity or related Hatch-Waxman issues 6 that are out of our control, then how is it fair 7 to say that there's a billion dollars in lost cost 8 savings that could otherwise have been reaped if 9 the submission is not of high quality and there 10 are outstanding Hatch- Waxman issues? 11 MS. McCLINTIC COATES: Yeah, I can't 12 speak to these are not high quality from the ones 13 that you're referencing for the time period of 14 which they are at, and these are ones that the 15 date has passed by, a patent has expired or so 16 forth. So in terms of the straightforward pending 17 Hatch-Waxman pieces, it's not known to whether 18 those have those, but I think the broader point 19 that you're raising, and it's a big one, it is a 20 shared commitment between the Agency and the 21 industry to get there on Day 1. It is a 22 partnership between both of us dialoguing back and</p>
<p style="text-align: right;">151</p> <p>1 couldn't tell you if they have those outstanding 2 because not the full visibility of the status of 3 the applications are available to know where delay 4 may sit, but the median review time for that 5 category is around 55 months of pending Agency 6 review. 7 MR. FLANAGAN: I'm sorry. So the answer 8 to my question is we don't know? 9 MS. McCLINTIC COATES: Well, as part of 10 the follow-up with the Agency, many of them vary. 11 Some of them do have -- are pending and you know 12 because the agencies recently ask you for a 13 comment. I don't have full visibility into all of 14 them because it was a blinded pulse check with 15 (inaudible), but some of them, we don't know if 16 things, where they're still -- some of them are 17 kind of languishing because you don't have that 18 full transparency about where the state may be. 19 MR. FLANAGAN: Well, the implication is 20 that -- or maybe I'm being hyperdefensive -- but 21 the implication of the number, which is large, 22 and, you know, arguably inflammatory, is that</p>	<p style="text-align: right;">153</p> <p>1 forth. In order for us to both get there on Day 2 1, we have to know where things stand, and the 3 Agency has its piece of review also. If we're 4 both going to get there on Day 1 and you send us 5 back comments and we then take an eternity to 6 respond to those back, then that also pushes out 7 Day 1. 8 So your point is the right one from a 9 standpoint of it's a share between Agency and 10 industry of where it is. It isn't necessarily 11 that all of that is on FDA, but it's on all of us 12 if we are missing the opportunity for Day 1s when 13 we can strive to get there, and that's why some of 14 the comments from this morning I think are very 15 helpful in terms of, what can we do up front to 16 make sure that some of the things that straggle on 17 down the road in your review, that you can try to 18 avoid them. So things like the controlled 19 correspondence guidance, clarification calls that 20 are maybe needed whenever guidances are coming 21 back, some presubmission meetings if it 22 necessarily warrants it, if you're dealing with a</p>

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154	<p>1 complex novel much like what Rob Lionberger 2 outlined at the GPhA Fall Tech meeting. All of 3 those sorts of things collectively go toward that. 4 So I'm not suggesting that it's as straightforward 5 as that, and this is a point, and no one should 6 interpret that. It's on both of us on both sides, 7 and it's a reality that as we look at this issue - 8 - and I'm pleased that the Agency is really 9 looking at it from that Hatch- Waxman lens right 10 now and the unique scenarios -- the reality is no 11 two applications are alike, and as we look at the 12 freight -- and there is over 3,000, or whatever 13 that number is -- that's the piece that we're 14 looking at, and what are the ones that we can take 15 off, and how do we move them forward quicker at 16 the end of the day, our same shared goal? 17 MR. FLANAGAN: And second question, you 18 said that GDUFA contains a productivity level 19 obligation for FDA. You did not qualify that 20 statement. My admittedly imprecise recollection 21 of the language exactly on point was that we had a 22 productivity maintenance of efforts obligation</p>	156	<p>1 applicant to a particular RLD drug shortage and 2 other high priority health care needs, but you 3 also mentioned second generics, and that raises a 4 question I have, which is, how would you propose 5 that we prioritize within those products that have 6 been designated for priority? I would assume that 7 if you have a first-to-file and a second-to-file, 8 that the one -- they wouldn't be treated as 9 equals. 10 So my question is, within all of these 11 ANDAs that are designated as priority, do you have 12 a suggestion as to how we would prioritize within 13 them? 14 MS. McCLINTIC COATES: Sure. So with 15 respect -- and we can provide more comments 16 certainly to the docket because, of course, all 17 things in Hatch- Waxman are nuanced and fun, but 18 in terms of your question here, I would say that 19 the ultimate goal of Hatch-Waxman is to get there 20 on the earliest date that no legal barrier to 21 approval exists. So for that first-to-file, that 22 we're all doing -- it's in all of our interests to</p>
155	<p>1 that was basically a best efforts provision given 2 a laundry list of other -- 3 MS. McCLINTIC COATES: You're right, 4 it's an aspiration. And I'm sorry, I thought I 5 said FDA will aspire to maintain the languages, 6 that FDA will aspire to maintain pre-GDUFA levels 7 as FDA ramps up the program. So you're right, 8 it's an aspiration, it's not an obligation with 9 the program, but it's an aspiration that I suggest 10 that we should consider in terms of addressing 11 much of the comments and feedback from folks about 12 this backlog and how can we make sure that the 13 public health goals are continued to be met, that 14 those important medicines that are in there? Is 15 that something we can all push ourselves to strive 16 for, both us, and the timeliness and responses 17 with pieces, and on your end as well? 18 MR. REED: I have a question on 19 priorities. You gave quite a reasonable summary of 20 what might qualify as a first generic. 21 MS. McCLINTIC COATES: Yeah. 22 MR. REED: I think you mentioned first</p>	157	<p>1 fight for the 180, do not have inadvertent 2 forfeitures, et cetera, to encourage that 3 important incentive. But with respect to 181 4 qualifying, so for those, the legal barrier to 5 approval, keeping with the purpose of Hatch-Waxman 6 to get there on the moment that that legal barrier 7 is lifted, that's going to be lifted on Day 181. 8 So in terms of moving that thing through the 9 process, that should be the striving goal in terms 10 of any compliance that needs to get wrapped up, et 11 cetera. 12 MR. REED: And there might be a dozen of 13 them. So do we strive to have all dozen ready on 14 181? 15 MS. McCLINTIC COATES: I think that it 16 is an important goal to strive toward. Every 17 application is different in terms of where it's at 18 in review, but in terms of the second and third 19 and fourth generics, the overarching purpose -- 20 and that's more of what I'm speaking from because 21 a lot of these are fact- specific, but the 22 overarching purpose to drive competition, we know</p>



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<p style="text-align: right;">158</p> <p>1 that when -- we know that from 30 years in the 2 industry that more players in the market are going 3 to drive down to more affordable pricing, and the 4 earlier entry that you can get there, how critical 5 that is. 6 So I just want to make sure I provide 7 that to make sure that those are not forgotten 8 about because there are a number of important ones 9 that are out there. And as the demand has 10 increased, it's difficult for one supplier perhaps 11 to absorb all of the U.S. demand for that, and so 12 for the purposes of shortages and availability and 13 scale and the medication that's involved, those 14 are still very important public health priorities, 15 that as we look at this that we want to make sure 16 are not forgotten. 17 MR. REED: Thanks. 18 MS. TOUFANIAN: Just a follow-up 19 question because I think it's easy for us to 20 identify that first date and it's easy for us to 21 identify that 181 date -- 22 MS. McCLINTIC COATES: Yeah.</p>	<p style="text-align: right;">160</p> <p>1 here, and I think we should add that to the docket 2 as well to be able to provide that information. 3 That's just the very fluid nature of the 4 Hatch-Waxman scheme, but our ability to pivot and 5 to be dynamic and move, and it's a balancing act 6 because FDA right now is putting forth any 7 processes and policies and procedures, so given 8 the volumes that we're dealing with, to make sure 9 we strike that same balance that Hatch-Waxman 10 struck to balance whenever that happens because 11 some things are going to get rattled and changed, 12 so how can we do that? I would urge my other 13 industry colleagues to submit comments around 14 exactly that point as the Agency struggles with 15 that and we struggle with you with that to make 16 sure that that happens. 17 DR. UHL: So in the spirit of clarity 18 here, because you and Keith are going back and 19 forth about language, I would just like to set the 20 record straight -- and we do have a recording for 21 this -- so since I carry my GDUFA commitment 22 letter with me everywhere I go, Page 3 of the</p>
<p style="text-align: right;">159</p> <p>1 MS. TOUFANIAN: -- but you referenced a 2 bucket of applications for which they become 3 available due to a settlement agreement sort of 4 off the calendar. And obviously that is a very 5 fluid situation and we may not be able to approve 6 a product the day after we receive notification of 7 a settlement. 8 MS. McCLINTIC COATES: Right. 9 MS. TOUFANIAN: Either today or I would 10 encourage in your comments to identify some 11 mechanisms that we could implement in our office 12 and together with industry to make sort of those 13 spot changes easier to administer if those are 14 going to be contained in that first generic 15 prioritization definition. 16 MS. McCLINTIC COATES: Yeah. Yeah. 17 It's a great point because many of them, to your 18 point, may be through a confidential settlement 19 discussion and sharing that information, and the 20 earlier that we can get that information to FDA 21 obviously, that's critical. So that's a good 22 topic I think for all of industry to consider with</p>	<p style="text-align: right;">161</p> <p>1 commitment letter or the goals letter or whatever 2 it is you want to call it, so we're all talking 3 about the same document, Roman numeral Number VII, 4 "FDA will aspire to the extent possible to 5 maintain levels of productivity at least similar 6 to pre-GDUFA levels while hiring and training 7 incremental staff necessary to achieve the program 8 performance goals, building necessary systems, and 9 implementing outlined program changes in Years 1 10 and 2 of the program." So just so we're all clear 11 on language. 12 But I do have a couple questions for 13 you, Marcie, if you wouldn't mind. 14 MS. McCLINTIC COATES: Sure. 15 DR. UHL: You state that not all 16 applications should be treated alike. So in a 17 GDUFA system where there are goals, GDUFA goal 18 dates, attached to an application, how would you 19 propose that? And maybe you're not talking about 20 ones with goal dates and you're talking about 21 stuff that's in Years 1 and 2. 22 MS. McCLINTIC COATES: Yeah. No. I</p>

