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-2016-N-1092:
Over-the-Counter Monograph User Fee Public Meeting

Date: July 8, 2016

The Pharma & Biopharma Outsourcing Association ("PBOA") respectfully submits the enclosed comments in response to the Over-the-Counter Monograph User Fee Public Meeting, Docket No. 2016-N-1092.

The enclosed comments include a transcript of remarks on behalf of PBOA presented at the meeting by Cornell Stamoran, a member of the PBOA's board of trustees, along with accompanying presentation materials attached hereto and displayed at the public meeting held on Friday, June 10, 2016 at the FDA's White Oak Campus.

PBOA Remarks, FDA Public User Fee Meeting, June 10, 2016

"Thank you to the FDA for allowing our association to present today. I'm Cornell Stamoran, I serve as head of strategy for Catalent, and today I'm here in my capacity as Trustee of the Pharma & Biopharma Outsourcing Association (PBOA for short).

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Very briefly, PBOA is a trade association representing the interests of Contract Developers and Manufacturers serving the pharmaceutical, biotech and consumer health industry. To be clear, our companies typically help other companies develop and manufacture finished drug product (or dose forms); those companies typically own the filings, such as NDAs or ANDAs, and are the ones whose name you'll see on bottle or box of OTC monograph products, not ours. Additionally, some of our members – like my own company, Catalent – provide enabling advanced delivery technologies that help drugs and consumer health products work better for patients and consumers.

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Generally, there are some company names you will likely recognize, but again, you will not find most of these company names on boxes of consumer health products or prescription drugs.

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One final point – we do play an integral role supporting the prescription and consumer health industry. We produce over 200 billion doses a year – this represents approximately 1of every 7 doses of combined Rx and consumer health products taken globally each year, or about 15% of the global market. About one-quarter of that is OTC product. We employ approximately 30,000 people around the world, and we have extensive broad and deep relationships with the FDA and other global regulatory bodies due to our

product development and manufacturing activities, seeing 200+ regulatory audits a year. That is where we "fit."

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Now, to why we're here.

PBOA strongly supports the OTC Monograph model in place in the US. OTC products play a critical role in supporting the health of consumers in the US. Importantly, OTC products are often the primary available means of treatment for economically disadvantaged segments of the population. And broad availability of safe and effective OTC products, taken properly by patients, helps reduce the country's overall health care cost.

We have this broad and diverse range of consumer health products that are safe and efficacious directly as a result of the Monograph-driven system in place in the US, which, despite its shortcomings, remains a model for OTC medicine product regulation worldwide. Our members provide consumer health products in many countries around the world, so we're familiar with the regulatory systems in place, both Monograph-driven systems and under advance-filing based ones, and we strongly believe that the US model drives consumer-centric new products and dose form innovation, and increases competition, both of which are very much in the public's interest.

We also agree that the FDA is critically under-resourced for the OTC area, given the role and importance of the Monograph process to a vibrant and consumer-centric OTC market.

Finally, we note that many very good ideas about enhancing the Monograph process were proposed by organizations during the 2014 hearing which has been referenced a couple of times today. We believe some of those are relevant to user fee deliberations moving forward.

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Our members are currently involved directly or indirectly with most currently active FDA user fee programs in place, so we bring a different perspective on what works and what doesn't, and on design principles here.

Because of this involvement, we have developed some key principles for user fee design that may seem basic but can be quite difficult to implement in practice.

1) The party who receives the economic benefit from the program should pay the fees. While this seems obvious – with the complex nature of the industry, and even more so with the complicated go-to-market process for consumer health products – it doesn't always play out like you'd expect.

   For example, under GDUFA I, if a Generic product is outsourced to a CDMO, the CDMO will in general capture about 1% of the economic value of the product, while paying 90% of the GDUFA fees over that same period.

2) The fee should fully recover cost of services provided unless there's a public policy reason to do otherwise. (We can discuss that offline.)

3) There are certain things which make user fees more implementable from an FDA standpoint, we've learned – if the fees are based on the data the FDA already has in a structured way, it's much easier to implement – like NDCs or SPLs for OTC products. This is preferable to creating a new reporting requirement in order to drive a basis to assess fees.

Getting this right is crucial. Again, with GDUFA I, our members and other CDMOs ended up paying about 15%, or $45M of fees, for virtually no incremental volume or resulting value, compared to pre-GDUFA I. This led some of our members to layoff employees, and others to reduce capacity available to generics, or reduce the ability to invest in innovation.

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Before progressing too far on user fees, we recommend that the FDA and other stakeholders revisit the process improvement opportunities identified in 2014, many of which we believe are readily implementable, and would improve the efficiency of the Monograph process.

Once that's done, and the remaining "gap" to full support is understood, only then do we believe can effective conversations about user fees take place – how much, for how long, what type, who pays, etc.

Once that point is reached, we currently would recommend consideration of either or both of:

a) A one-time "license-type" fee associated with future substantive updates to final monographs, potentially including addition of new ingredients or technologies, and creation of new monographs. A license model, perhaps combined with some advance market access for a limited duration, could create real economic incentive for companies to make leading investments required to support these, while providing a corporate accounting-friendly vehicle to make it more feasible.

b) Annual product fees for active products (using FDA's existing datasets) would be used to support enhanced safety surveillance, timely label updating, and Monograph process management. Due to the broad number of products on the market, we believe this would likely prove to be a relatively small fee each to support these activities.

We do NOT support facility-based fees for this initiative, based on the incremental degree of work required for the FDA to implement that system, and what we see as inadequate alignment of fees with benefits.

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Finally, we request that the FDA aggressively continue to progress turning TFMs to Final while these deliberations are ongoing – consumers have need and will benefit.

We have some preliminary thoughts on performance goals, largely around adherence to plans for Monograph updating/development, timeliness of safety-related label revisions, and pace of additions of new ingredients, dose forms and technologies to existing Monographs. As program specifics become clearer, these will evolve.

Though the lowest hanging fruit to improve the Monograph system is related to current active ingredients and uses, there is significant value for all to integrate CMC development topics such as those covered by USP monograph and ICH. One other comment – certainly, many of the ANDA-based ingredients contribute to the backlog issues that OGD faces, so the addition of those ingredients to monographs might reduce stress points in other parts of the FDA.

In closing – PBOA supports consideration of an OTC monograph user fee system that aligns payment of fees with those that will realize the greatest value.

Thank you.

Sincerely,

Gil Roth
President
Pharma & Biopharma Outsourcing Association

PBOA

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