



**PHARMA & BIOPHARMA
OUTSOURCING ASSOCIATION**

December 21, 2016

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

Re: Docket Number FDA-2015-D-2537: Request for Extension of Comment Period Regarding the Request for Quality Metrics; Notice of Draft Guidance

To Whom it May Concern:

Pursuant to 21 CFR§10.40(b)(3), the Pharma & Biopharma Outsourcing Association (“PBOA”) respectfully requests a 60-day extension to the comment period the Food and Drug Administration (“FDA”) specified in the Federal Register (FR) of November 25, 2016, in which FDA was seeking public comment to the revised draft guidance entitled “Submission of Quality metrics Data”.

The PBOA and our member companies recognize the significant nature of revisions to the previous draft guidance and appreciate FDA’s efforts to enhance this new draft and incorporate feedback from industry and other stakeholders. There are still many significant topics within the guidance warranting thoughtful review from multiple cross-functional stakeholders.

The PBOA represents Contract Manufacturing Organizations and Contract Development and Manufacturing Organizations (“CDMOs”). Our members provide the services and technologies that enable their pharma and biotech partners to develop and manufacture drugs, biologics, vaccines and other therapeutics safely and cost effectively.

Our intent is to conduct thorough and robust review of the draft guidance both with our members and with their partners, as represented in cross-industry working groups. In this way, we can develop a clear understanding and ensure that comments to the draft reflect the perspective of various stakeholders, including CDMOs.

To that end, PBOA respectfully requests a 60-day extension of the comment period to ensure we can provide thoughtful, comprehensive comments back to the FDA.

We appreciate your consideration and timely response to this request. If you have any questions about the information in this submission, I may be reached at (201) 788-7994.

Sincerely,

Gil Roth
President
Pharma & Biopharma Outsourcing Association



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PBOA

MEMBER COMPANIES

3M Drug Delivery Systems
Alcami Inc.
Afton Scientific
AMRI
Baxter BioPharma Solutions
Catalent Pharma Solutions
Coating Place, Inc.
Confab Laboratories
CPC - Contract Pharmacal Corp.
Cook Pharmica
DPT Laboratories
Ei, A Pharmaceutical Solutionworks
Emergent BioSolutions
Groupe PARIMA
Halo Pharma
IDT Biologika
Jubilant HollisterStier
LSNE - Lyophilization Services of New England
Metrics Contract Services
Mission Pharmacal / ProSolus Pharmaceuticals
Patheon Inc.
Pfizer CentreOne™
Pharmaceutical Packaging Solutions
Piramal Pharma Solutions
Tapemark
Therapure Biomanufacturing
WellSpring Pharma Services

AFFILIATE MEMBERS

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