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<p style="text-align: right;">162</p> <p>1 actually am referring to all of it. Just from a 2 standpoint of from an alike standpoint, it comes 3 back to public health. So the goal dates in the 4 CR letters and so forth were all vehicles to help 5 us get to that ultimate end of fulfilling that 6 public health piece. So from that standpoint and 7 appreciating that the applications that are 8 submitted regardless of what goal date they may 9 have to try to keep them moving through given the 10 mass volume that the Agency is working through, in 11 terms of treatment of appreciating that these all 12 may have different nuances, it's because of the 13 fact that, goal dates aside, the Hatch- Waxman 14 framework that links the patent resolution process 15 to the approval process, that linkage that exists 16 here and unlike anywhere else in the world, it 17 makes applications by their very nature different 18 and, additionally, so do the public health needs 19 of each of those applications. So, you know, an 20 application may be there to address a shortage, an 21 application may be there to cover an orphan 22 indication that hasn't had a more affordable</p>	<p style="text-align: right;">164</p> <p>1 was a first generic is when the product is brought 2 to market. So are you saying that a first generic 3 that's approved and not brought to market, because 4 that happens obviously in some of the settlements 5 that you guys have, where would you consider that 6 in the scope of first generic? 7 MS. McCLINTIC COATES: So what I 8 reference is that so first generics that include 9 applications which no other generic version of the 10 same reference has even yet brought to market. So 11 technically in that example, you may be your 12 traditional first-to- file qualifying for 180, 13 going to open up the marketplace, but there are 14 scenarios where that very first filer just decided 15 to withdraw and they never actually marketed the 16 product. So the American marketplace, patients 17 continued to not have access to a generic, and so 18 that would technically be a first generic that's 19 opening the door for that. 20 So they are not necessarily a P4 21 traditional first-to-file. There are those 22 scenarios. Does that help?</p>
<p style="text-align: right;">163</p> <p>1 generic, and we would urge that as we are 2 implementing this program aimed at giving FDA the 3 resources needed to continue to achieve the 4 purposes, that we not lose sight of those same 5 purposes of allowing for the public health ones, 6 most impacting public health ones, and the ones 7 that are linked to Hatch-Waxman, to move through 8 on their earliest date. The Hatch-Waxman statute 9 continues to provide that FDA should strive for 10 180 days, and that's still in the statute. These 11 goal dates are, though, intended to continue, 12 compared to where we have been, with the volumes 13 at 31 to get those pieces back and to help us move 14 to a place over time the first cycle approvals. 15 DR. UHL: So I think it would be helpful 16 for the Agency to hear in the docket what industry 17 thinks public health impact is because I think 18 that's a -- you've seen in the Prioritization Map 19 what we think are public health priorities, but I'm 20 hearing much broader than that from you, Marcie. 21 I would like another bit of 22 clarification because one of the comments you made</p>	<p style="text-align: right;">165</p> <p>1 DR. UHL: It does. Thank you. 2 MS. TOUFANIAN: Anybody else? 3 MR. FLANAGAN: I just want to express 4 gratitude and appreciation for the amount of time 5 you invested in preparing for this. You took it 6 really seriously and devoted a lot of thought to 7 it. So thank you. 8 MS. McCLINTIC COATES: Thank you for 9 your time. I appreciate the opportunity and look 10 forward to working with you more as we work to 11 tackle our shared challenge of getting access. 12 Thank you. 13 MS. TOUFANIAN: Thank you very much, 14 Marcie. Unfortunately, the agenda I have in my 15 book may be out of date, so are we moving to -- 16 MR. FLANAGAN: Is that on? It's open? 17 Is it open? 18 UNIDENTIFIED MALE SPEAKER: No. 19 MR. FLANAGAN: It's open mic, though not 20 totally open. 21 MS. TOUFANIAN: I believe that certain 22 individuals did indicate a wish to speak. And</p>

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<p style="text-align: right;">166</p> <p>1 we're having some technical difficulties. 2 (Pause.) 3 MS. TOUFANIAN: Terrific. It looks like 4 Ken Cappel. And I have to apologize in advance, I 5 am reading sideways, so I will obviously 6 mispronounce some of these names. 7 Ken, can you go ahead and introduce 8 yourself and indicate where you're from? 9 MR. CAPPEL: Sure. Good afternoon. My 10 name is Ken Cappel. I'm the Vice President of 11 Global Intellectual Property for Amneal 12 Pharmaceuticals. I would like you to know that 13 I'm a pharmacist as well. I take my 14 responsibilities to the patients very seriously. 15 And I'm also an attorney and take my 16 responsibilities to the client very seriously. 17 I gather I have a little extra time, so 18 I'm going to do my whole statement. 19 Amneal would like to thank you and the 20 Agency for holding this conference. We appreciate 21 the opportunity to assist the FDA in matters that 22 are important to the public health and the generic</p>	<p style="text-align: right;">168</p> <p>1 outside the U.S. Amneal currently employs more 2 than 2,300 people globally. Over half of these 3 R&amp;D, manufacturing operations, and other 4 professionals are employed within the United 5 States. 6 Our portfolio of approved products 7 includes about 100 solid, oral, topical, and 8 liquid finish dosage forms. We currently have 9 over 100 ANDAs pending at the FDA and several of 10 these filings are believed to be first-to-file 11 opportunities. Obviously these filings are 12 exceptionally important to Amneal. 13 Amneal has achieved exceptional growth 14 over the past 10 years. This growth has resulted 15 in the creation of over 1,000 U.S.-based jobs. 16 Amneal's expansion is supported by a strong 17 commitment to investing in R&amp;D and growing its 18 infrastructure to support manufacturing in the 19 United States and abroad. 20 Amneal's ability to reinvest depends 21 heavily on the revenues generated by sales of 22 products which, without timely FDA approval, will</p>
<p style="text-align: right;">167</p> <p>1 industry. 2 The Agency and our industry are aligned 3 in that together we seek to provide the U.S. 4 health care system with cost effective medicines 5 that are equally safe and effective when compared 6 with our brand counterparts. This is clearly our 7 common goal. 8 Our parents, grandparents, and children, 9 our neighbors and friends, and countless other 10 patients benefit from the availability of generic 11 medications. In fact, this very sentiment is 12 reflected in the following quote from Amneal's 13 website. "We at Amneal understand that every 14 product the company manufactures is destined for 15 someone's loved one. Quite simply, together we 16 have a responsibility to these individuals. 17 Hearings like this provide an opportunity to 18 facilitate dialogue and change. Ultimately we hope 19 to achieve our common goal." 20 As background, Amneal is a U.S. company 21 headquartered in New Jersey with additional key 22 sites in New York, Kentucky, and other locations</p>	<p style="text-align: right;">169</p> <p>1 almost certainly fall short of the expected return 2 on investment needed to sustain growth. Amneal 3 fully recognizes that this is a two-way street, 4 improving transparency in the approval process 5 specifically regarding first-to-file products will 6 help to achieve our common goal. 7 GDUFA was supposed to improve many 8 aspects of the ANDA approval pathway. Notably, 9 Amneal expected that GDUFA fees would improve 10 communication and feedback from the FDA, which in 11 turn would lead to higher quality ANDA filings and 12 decreased approval times. Unfortunately, this has 13 not yet been realized. 14 Amneal would like to address GDUFA and 15 180- day exclusivity. Specifically, we are deeply 16 concerned with the lack of communication 17 surrounding first-to-file opportunities and the 18 need to obtain tentative approval within the 30 19 months of ANDA filing. 20 As you know, to be eligible for 180 days 21 of marketing exclusivity, a generic filer must be 22 the first applicant to file a substantially</p>

