PHARMA & BIOPHARMA
OUTSOURCING ASSOCIATION

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To: Division of Dockets Management (HFA-305)

From: Pharma & Biopharma Outsourcing Association

Subject: Comments for Docket #: FDA-2014-N-1168

Date: March 6, 2015

The Pharma & Biopharma Outsourcing Association ("PBOA") appreciates the opportunity to provide comments to the Food and Drug Administration ("FDA") on the Generic Drug User Fee Amendments of 2012 (GDUFA); Public Hearing on Policy Developments; Request for Comments.[1] Several members of the PBOA attended the public hearing on September 17, 2014, and the association's President, Gil Roth, spoke in the Open Comments session that ended the morning portion of the hearing.[2]

The PBOA is a non-profit trade association for pharmaceutical and biopharmaceutical Contract Manufacturing Organizations ("CMOs") and Contract Development and Manufacturing Organizations ("CDMOs") operating in or making goods to be sold in the U.S. Our members provide the manufacturing and support services that help the pharma and biopharma industry develop and make drugs, biologics, vaccines, and other treatments safely and cost effectively. The association was founded in 2014, and thus was not involved in the negotiations for the initial authorization period of GDUFA.

The PBOA and its member companies support the intent of GDUFA, as published in the "Generic Drug User Fee Act Program Performance Goals and Procedures,"[3] of increasing Safety, Access, and Transparency. We recognize the need for industry user fees to fund an overhaul of the generic drug review program and inspection of facilities to achieve these goals. However, we believe that the current structure of the user fees, with 56% of the annual budget supplied by Finished Dosage Form ("FDF") manufacturing and packaging facilities, has a disproportionate impact on CMOs and other companies that are not the prime beneficiaries of improved ANDA approval times. CMOs will not benefit from improved timelines to the extent that generic drug makers will, yet they currently pay an identical fee for each FDF manufacturing or packaging facility. Furthermore, with the continued

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1 80 FR 6729 (providing until March 9, 2015 to submit comments)

2 http://www.regulations.gov/contentStreamer?objectId=09000064819d9e7e&disposition=attachment&contentType=pdf

3 https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0CCUQFjAB&url=http%3A%2F%2Fwww.fda.gov%2Fdownloads%2FDrugs%2FDevelopmentApprovalProcess%2FSmallBusinessAssistance%2FUCM358189.pdf&ei=-tr5VI-8HomeNqeOgpgL&usg=AFQjCNEqpYNOGT-yXKcEQEUyfbP1ji7aYg&sig2=cTIror34fZhrN2BVb3o5SQ&bvm=bv.87611401,d.eXY

strategy of pharmaceutical and generics companies to outsource manufacturing activities, CMOs and CDMOs are in many cases paying the lion's share of the facility fees.

Under GDUFA, the flat-rate Facility Fees for FDF sites make no distinction between a dedicated, in-house generic drug company's facility and one owned by a CMO that may produce only one or two generic products each year. A one-size-fits-all approach to Facility Fees, while perhaps fair on the surface, has the unintended consequence of driving CMOs and contract packagers out of the generic drug market, leaving fewer choices for generic drug companies that do not possess facilities of their own.

In addition, as companies exit the generic manufacturing space, GDUFA fees will rise for the remaining companies, further challenging the economics of a very competitive marketplace and potentially leading to drug shortages and increased consumer costs for generic products. We believe it is critical that the Facility Fee structure be revised in a manner that will allow different classes of companies to pay their fair share of the annual budget, proportionate to their demand on FDA resources and financial benefit from generic products.

During the PBOA's Open Comments presentation to the panel at the Public Hearing, we proposed a "checkbox" system that would allow FDF facilities to self-identify as CMOs. This would be a relatively inexpensive way of classifying FDF facilities for the purpose of creating a tiered system for Facility Fees.

In addition, the lack of "small business" waivers or fee reductions under GDUFA creates an unfair barrier for smaller companies. This could leave some CMOs in a position where they may have to choose between laying off workers or exiting their contracts with generic companies, potentially causing shortages of medicines. There is no mechanism in the existing GDUFA framework as approved by Congress to permit issuance of waivers or fee reductions. We urge the FDA to request this authority in the reauthorization for GDUFA, and that Congress in the interim empowers FDA to issue waivers or reductions during the current GDUFA period.

Our members would also appreciate greater transparency on timelines for backlogged ANDAs, a firm commitment as to when the current backlog will be cleared, and communication on the review process for newly filed ANDAs. For CMOs, the sudden news of a client's ANDA approval after a delay of more than 30 months can make it difficult to ramp up production. Based on discussions with their customers, our members are reporting that there is considerable confusion regarding what to expect from the approval process, and most manufacturers have no understanding of where their submission resides in review. As a result, companies are making a best guess of when they need to prepare for product launch, which leads either to inadequate supplies at launch, leaving patients without necessary medications, or to short-dated product that has to be disposed, which has both financial and environmental implications to the public.

One of the goals of GDUFA is to reduce the overall review times, and while there are published objectives on this front, there remains no clear requirement as to when these objectives must be achieved. To date, the review cycles for ANDAs have not been reduced and in fact, many feel have actually continued to increase following GDUFA enactment. We strongly recommend that a deadline for achieving a target review cycle be set.

Another area of interest for the PBOA is how CMOs' facilities have turned up on the GDUFA Self-Identified Facilities List without the CMOs' knowledge and despite the fact that those facilities are not involved in handling generic drugs. This has generally been the result of a generic drug maker including a CMO's facilities in its ANDA as an "alternate supplier" without ever consulting the CMO. We urge the Agency to publish a transparent process for getting a facility removed from the Self-Identified Facilities List in such circumstances, and to provide a timely process for removing inadvertently added facilities without having to appear on the GDUFA Facility Arrears List.

Thank you in advance for considering our comments. If you have any questions regarding this letter, please feel free to contact me directly at gil.roth@pharma-bio.org.

Sincerely,

Gil Roth
President
PBOA