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-2012-N-0882

Date: July 14, 2015

The Pharma & Biopharma Outsourcing Association ("PBOA") greatly appreciates the opportunity to speak at the June 15th hearing the Food and Drug Administration ("FDA") held on reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA). One-third of our association's member companies attended the hearing, and the association's President, Gil Roth, spoke during the trade association session that ended the morning portion of the hearing. We have included our presentation as part of our comments to this docket.

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 pharmaceutical products to be sold in the U.S. Our members provide the manufacturing technologies 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. As we stated in our presentation, we request to be included in the upcoming negotiations in order to help shape GDUFA II in a manner that takes into account the economic realities of the CMO/CDMO industry as it relates to the generic pharma industry.

A substantial portion of generic drugs utilize a CMO or CDMO, but the current Facility Fee structure fails to reflect the risks and benefits of those companies in the generic space. The current user fee structure has a disproportionate impact on CMOs and other companies that are not the major beneficiaries of improved ANDA approval times.

Retaining the GDUFA I fee-structure for the next five-year period could compel some CMOs/CDMOS to exit the generic space or elect not to enter it, reducing manufacturing options for generic drug-makers and potentially reducing the available capacity available for generic production in critical areas. Our presentation contains several suggestions for improving GDUFA II, and we hope to work with the Office of Generic Drugs and industry

associations to help fine-tune other areas of GDUFA II to achieve the admirable goals of increasing safety, transparency and access to generic drugs.

We are presently collecting data from both members and non-members about the effect of GDUFA fees for backlogged ANDAs (i.e., CMOs that have paid multiple years of Facility Fees without a client's approved ANDA), as requested by Mary Beth Clarke at the conclusion of our presentation at the public heari. We plan to present that data at an appropriate time.

Sincerely,

Gil Roth
President
PBOA

PBOA

MEMBER COMPANIES

AAIPharma/Cambridge Major Laboratories
Afton Scientific
Baxter BioPharma Solutions
Catalent Pharma Solutions
Coating Place
Coldstream Laboratories
Cook Pharmica
DPT/Confab
Halo Pharma
Hospira One 2 One™
IDT Biologika
Jubilant HollisterStier
Metrics Pharma Services
Mission Pharmacal
Patheon Inc.
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