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170	<p>1 complete ANDA containing a paragraph for 2 certification. Congress enacted numerous 3 amendments to the Hatch-Waxman Act under the 2003 4 Medicare Modernization Act, and under the amended 5 statute, the first applicant could be deemed to 6 forfeit its eligibility if it failed to receive 7 tentative approval 30 months from the date the 8 ANDA was accepted by the FDA unless that failure 9 to obtain tentative approval was caused by a 10 change to the requirements for approval of the 11 application imposed after the date on which the 12 application was filed.</p> <p>13       There is a lack of communication from 14 the FDA on these first-to-file applications, which 15 creates uncertainty for the applicant and the 16 other ANDA filers. This unpredictability actually 17 creates additional work for the Agency because the 18 industry that's really seeking feedback -- excuse 19 me -- that's really seeking feedback from clarity 20 typically undertakes letter writing campaigns in 21 an effort to ascertain the status of the 22 application as the critical 30-month date rapidly</p>	172	<p>1 first-to-file submissions. As the FDA has 2 indicated, it intends to focus on new submissions 3 beginning October 1, 2014. The Agency has said 4 that it will issue target action dates only for 5 prioritized applications, and this creates an 6 intolerable level of uncertainty around critical 7 first-to-file ANDAs.</p> <p>8       On behalf of Amneal, I request the FDA 9 to issue target action dates for every first-to- 10 file submission within 60 days. In addition, we 11 request the FDA to open its channels to allow for 12 early and frequent communication on these 13 immensely important filings. Our common goal can 14 only be met through a stronger partnership, and I 15 assure the Agency that Amneal and the generic 16 industry stand together with you. We recognize 17 the hard work and dedication of the FDA, and we 18 are committed to working with the Agency in its 19 efforts to continually improve the ANDA approval 20 process. Thank you again for the opportunity to 21 speak on behalf of Amneal Pharmaceuticals. 22       MS. TOUFANIAN: Thank you, Ken. Any</p>
171	<p>1 approaches. Unpredictability also hinders launch 2 planning and can result in a delay of generic 3 products reaching the public as early as possible 4 as well as potentially costing first filers 5 significant revenues generated during the 6 exclusivity period.</p> <p>7       We also understand that the Agency is 8 navigating relatively new issues regarding risk 9 evaluation and mitigation strategies and abuse- 10 deterrent dosage forms. Dealing with these issues 11 may significantly delay FDA approval, which poses 12 a risk to the 180-day exclusivity. The industry 13 needs transparency regarding FDA's expectations 14 and concerns in these areas. This will allow the 15 industry to have some measure of predictability 16 while the FDA attempts to navigate these new 17 waters.</p> <p>18       The FDA's anticipated use of target 19 action dates are an important step in the right 20 direction. Amneal now has more than 100 ANDAs 21 pending review, none of which has a goal date. We 22 have a heightened concern about the future of our</p>	173	<p>1 questions from the panel?</p> <p>2       MR. FLANAGAN: Sorry. I do have a 3 question. Thank you very much.</p> <p>4       So on the communications transparency 5 issue with respect to the first-to-files, you 6 know, we're building a robust RPM staff, and 7 hiring and training to make that happen. They 8 won't be able to be -- in the immediate short 9 term, they're not going to be like legacy OGD 10 staffers who have been here for decades and can 11 give you a sophisticated read on the regulatory 12 path forward on that submission; right? As a 13 practical matter, if we're going to give you some 14 sort of update, it probably needs to be kind of 15 formulaic, enough into the review so that we have 16 something to report, but far enough back from the 17 goal date so that it gives you enough advanced 18 notice.</p> <p>19       It's the same question that I had for 20 Mr. Gaugh, is in your view, which data points in 21 general are the most helpful to you in trying to 22 plan a product launch? What data points do you</p>

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<p style="text-align: right;">174</p> <p>1 most crave? 2 MR. CAPPEL: Right. So I'm not punting, 3 but from my experience, each product really it's 4 like a person with its own personality, and so the 5 issues that you're dealing with each product are 6 so different. So, for example, chemistry may be 7 the critical datapoint for certain products, but 8 then if you're dealing with REMS or ADF, then the 9 labeling is clearly critical as well. You know? 10 So it's hard to really give you a clear answer, I 11 wish I could, but I think it's very fact 12 sensitive. 13 DR. UHL: Can I build on Keith's? Just 14 so -- I understand your point, but there is a need 15 for consistent processes, and so where are there 16 similarities that would be helpful for us so that 17 we can find these touchpoints, which Keith is 18 trying to elucidate from you? So I understand 19 every product is unique, but not all products are 20 entirely unique. There are a range of similarities 21 across them. 22 MR. CAPPEL: I agree.</p>	<p style="text-align: right;">176</p> <p>1 information for product launch purposes. We 2 understand that. 3 MR. CAPPEL: Great. Thank you very much 4 for your time. 5 DR. UHL: Thank you. 6 MS. TOUFANIAN: I just have one follow- 7 up request. I think I will be the one giving 8 everybody homework today. One of the things you 9 mentioned was increased communications with regard 10 to ANDAs that are approaching a 30- or 40-month 11 forfeiture date. I would encourage you in your 12 comment to identify precisely when and what 13 mechanisms you would want us to use for those types 14 of communications. 15 MR. CAPPEL: Okay. Thank you very much. 16 MS. TOUFANIAN: Thank you. 17 Carolyn Huntenburg, from Momenta. 18 Welcome. 19 DR. HUNTENBURG: My name is Carolyn 20 Huntenburg. I'm with Momenta Pharmaceuticals, and 21 I thank you for the opportunity to talk about from 22 Momenta's perspective. Much of what I am going to</p>
<p style="text-align: right;">175</p> <p>1 DR. UHL: And that would be helpful for 2 us to hear. 3 MR. CAPPEL: Right. So I think maybe 4 what we could do as an industry is go back and 5 discuss trying to put some comments into the 6 docket for you and maybe put different buckets of 7 projects together, and obviously there will be one 8 miscellaneous, which is going to be difficult, but 9 we'll talk about that. 10 DR. UHL: Because you would hate to hear 11 us say back to you that everything is unique, so 12 we can't create any process. 13 MR. CAPPEL: Of course. I realize that. 14 I realize that I've heard a lot of that today, and 15 we talked about that at lunch, that it's a problem 16 that we need to work together to overcome. You 17 shouldn't be put in that position by us, and we 18 don't want to be put in that position by the 19 Agency. 20 MR. FLANAGAN: And I think the message 21 we do want to send today as an Agency is that we 22 do get it, we do understand that you need some</p>	<p style="text-align: right;">177</p> <p>1 say has been said throughout the day, so I'll go 2 ahead and start. 3 Momenta believes that in order to bring 4 new generic drugs to the market effectively, 5 frequent and informative and timely communications 6 between the FDA and the ANDA sponsor are critical. 7 Timely two-way communication calls for both 8 parties to anticipate and/or respond to the 9 actions necessary to bring new generic drugs to 10 market in a safe, efficient manner. 11 One of the key components of the GDUFA 12 program is transparency, which includes 13 communication to the industry. Transparency and 14 communications were critical issues during the 15 GDUFA notifications. One of the principle reasons 16 for paying a user fee was to establish a 17 predictive process that will support industry to 18 be able to provide safe, effective, and affordable 19 medications to patients. 20 Over the past year, since the 21 implementation of GDUFA as well as complete 22 response letters, our experience has been that</p>

