



# **CMO/CDMOs and GDUFA**

**GDUFA Reauthorization**

**June 15, 2015**

**Gil Roth, President, PBOA**



PHARMA & BIOPHARMA  
OUTSOURCING ASSOCIATION

# PHARMA & BIOPHARMA OUTSOURCING ASSOCIATION

The PBOA is a non-profit trade association for **Contract Manufacturing Organizations (CMOs)** and **Contract Development Manufacturing Organizations (CDMOs)**, founded in 2014.

We work collaboratively to:

- **Advocate** for our industry before regulatory and legislative bodies, informing members of relevant developments
- **Educate** members, customers, the general public and other stakeholders on the value that we bring to the development and manufacture of therapeutics and to patients' well-being
- **Advance** common industry goals in the public interest



PHARMA & BIOPHARMA  
OUTSOURCING ASSOCIATION

# PBOA Members

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  
Mission Pharmacal • Metrics Pharma Services  
Patheon Inc. • ProSolus Pharmaceuticals  
Therapure Biomanufacturing  
WellSpring Pharma Services



PHARMA & BIOPHARMA  
OUTSOURCING ASSOCIATION

# CMOs/CDMOs' Role

- CMO/CDMOs were involved with more than 44% of NDAs last year (*PharmSource*)
- CMO/CDMOs provide cost-effective solutions to capital-intensive manufacturing needs, freeing client funds for R&D
- CMO/CDMOs develop novel formulations and delivery platforms
- CMO/CDMOs are involved in approximately 15% of generic drugs (*PharmSource*)
- At least 15% of Final Dosage Form facilities on GDUFA FY 2015 list are CMO/CDMOs (same % for Primary Packaging facilities)



PHARMA & BIOPHARMA  
OUTSOURCING ASSOCIATION

# PBOA GDUFA Goals

- Timely review of ANDAs
- Effective, risk-based inspection of manufacturing sites
- Enhanced Office of Generic Drugs (OGD) communication with stakeholders, including CMOs/CPOs
- Contribution to regulatory guidances
- A seat at the industry negotiating table



PHARMA & BIOPHARMA  
OUTSOURCING ASSOCIATION

# GDUFA Facility Fees

## Domestic FDF Facility Fees

- 2013 – \$175,389
- 2014 – \$220,152
- 2015 – \$247,717
  - *Ex-US: \$15k higher*
- *Flat fee: same rate for in-house generic manufacturing site as for CMO that has only a single generic client.*
- *No reduction/waiver for small businesses, creates disproportionate impact on small manufacturers.*



PHARMA & BIOPHARMA  
OUTSOURCING ASSOCIATION

# Potential Impact

- Some CMOs may have no choice to but to exit generic space/not renew generic contracts
- CMOs may not be able to accept generic clients in new, advanced manufacturing facilities
- Reduced competition and fewer manufacturing options for generic clients
- Facility Fees will grow larger for remaining sites
- Small-scale product and orphan drugs will become scarce and more expensive; potential drug shortages in critical areas, such as generic injectables



PHARMA & BIOPHARMA  
OUTSOURCING ASSOCIATION

# GDUFA II Recommendations

## ECONOMIC

- ***Preferred Option - Mirror PDUFA:*** Facility Fees should be folded into drug filer fees, not levied on individual sites
- **Establish Facility Fee Tiers:** ANDA owners/CMOs (non-ANDA-holding)
  - **Create Categories for Contract Facilities** on Self-Identified Facilities List: identify CMOs, as well as contract primary & secondary packagers
- **Small Business Exemption:** empower FDA to issue reductions/waivers for companies under a certain size





PHARMA & BIOPHARMA  
OUTSOURCING ASSOCIATION

# GDUFA II Recommendations

## GENERAL

- **Add CMOs/CDMOs to Target Action Date (TAD) letters,** so they can better prepare: with ANDA reviews taking so many years, key contacts between generic clients and CMOs may have moved on
- **Transparency:** establish a clear pathway to get a site removed from the Self-Identified Facilities List, if it doesn't make generic products



**Gil Roth, President**  
**[gil.roth@pharma-bio.org](mailto:gil.roth@pharma-bio.org)**  
**[www.pharma-bio.org](http://www.pharma-bio.org)**