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178	<p>1 meaningful communications about ANDA status has 2 become significantly restricted. This restriction 3 and allowable and substantive communication 4 between the ANDA sponsor and FDA is dictated by 5 OGD policy where OGD staff are not allowed to 6 provide ANDA sponsor with any specific information 7 regardless of whether it is critical or not until 8 the complete response letter is received. This 9 restrictive communication has undoubtedly delayed 10 the sponsor's ability to react to the information 11 when received and likely results in a delay in 12 approval. These issues will be only further 13 magnified by the complexity of applications 14 received by the FDA increases.</p> <p>15 Patients benefit from earlier approvals. 16 If there are more timely informal communications, 17 particularly with complex applications, the 18 applicant can work in parallel on important 19 additional development requirements while the FDA 20 reviews other aspects of the filing. This will 21 allow parallel processing and would significantly 22 improve the advancement of approval dates.</p>	180
179	<p>1 Currently, if all feedback is held, then the 2 effort of the Agency is magnified in scope for 3 each review, and the applicant sits idle during 4 the review period, which is a highly inefficient 5 process.</p> <p>6 Momenta strongly urges the FDA to 7 implement an effective ongoing and substantive 8 communication process between the industry and the 9 FDA throughout the ANDA review process. By doing 10 so, the use of resources and times on both sides 11 is conserved. The benefit of increased 12 communication will surely reduce inefficiencies in 13 the process that currently exist and, more 14 importantly, assure timely access to affordable 15 generic medicines. Thank you very much for this 16 opportunity.</p> <p>17 MS. TOUFANIAN: Thank you. Any 18 questions from the panel? 19 (No audible response.) 20 MS. TOUFANIAN: Thank you for your time. 21 DR. HUNTENBURG: Thank you very much. 22 MS. TOUFANIAN: Carole?</p>	181

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182	<p>1 obviously have benefited through this competition 2 and the availability of lower cost products. 3       In the last 10 years, as you heard 4 earlier, we saved over a trillion and a half 5 dollars. \$239 billion of that was just in 2013 6 alone. This is as a direct result of the 7 availability and access to generic drugs, so it's 8 crucial that as GDUFA is implemented, we don't 9 undermine patient access to high-quality, low-cost 10 generics. 11       Competition is critical to the continued 12 success of Hatch-Waxman. Maintaining competition 13 serves the public good and decreases health care 14 costs. 15       With that in mind, focusing on complex 16 products where there are no generics available and 17 a pathway for those is important. Focusing on 18 first generics and P4 filings and ensuring access 19 at the earliest legal point is important, but that 20 doesn't minimize the need and let us lose sight of 21 the need for competition where the science may be 22 simple or where there are multiple products out</p>	184	<p>1 transparency with regard to review time, GDUFA 2 intended to increase and expedite access to low 3 cost, high quality generic drug products. I think 4 it's important to remember that if you talk to 5 generic customers, they would find that price 6 decreases with the introduction of each and every 7 generic drug drives down costs. These costs 8 continue to decrease with the entry of multiple 9 generics, even the fourth, fifth, and sometimes 10 sixth and seventh generic drugs. So simply 11 looking at the very first one is really the 12 beginning of the story, it's not the end of the 13 story. 14       In addition, all products have a product 15 lifecycle. Even older products in mature markets 16 where there have been multiple approvals and 17 intense competition don't always exist and stay on 18 the market. There are many products that we all 19 know exist have 5, 7, 10 approved ANDAs, but there 20 may only be two products commercially available. 21 In some of these cases, ANDAs are discontinued, 22 plants are closed, applications are withdrawn,</p>
183	<p>1 there that could at any point become an issue for 2 shortages. So looking at all of these 3 applications is important. 4       And I'm very sensitive to the need to 5 prioritize. And I don't want to underestimate the 6 challenge that exists at FDA with the volumes of 7 applications you have. That said, it is only 8 through competition that we actually achieve our 9 goals, increasing access and controlling costs. 10       So although it is critical to ensure 11 that the first generic is approved and available 12 at the earliest legal date, accomplishing that 13 goal is just not enough, it doesn't get us where 14 we need to go. In order for competition to thrive 15 and truly maximize value to the consumer, it is 16 essential that the Agency continue to prioritize 17 and approve multiple applications for the same 18 references to drug. In fact, the opening 19 paragraphs of the GDUFA goals letter clearly lays 20 that purpose out. 21       By bringing greater predictability to 22 the review process and ensuring greater</p>	185	<p>1 whatever the reason, the market ends up being only 2 a very few commercially available products. 3       Because these products have no patents, 4 they may actually be more attractive to smaller 5 companies because they don't have to pay the 6 litigation fees and sometimes the cost of 7 development or the path to approval is more 8 straightforward. So they seem simple and they 9 seem unimportant, but if you look at it in the 10 eyes of the consumer, they actually are very 11 important. And so with that said, it is really 12 important that we continue to look at these 13 products. 14       The approval of these ANDAs may aid in 15 preventing drug shortages. As we know, it's an 16 incredible problem, but there are many cases in 17 the industry where there are only two products on 18 the market, something happens to the API supplier 19 of one, something happens to the ability of that 20 company to manufacture, and all of a sudden we're 21 facing a shortage in those arenas, and they're not 22 always foreseeable. It also maintains</p>

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186	<p>1 competition, which will also increase and ensure 2 the continued low cost availability of these 3 products. 4       So with that in mind, first generics I 5 think really, like I said, are incredibly 6 important, but we need not to ignore all the 7 others. 8       It is for these reasons, while I 9 recognize the importance of reviewing and 10 approving the first generic, that's not where we 11 can stop. Timely approval of subsequent generics 12 is immensely important to a healthy generic 13 market. Each and every ANDA, whether submitted in 14 year 3, 4, or 5 of GDUFA implementation or whether 15 submitted in year 1 or 2, or, for that matter, 16 sitting in the pile of more than 3,000 17 applications in the backlog, serves to ensure a 18 robust generic supply. This in the end serves 19 patients and consumers and ensures access to low 20 cost generic drug products. 21       I really want to assure the Agency that 22 all of us in this room are sensitive to the</p>	188	<p>1 just dedicate somebody to the issues that you deal 2 with. 3       And so I think if we can reach out -- if 4 some of the smaller companies, you can reach out 5 to them, you can hear some of the issues that we 6 deal with that not all of the big companies may be 7 dealing with. A lot of the smaller companies 8 don't have P4s, they just don't do them because 9 they don't have the legal wherewithal, they don't 10 have the financials, to support the P4 11 environment, but it's the small companies 12 that ultimately become big companies. 13       And I've worked for many small companies 14 who quite honestly 20 years ago were very small 15 and today they're really big. And so it's those 16 small companies that actually grow and help 17 improve and ensure the competition and the success 18 of Hatch-Waxman. So we look forward to working 19 with you, we look forward to the implementation of 20 GDUFA, and we look forward to GDUFA2. 21       So I'll open it to questions. 22       MS. TOUFANIAN: Thank you very much for</p>
187	<p>1 magnitude of what we're undertaking. Quite 2 honestly, I've worked on the brand side and the 3 generic side, and I think PDUFA pales in the face 4 of GDUFA. The dollars involved are very 5 different. The length of review, the types of 6 data, the number of applications for any one 7 reference listed drug is a real challenge. And so 8 I don't think it's that we aren't sensitive to the 9 issues, we are very sensitive to the issues, and, 10 as Marcie said, I think we want very much to 11 partner with the Agency. 12       I also want to say something else about 13 small and mid-sized companies that I think is 14 important. It may appear to the Agency that those 15 companies are not engaged in this process. They 16 are very much engaged. We just don't have the 17 resources that some of the bigger companies do. 18 We don't have somebody dedicated to government 19 affairs. I am it. So we use our industry 20 association often as a resource to help supplement 21 some of our issues and to engage with you because 22 we don't have the number of people that we can</p>	189	<p>1 your comments. Any questions from the panel? 2       DR. UHL: Yeah, I have questions. So I 3 recognize what you're saying about the smaller 4 companies maybe not having a stake in the ground 5 for the P4 first-to-files. So do you have any 6 suggestions, recommendations, et cetera, around -- 7 because your point is don't leave the other ones 8 behind. 9       DR. BEN-MAIMON: Yeah. 10       DR. UHL: There may be circumstances 11 where the not first-to-file is a bolus of a large 12 number of applications. 13       DR. BEN-MAIMON: Yeah. 14       DR. UHL: So are there recommendations 15 on how do we prioritize that or how do we look at 16 that? 17       DR. BEN-MAIMON: And it's a struggle. 18       DR. UHL: Yeah. 19       DR. BEN-MAIMON: It's a struggle because 20 obviously in an ideal world you would have the 21 resources to approve all the applications in a 22 timely fashion, and we know it's not likely to</p>



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<p style="text-align: right;">190</p> <p>1 happen and it's clearly not likely to happen in my 2 lifetime. 3 MR. FLANAGAN: We'll get there. 4 DR. BEN-MAIMON: What? 5 MR. FLANAGAN: We'll get there. 6 DR. BEN-MAIMON: So obviously at least 7 in the short term we need to look at that. 8 And I've sort of toyed around with 9 ideas, and I would like to go back, and we will 10 file something to the docket, but the concept of 11 really trying to look at an argument for the 12 public good, I've sort of thought about, is there 13 something that's similar to the benefit-risk 14 assessment that you do on a brand product that 15 would allow you to make the arguments on a generic 16 product? But then that throws it sort of back in 17 your line where you've got to go through all these 18 benefit-risk assessments and trying to figure out, 19 well, which one fits where? 20 And so I think we, as an industry, have 21 to hash it around, but what I really wanted to do 22 today was really introduce the concept that it's</p>	<p style="text-align: right;">192</p> <p>1 being work on our reviewers' shoulders, so we have 2 multiple highly skilled technical reviewers 3 spending a lot of time reviewing these for the end 4 result of an approval but a product that doesn't 5 appear in the marketplace, and we end up hearing 6 time and again we need all these approvals to get 7 -- drive prices down, yet ultimately when we have 8 10 or 12 or 14 approvals for a drug, not everybody 9 goes to market. How would you suggest that we, as 10 an agency, balance that in any of our 11 considerations? Could we or should firms state 12 that they will go to market for a specified period 13 of time? 14 DR. BEN-MAIMON: So I hear you and I 15 think that's a really important point because we 16 all know of a bunch of different situations. 17 There are the 10 or 12 approvals and only 6 18 launch. We know the resources are still spent on 19 the others. There are situations more recently, 20 quite honestly, where there were companies decided 21 not to launch and were sorry because only four or 22 five companies came out and then there was a</p>
<p style="text-align: right;">191</p> <p>1 not so obvious. And it's important to the small 2 companies, but more important, like I said, it's 3 important to consumers because it's a lot of the 4 smaller companies that are manufacturing the older 5 drugs that aren't quite as sexy where companies 6 have gone out of the marketplace, and we are at 7 risk either for shortages or for less competition 8 and therefore not meeting the requirements or the 9 intent of Hatch-Waxman. 10 And so I think we need to toss it around 11 as an industry, but I think opening the dialogue 12 was really my intent. 13 MS. TOUFANIAN: Thank you. 14 Anything else? 15 MR. SHIMER: I have a comment. One of 16 the things -- you know, I've worked at the Office 17 of Generic Drugs for a little over 14 years now, 18 and one of the things I've seen over time is when 19 we do endeavor to get multiple applications 20 approved for a specific drug product by a goal 21 date, it's very seldom that all of those folks end 22 up launching their products, yet that all ends up</p>	<p style="text-align: right;">193</p> <p>1 shortage in the marketplace and really prices did 2 hold up. So from a perspective of the industry, 3 they wish they had been there. 4 There are situations clearly where you 5 spend resources and we pull applications. And 6 that's a very big issue I think is more that we 7 can't -- we are making business decisions. If the 8 drug isn't going to be profitable, if we can't 9 even make back the money on our validation 10 batches, why would we launch? And where that 11 occurs, whether it's at 4, 5, 6, or 7, I can't 12 tell you, but the fact of the matter is -- and I'm 13 going to be a little bit of a bull in a china 14 closet, and I'm not meaning to offend anybody, all 15 of those applications pay user fees, so they're 16 entitled to a review technically. So, I mean, if 17 you don't want to charge the seventh, eighth, and 18 ninth, that may be a solution. I'm only kidding. 19 But the fact of the matter is in the user fee 20 world, there is an obligation to pay the user 21 fees. I mean, that's sort of I think where a lot 22 of us feel about the backlog issue, is we paid</p>

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<p style="text-align: right;">194</p> <p>1 backlog fees. 2 Now, again, I understand you have 3 thousands and thousands of applications with 4 limited resources and lots of new people and this 5 isn't all going to work itself through in 6 6 months, I get it, and we run companies and we have 7 our own challenges, but you can see from our 8 perspective that we obviously file the application 9 with the intent to launch. We don't make the 10 investment in the R&amp;D dollars and in the GDUFA 11 numbers and all that. Sometimes delays occur and 12 we get in too late, and so we don't launch the 13 product. 14 But I would also say one other thing, 15 and that is that an approved product still has 16 value, an approved ANDA still has value, and there 17 are also situations where, at least at our 18 company, we have chosen not to launch but 6 or 8 19 months later we decide the market is actually more 20 attractive than we thought it would be. We go 21 back and we make sure we have done all of our 22 validation and everything and we do launch. So I</p>	<p style="text-align: right;">196</p> <p>1 of the application. We also support the 2 possibility of a reduced fee for us because we do 3 make a very small profit on what we do make, so 4 maybe a sliding scale or 10 percent of profit or 5 something like that that might be associated with 6 the GDUFA fees because we do push those fees on to 7 our customers. Some are hemming and hawing about 8 it, others are grudgingly accepting it. However, 9 it does increase the cost of generics, and so the 10 cost of generics are going to go up. That's 11 eventually going to be passed on to all customers. 12 That said, I have a series of topics I 13 would like to discuss. One is -- it was just 14 brought to my attention -- that the ANDA checklist 15 was just kaput and I think that was a bad idea, a 16 really, really bad idea, because the content and 17 format and the other guidance documents that are 18 coming out are piecemeals that kind of explain 19 some of the sections associated with that, but not 20 having a whole entire list of what's required in 21 an ECTD, we have that list, what's required ECTD, 22 but not everything in there is required for an</p>
<p style="text-align: right;">195</p> <p>1 think an approved application is an application 2 that still I think has value to every company. 3 MS. TOUFANIAN: Thank you very much. 4 MR. LAWRENCE: Good afternoon. My name 5 is Leonard Lawrence, and I'm from Sovereign 6 Pharmaceuticals, and we're that small company that 7 Carole was just talking about. We have about 130 8 people in our company. We're a contract 9 manufacturer, and we do contract manufacture of 10 both generics and NDAs. We also have filed some 11 NDAs and ANDAs under our own name for somebody 12 else to distribute for us because we have no 13 distribution capabilities. So we kind of fit in 14 with all of the things that were discussed today. 15 And so I would like to bring up some information 16 regarding some of the things that were talked 17 about this morning and this afternoon. I have a 18 series of questions for you -- not questions but 19 comments. One is we support some of the comments 20 we're talking about on contract manufacturing this 21 morning about maybe some exemptions for contract 22 manufacturing, so we're pushing that to the owners</p>	<p style="text-align: right;">197</p> <p>1 ANDA. So it really gives companies, especially 2 smaller companies, an opportunity to make sure 3 that we have all the information that's needed to 4 be included in an ANDA. In fact, one of the 5 things, being in charge of regulatory affairs for 6 the company, one of the things that we do is we 7 take that list, that checklist, and we put it in 8 Word format, and we link it, so it's like a table 9 of contents in the application, so we link every 10 single thing so it makes it very easy for the 11 reviewer to say, "Okay, you got this, you got 12 this, you got this." By taking it away, then I 13 think it makes it more difficult for us to make 14 sure we're not missing everything and makes it 15 more difficult for you to make sure everything is 16 there. So I would suggest that you reconsider 17 bringing that back in as a tool for the industry 18 to use. 19 Some of the other topics that I do have, 20 talking about the backlog, we do have several 21 applications in the backlog, and we're just 22 concerned that they're not going to get lost in</p>

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<p style="text-align: right;">198</p> <p>1 this whole transition into the GDUFA, and we feel 2 like the GDUFA is a good idea because you have a 3 plan to move forward because going before wasn't 4 working really well because you kept on getting 5 backlogs, and so it's a good thing to move forward 6 to have a plan to move there, but we want to make 7 sure that the applications that are in the backlog 8 don't get lost. If you look at it in the Year 9 2017, I believe it says that 90 percent of the 10 backlog will have a decision made on it. Well, 11 that leaves 10 percent of the applications over 5 12 years or more without any type of decision made on 13 it, and that's a long time. And if you have 14 3,000, well, you've got 300 applications, that's 15 significant. And to a small company like us, that 16 makes a big difference because we are dependant on 17 these applications. We have a little bit of them, 18 we don't have a lot of them, and we're actually 19 getting more, but we're still dependent on these 20 applications, so it can make or break a smaller 21 company in what we do. 22 The next topic is some of the things,</p>	<p style="text-align: right;">200</p> <p>1 -- we get a stay on the refuse- to-receive issue 2 associated with that if we're within a reasonable 3 amount of time, again if it is listed as a food 4 product and it's listed in the CFR. There are 5 other references. We're not trying to just give a 6 whole -- a higher amount of excipients in there. 7 However, but if it's been a standard across the 8 industry for a long time, then maybe we should get 9 a little bit of relief from that until that IID is 10 there because it makes it very difficult for an 11 application. 12 Another thing that we've come across 13 that is a policy issue that I think needs to be 14 addressed is the fact that some of the chemicals 15 that we get we need to be within 1.5 micrograms 16 per day. Well, we get that a lot. However, the 17 FDA has already issued toxicology studies to 18 toxicology programs saying that you can have more 19 than that. Also, for example, one of them is a 20 flavoring agent that's commonly used in food, yet 21 we're to keep it down 1.5 micrograms per day, 22 which we can, however, just to go into the</p>
<p style="text-align: right;">199</p> <p>1 difficult things, that I come across in an 2 application is the IID. I know it was talked 3 about earlier today. We make some liquid products, 4 and it's very difficult with the way it's written 5 to use a tablet for an excipient for a liquid 6 product because tablets don't use the same 7 excipients as a liquid product. You don't use 8 much glycerin or propylene glycol in a tablet than 9 you would in a liquid, so it makes it very hard. 10 And so we end up having to write this huge 11 justification for having a product that -- an 12 excipient that has been accepted in the past that 13 now can be a refuse-to-receive. Also, being a 14 contract manufacturer, we may know that another 15 application has a certain level in it and it has 16 been approved, however, we're making this other 17 application for somebody else, and we can't cross- 18 reference those applications, and so it makes it 19 really difficult, so we end up having to do this 20 complex time-consuming process to justify every 21 time. And my suggestion is that if the IID, until 22 the database is more fully populated, that it may</p>	<p style="text-align: right;">201</p> <p>1 justification for that is very, very time- 2 consuming and onerous on us, so I would like to 3 consider that if there is an established level of 4 toxicity, that you look at that first before 5 forcing that onto a complete response letter. 6 Also, controlled correspondences. One 7 of the things that's associated with controlled 8 correspondences is the fact that we are trying to 9 develop product, but if we don't get a response 10 back within 9 months, then it makes it very 11 difficult because we have somebody that wants to 12 make it and give us money to make it, which is 13 what we're in business for, one of the reasons, 14 and we can't make it because we don't get an 15 answer, and so it makes it very difficult, the 16 time delay, and I know that it will be better, but 17 even 4 months is a long time for certain type of 18 controlled correspondences. 19 And I understand there is a level of 20 difficulty, but I didn't hear anything about 21 prioritizing some of the controlled 22 correspondences, ones that are easy to get done</p>

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202	<p>1 that are quick, 5- minute answers like Q1/Q2.  2 That's probably not a whole difficult time. You  3 go back to what the NDA is and you can see, are  4 you within 5 percent? Yes or no. It doesn't seem  5 like to be that difficult, yet it's taking months  6 and months and months to get that type of  7 information.  8 Also, putting requirements on  9 generalized requirements, I think it's more of a  10 procedural thing. For example, we do make some  11 solutions and they are oral solutions, and they  12 are pretty much water, and we keep on getting this  13 viscosity thing coming back in there where we need  14 to put a viscosity, and that's really the  15 viscosity is like less than 10. Really there is  16 not really any viscosity to it, yet we're asked to  17 put a viscosity spec in when it really doesn't  18 seem to make sense for it. Now, if it was a syrup  19 which was thick or something like that, it might  20 be applicable, but sometimes it's not applicable.  21 So maybe look at when those type of responses come  22 back, is it really appropriate for this type of</p>	204	<p>1 Any questions from the panel?  2 (No audible response.)  3 MS. TOUFANIAN: No? It sounds like  4 you've put a lot of thought. I would encourage,  5 as we have with all the speakers, to submit to the  6 docket.  7 MR. LAWRENCE: Yes, we will be doing  8 that. Thank you.  9 MS. TOUFANIAN: Thank you.  10 So now in the afternoon we'll go ahead  11 and take a 15-minute break, reconvene at 2:45 for  12 the remainder of the comments. Thank you.  13 (Break.)  14 MS. TOUFANIAN: This afternoon we'll  15 have four more comments starting with John.  16 MR. DUCKER: Unlike Carole, I don't need  17 to think about whether I need the glasses or not.  18 (Laughter.)  19 MR. DUCKER: So good afternoon,  20 everybody. My name is John Ducker. I'm the  21 President and CEO of Fresenius Kabi USA. So I'm  22 not one of these technical guys, don't get too</p>
203	<p>1 product?  2 Also, the last thing I would like to  3 talk about is the USP. There was a guidance  4 document put out in 2004 on discretion use of USP  5 compendium method changes, but then when the new  6 draft guidance came out, it does say that for a  7 change in USP, you need to do a CBE-30 if you're  8 going to delete a test or you're going to relax a  9 test. However, I understand for active  10 ingredients that's probably not anything that you  11 would want to do, but for excipients, it's  12 creating a lot of difficulty because either we  13 file it or our clients have to file a CBE-30 to do  14 it, and by the time you get that chain moving and  15 getting it there, the reality is if you have a new  16 application that has the current USP in it, you're  17 going to approve it most likely that way, so it  18 really doesn't affect the other one, it's just a  19 process, and you're just adding more to your CBE-  20 30 pile.  21 So those are my comments.  22 MS. TOUFANIAN: Thank you very much.</p>	205	<p>1 tough with me on the questions.  2 Thank you for the opportunity to share  3 our experience of the GDUFA implementation thus  4 far. This is a topic that is of critical  5 importance to my company, and my hope is that  6 through dialogue and public hearings like this  7 one, positive change will take place in how the  8 FDA and the generic pharmaceutical companies work  9 together to achieve our common goal of better  10 serving patients and those who care for them.  11 Fresenius Kabi is a global health care  12 company with more than 30,000 employees that  13 specializes in life-saving medicines and  14 technologies for infusion, transfusion, and  15 clinical nutrition. In the United States, we are  16 the second largest supplier of generic injectable  17 pharmaceuticals.  18 U.S. headquarters is near Chicago in Lake  19 Zurich, Illinois. Our portfolio comprises more  20 than 100 injectable drugs and approximately 400  21 dose presentations and includes oncologytics,  22 anesthetics, analgesics, and a wide range of anti-</p>

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<p style="text-align: right;">206</p> <p>1 infectives and other critical care drugs. 2 Fresenius Kabi invests heavily in 3 research, development, and manufacturing 4 operations in the United States and overseas, and 5 the return on these investments relies on the 6 timely approval of our ANDA and prior approval 7 supplements. 8 The promise of GDUFA back in 2012 was to 9 achieve three critical public health goals: 10 improved safety through an increase in inspectors 11 and inspections, creating a level playing field 12 between foreign and U.S. manufacturers; improved 13 access by expediting the approval of low cost, 14 high quality generics; and bringing greater 15 predictability to review timelines, and improve 16 transparency by identifying the facilities 17 involved in the U.S. supply chain and improving 18 the Agency's communications and feedback to the 19 manufacturers. 20 The FDA said it would need additional 21 resources to achieve these goals and made a 22 commitment to drug developers that with new fees</p>	<p style="text-align: right;">208</p> <p>1 help alleviate critical shortages. And I would 2 like to take this opportunity to express our 3 appreciation to FDA's Office of Drug Shortage. I 4 think this is the type of working relationship 5 that could serve as a model for the Agency in 6 terms of information sharing and collaboration. 7 Our experience with drug shortages that 8 are not on shortage tells -- I'm sorry, with drug 9 approvals that are not on shortage tells a very 10 different story. Fresenius now has more than 50 11 ANDAs pending review, none of which has a goal 12 date, and we are concerned about the future of 13 these submissions because the FDA has indicated 14 that beginning October 1st this year it intends to 15 focus on new submissions in order to hit 16 obligatory performance metrics. 17 For the 3,300 total backlog submissions, 18 the Agency has said it will issue target action 19 dates only for prioritized applications. The 20 remaining applications are therefore likely to be 21 further delayed and the drugs that are caught in 22 this regulatory limbo may lose value as generic</p>
<p style="text-align: right;">207</p> <p>1 paid to the FDA, we could expect over time 2 measurable improvement in the backlog of drug 3 approval applications in communications and in 4 compliance activities. 5 The GDUFA commitment letter further 6 anticipates at least the aspiration, as Cook said, 7 that during the first 2 years of GDUFA things 8 would not get worse and that productivity would be 9 maintained. Unfortunately, our experience since 10 October 2012 is just the opposite. In the 5 years 11 prior to GDUFA, Fresenius Kabi's average approval 12 time for an ANDA was around 17 months. Today the 13 average is more than 36 months and rising. At the 14 same time, a lack of communication during the 15 approval process has added uncertainty and 16 unpredictability that has further slowed access to 17 lower cost generic medicines. 18 On the positive side, the Agency has 19 been doing a better job of prioritizing approvals 20 and importation of medicines where there has been 21 a drug shortage. In some cases, our products have 22 been approved in weeks, enabling Fresenius Kabi to</p>	<p style="text-align: right;">209</p> <p>1 prices fall or other companies receive approvals. 2 These drugs represent hundreds and hundreds of 3 millions of dollars of R&amp;D investment to the 4 industry. 5 So on behalf of Fresenius Kabi, I 6 request that the FDA allocates dedicated resources 7 to reduce the ANDA and PAS backlogs in a timely 8 manner and that the Agency issues a target action 9 date for every backlogged application within 6 10 months. 11 Many of you have a service background, 12 and this is an expression that Keith used when he 13 addressed the CEO Summit I think a couple of weeks 14 ago, and it's the principle that no file will be 15 left behind. I think that's critical, Carole 16 talked to it earlier, and I think it's critical to 17 us. 18 Turning to transparency, things 19 unfortunately have deteriorated here as well. As 20 you've heard, the planning and execution of a 21 generic launch is complicated and takes many, many 22 months. Unless manufacturers have line-of-sight to</p>

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<p style="text-align: right;">210</p> <p>1 approval dates, they cannot start these 2 preparations since GDUFA FDA is communicating 3 less, not more. 4 As an example, my company filed a 5 Paragraph 4 ANDA in September 2012, and we have 6 had no response from the Agency in 2 years despite 7 Paragraph 4 filings supposedly being one of the 8 FDA's priorities. When we inquire -- and we do 9 regularly, believe me -- we receive a standardized 10 response asking us to contact the Agency in 3 11 months. We might as well talk to an answering 12 machine. Market formation for this drug is 13 expected to take place in May 2015, and 2 years 14 after filing we still have no idea of whether 15 Fresenius Kabi will have the opportunity to 16 participate. It is deeply frustrating and 17 challenging to manage our business in this 18 communications vacuum. 19 I think maybe some of you experience 20 that vacuum and that frustration in the restaurant 21 at lunchtime. You study the guidelines, the menu, 22 you submitted your order in plenty of time, no</p>	<p style="text-align: right;">212</p> <p>1 speak today. I encourage you to support the 2 changes I've outlined, as they will have a 3 positive effect on the FDA's mission, reputation, 4 and on the U.S. health care system. We would 5 welcome the opportunity to work more transparently 6 and effectively with the Agency and we hope that 7 this meeting will be the start of such a process. 8 Thank you. 9 MS. TOUFANIAN: Thank you very much. 10 Any comments from the panel? 11 Yeah, go ahead. 12 DR. UHL: Thanks, John. I appreciate 13 your comments this afternoon. So about your 14 request that all applications be given a target 15 action date, how would industry respond -- or 16 think about this because that plays into the 17 prioritization scheme as such -- because of other 18 aspects of GDUFA, the hiring, training, et cetera, 19 so there will be more staff and more capacity. So 20 being given a target action date that's 2 years 21 out, that's not fixed because that could very well 22 move. So you would want to know about every</p>
<p style="text-align: right;">211</p> <p>1 food arrived. You finally managed to track down 2 your project manager or waitress who could only 3 tell you that the kitchen has a backlog of 3,300 4 orders and she can't tell you when your food will 5 arrive. Frustrating. And unfortunately we had a 6 deadline, too, to be back here at 5 past 1:00, so 7 I know some of you didn't get food. So you know 8 what it's like; right? This is the experience of 9 our life. 10 My second request to you, therefore, is 11 that the FDA provides clear and open communication 12 to applicants. If our target action date is still 13 2 years away, tell us so that we can tell 14 physicians, patient groups, and GPOs, and just as 15 important, plan our business in manufacturing. 16 Allow us to be part of the prioritization process. 17 Not all of our submissions have equal priority, 18 not all of them have equal commercial value. So 19 we would like to help the Agency focus its limited 20 resources appropriately, and this, too, requires a 21 greater level of communication than we have today. 22 So thank you for the opportunity to</p>	<p style="text-align: right;">213</p> <p>1 single application that you have pending with a 2 target action date that's not fixed. 3 MR. DUCKER: Well, it depends on -- then 4 a target action date has little value if you don't 5 consider it to be fixed or some level of 6 commitment. I understand that a target action date 7 would be a date by which you anticipated giving a 8 complete response. Now, that may not be met 100 9 percent of the time, that I also understand. 10 But we're encouraging a dialogue here. 11 We're all adults, and I think we're not going to 12 hold you accountable to everything you say. There 13 seems to be a fear when we communicate with the 14 Agency that you don't say anything to us in case. 15 You know? And we want to find a way in which we 16 can have a dialogue with you that is responsible 17 on both sides, and that requires trust, and that 18 trust will only come through more and more open 19 communication. But, yes, specifically, I would 20 like to know, even if that date is 48 months from 21 now, and even if it's not a guaranteed date, I 22 would rather know that because it allows me to</p>

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214	<p>1 plan. We've got this 50 ANDA backlog. We don't 2 know whether they're going to be approved in 3 3 months, 6 months, or 3 years. In 2017, we think 4 90 percent of them might be out; right? 5 DR. UHL: Right. 6 MR. DUCKER: Or at least have a complete 7 response. 8 DR. UHL: Or they'll be acted upon. 9 MR. DUCKER: Exactly. But, you know, we 10 have no knowledge at all, and 2017 is a long time 11 away, and we have to plan business. We have to 12 set budgets, we have to decide whether we're going 13 to lay people off waiting for those applications 14 to arrive, whether we're going to close down 15 manufacturing lines waiting for those applications 16 to arrive. Any transparency, even if it's 17 arranged, even if you took those 3,300 and said 18 these are A's, these are B's, these are C's, these 19 are D's, and these are E's, allow us maybe to 20 comment on that and say, well, we think that E is 21 really important to us. You may think it's a 22 fifth generic, but we think it's very important</p>	216	<p>1 send these into the docket on three areas where I 2 think you could do some guidance development in 3 the area of generic drug development. And they 4 include post-approval changes to tentatively 5 approved PEPFAR application to allow for CBE type 6 changes. The next would be to provide some 7 clarification and guidance and clarity on 8 inspection process revolving around the biomedical 9 research facilities involved in bioequivalence 10 studies both of clinical and analytical 11 facilities. And then to reiterate what David 12 Gaugh said about the suitability petitions, how 13 they could be addressed and provide some metrics 14 around the suitability petition so that they could 15 be handled in an expeditious fashion. So I thank 16 you, and we will send in our comments to the 17 docket. 18 DR. UHL: Can I just ask a clarifying 19 question? 20 MS. TOUFANIAN: Yes, please do. 21 DR. UHL: So thanks, Tim, for that. In 22 your comments to the docket related to clarity on</p>
215	<p>1 for these reasons, can you elevate it to a C? We 2 have that process. And then you can say, well, 3 all the A's, they're going to have 12 months, B's 4 are going to be 18 months, C's are going to be 24 5 months, whatever it is, but give us something 6 because this complete absence of information is 7 killing us, at least it's killing me. 8 DR. UHL: I don't have a follow-on 9 question. 10 MS. TOUFANIAN: Thank you very much. 11 MR. DUCKER: Thank you. 12 MS. TOUFANIAN: Tim? 13 MR. AMES: Well, I wanted to thank the 14 panel for the opportunity to make a comment at 15 this open session, but for the sake of time, I'm 16 going to make this really brief. I did want to 17 extend my sincere appreciation to the OGD people 18 and other people from other parts of the Agency 19 for putting together a Part 15 meeting where we 20 could provide you with comments and you could 21 listen to the comments from all of us. 22 I was going to comment, and I'm going to</p>	217	<p>1 inspections and BE studies, will you be more 2 specific about what it is you're looking for 3 clarity on? 4 MR. AMES: Absolutely. 5 DR. UHL: Okay. Thank you very much. 6 MR. AMES: We'll take care of that in 7 the docket. And thank you. 8 MS. TOUFANIAN: Thank you. 9 Candis? 10 MS. EDWARDS: Thank you for allowing me 11 to come back. So I wanted to address the 12 definition of first generics. You may not like 13 what I'm going to say, but I have something 14 interesting, let's put it that way. 15 So in addition to these general accepted 16 criteria for the category of first generics, which 17 today includes a first-to-file Paragraph 4 ANDA 18 with a 180-day exclusivity, a first-to-market ANDA 19 for which there is no generic competition and no 20 blocking exclusivity, and also drug shortage 21 products -- those are the three categories that 22 are routinely prioritized today -- I would like to</p>

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218	<p>1 propose a couple of additional categories that 2 could be considered to be included in the 3 definition for first generics. 4       The first category would be a product 5 for which the sponsor receives documented evidence 6 from an external source, such as a consumer or 7 pharmacy, wholesaler, distributor, saying that the 8 product is not commercially available or that the 9 product has limited availability. However, the 10 product has not yet made it to the FDA's drug 11 shortage list. And we've had several situations 12 where we've experienced that and have provided 13 that information to the Agency in order to ask for 14 their consideration to expedite a review. And 15 this occurs in this fluidity of this whole 16 industry that we're in where it will come and go 17 with the specific products, so we would ask you to 18 look at that category of products. 19       Another area is a product that is 20 supported by one APA manufacturer who would 21 provide API to all ANDA holders. If we were able 22 to include products in that category where someone</p>	220	<p>1 actually greater than that, that are pending 2 longer than 18 months, and so if we were able to 3 look at that bucket of ANDAs and say if you're 4 going to prioritize in order to address the 5 backlog, here is how we would ask that you 6 consider let's say the top 10 percent in that 7 category, we would look to have these prioritized 8 because we would feel that they would have the 9 most impact on a health care system and provide 10 the most added value into the whole market. 11       So those are some thoughts on how we 12 could potentially broaden that scope and also help 13 FDA to give them the ability to prioritize and 14 have a positive impact on the marketplace. 15       MS. TOUFANIAN: So one clarifying 16 question with respect to that last category. 17 Would that be from your description that would be 18 restricted to the backlog -- 19       MS. EDWARDS: Probably so. That would 20 help, yeah. 21       MS. TOUFANIAN: And that would be sort 22 of a one-time identification?</p>
219	<p>1 were coming in with a different API manufacturer 2 than what existed, even though there might be 3 other ANDAs approved, that would help mitigate the 4 risk associated with a potential shortage due to a 5 single-source API drug product, and that would 6 definitely have a positive impact on our health 7 care system, which is what we're looking for when 8 we look to define or make -- broaden this 9 definition. 10       And the other concept goes to asking the 11 Agency to work with the firms to prioritize let's 12 say the 10 top percent of ANDAs pending at OGD, 13 pending OGD approval for longer than 18 months, 14 that would be defined by a sponsor based on 15 accessibility and affordability of a specific 16 product that would potentially bring added value 17 to patient care and also have the potential to 18 possibly positively impact the health care market. 19 So it goes to who was speaking before me, the same 20 concept that says there are some -- you know, for 21 example, Amneal has over 100 ANDAs pending. We 22 have about 8 percent of our ANDAs pending,</p>	221	<p>1       MS. EDWARDS: A one-time, yes. 2       MS. TOUFANIAN: Any questions? 3       (No audible response.) 4       MS. TOUFANIAN: Good. 5       MR. READ: Just one. It strikes me that 6 your first one could almost be described as pre- 7 shortage. 8       MS. EDWARDS: It could be, yeah. 9       MR. READ: So it's an interesting one in 10 terms of trying to avoid a shortage before it 11 happens. 12       MS. EDWARDS: Before it occurs, yeah. 13 And I think we get information. We may, since 14 we're dealing in solid products, we may get 15 information. We have more direct contact with the 16 consumer, so we may get information before it 17 makes it through the processes at the Agency in 18 order to get officially identified as a drug 19 shortage product. 20       MS. TOUFANIAN: Anything else? 21       (No audible response.) 22       MS. TOUFANIAN: All right. Thanks very</p>



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222	<p>1 much.</p> <p>2 MS. EDWARDS: Okay. Thank you.</p> <p>3 MR. DILORETO: Good afternoon. My name</p> <p>4 is John Diloreto. I am the Executive Director of</p> <p>5 the BULK Pharmaceuticals Task Force. And I'm</p> <p>6 going to talk about a subject that I haven't heard</p> <p>7 too much today about, and that has to do with</p> <p>8 facility inspections. I heard it broached a</p> <p>9 couple of times. But when we began our discussions</p> <p>10 a few years ago under the original negotiations</p> <p>11 with GDUFA, one of our major concerns had to do</p> <p>12 with two aspects of facility inspections. One</p> <p>13 certainly was protecting the safety of the drug</p> <p>14 supply chain making sure that any drugs coming</p> <p>15 into the country met that same high standard from</p> <p>16 foreign facilities as they do from domestic</p> <p>17 facilities. And at the time, domestic facilities</p> <p>18 were being inspected at a rate of about every 2-</p> <p>19 1/2 years. Despite a legislative requirement that</p> <p>20 they be done every 2 years, 2-1/2 years was</p> <p>21 certainly close enough that no one was going to</p> <p>22 complain. But the second aspect of that certainly</p>	224	
223	<p>1 was leveling the playing field that the domestic</p> <p>2 manufacturers had to have a quality program in</p> <p>3 place to make sure that they met their regulatory</p> <p>4 obligations while it was felt that a lot of</p> <p>5 foreign facilities were actually skating by and</p> <p>6 never being inspected in some cases. So we felt</p> <p>7 like GDUFA was an excellent opportunity to kind of</p> <p>8 bridge that gap, understanding that it was going</p> <p>9 to take several years to hire the people, train</p> <p>10 the people, put them in place before actual</p> <p>11 inspections can be done at a frequency that was</p> <p>12 considered parity between domestic and foreign</p> <p>13 facilities, which is why within the GDUFA</p> <p>14 commitments the first couple of years there aren't</p> <p>15 any real inspection goals. Those goals for</p> <p>16 inspections typically are all at the back end of</p> <p>17 GDUFA.</p> <p>18 That said, we were a little dismayed to</p> <p>19 see within an HHS memorandum earlier this year</p> <p>20 that FDA is scaling back by 40 percent the number</p> <p>21 of domestic routine surveillance inspections that</p> <p>22 it plans to conduct in FY2014 and 2015. When we</p>	<p>1 all signed up for the program, I don't think we</p> <p>2 expected to see a reduction in domestic facility</p> <p>3 inspections, we expected those to remain largely</p> <p>4 the same with the real increase being done on the</p> <p>5 foreign facility side, understanding that it was</p> <p>6 going to take a time for the staff and resources</p> <p>7 to be put in place to do that, but we are here</p> <p>8 expressing concern about that reduction in</p> <p>9 domestic facility inspections.</p> <p>10 Now, you might ask, "What's the big</p> <p>11 deal? We've got a couple of years to meet our</p> <p>12 goals." We do, but we also have to keep in mind</p> <p>13 that many of our domestic facilities who are doing</p> <p>14 business with other countries have to have an</p> <p>15 inspection done every 3 years, and if we are at 2-</p> <p>16 1/2 years to begin with and we are going to reduce</p> <p>17 that number by 40 percent, that certainly means a</p> <p>18 large number of facilities which are not going to</p> <p>19 get inspected within 3 years and in fact may not</p> <p>20 within 4 or 5 years. And we understand that this</p> <p>21 is a complex situation, which is why we also were</p> <p>22 emphasizing a risk-based prioritization for when</p>	225

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<p style="text-align: right;">226</p> <p>1 session today. Keith will have some closing 2 remarks, but before that, I just want to once 3 again encourage comments submitted to the docket. 4 A transcript of today's proceedings, as Martha 5 indicated at the beginning of the day, should be 6 available in about a month. And we encourage you 7 to watch FDA's websites for other developments. 8 MR. FLANAGAN: And my only closing 9 remark is I would like to thank our colleagues who 10 put this together. That's Connie Wisner, Shaniece 11 Bowens, Tawni Schwemer, Ashley Jones, 12 Shannon Bacote, Pat Downs (ph), and Kim 13 Giordano, as well as Maryll and Martha. 14 Thanks. 15 MS. TOUFANIAN: Thank you, everybody, 16 for coming. 17 (Whereas, at 3:12 p.m., the Generic 18 Drug User Fee Amendments of 2012 Public 19 Hearing on Policy Development -- 20 Request for Comments Part 15 Public 21 Hearing was adjourned.) 22</p>	<p style="text-align: right;">228</p> <p>1 CERTIFICATE OF TRANSCRIBER 2 3 I, DEBORAH ARBOGAST, do hereby certify that 4 this transcript was prepared from audio to the 5 best of my ability. 6 I am neither counsel for, nor party to this 7 action nor am I interested in the outcome of this 8 action. 9 10 11 12 13 _____ 14 DEBORAH ARBOGAST 15 16 17 18 19 20 21 22</p>
<p style="text-align: right;">227</p> <p>1 CERTIFICATE OF COURT REPORTER 2 I, MICHAEL FARKAS, the reporter before whom the 3 foregoing hearing was taken, do hereby certify 4 that the witness whose testimony appears in the 5 foregoing deposition was duly sworn by me; that 6 the testimony of said witness was recorded by me 7 and thereafter reduced to typewriting under my 8 direction; that said deposition is a true record 9 of the testimony given by said witness; that I am 10 neither counsel for, related to, nor employed by 11 any of the parties to the action in which this 12 deposition was taken; and, further, that I am not 13 a relative or employee of any counsel or attorney 14 employed by the parties hereto, nor financially or 15 otherwise interested in the outcome of this 16 action. 17 18 19 20 _____ 21 MICHAEL FARKAS 22</p>	

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