PHARMA & BIOPHARMA
OUTSOURCING ASSOCIATION

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To: Division of Dockets Management (HFA-305)

From: Pharma & Biopharma Outsourcing Association

Subject: Comments from Pharma & Biopharma Outsourcing Association (PBOA) regarding Docket FDA-2017-D-2802: CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports.

Date: October 10, 2017

The Pharma & Biopharma Outsourcing Association (PBOA), a trade association representing Contract Manufacturing Organizations and Contract Development & Manufacturing Organizations (collectively described as CDMOs for purposes of this letter), appreciates the Food and Drug Administration's (FDA) efforts and goals to encourage continuous improvement within the pharmaceutical industry and supports initiatives that possess potential benefits for industry, for patients, and for the FDA. The comments below represent a majority view of participating PBOA members who share a unique perspective as organizations providing critical services and solutions within the pharmaceutical industry. Specific or differing views may be separately presented by individual member companies in their own docket submissions.

The CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports draft guidance does not define opportunities for postapproval change regulatory relief (e.g. allowing more annual reportable changes versus CBE-type changes) related to such initiatives as FDA's Draft Guidance on Quality Metrics. The PBOA suggests the Draft CMC Postapproval Manufacturing Changes guidance could be utilized to outline FDA's philosophy on reduced postapproval change regulatory requirements.

Lines 200-205:
Manufacture of an additional drug product (already licensed or an investigational product), in a multiple-product area listed in an approved BLA that is producing other products, if:
2.5.1. Specific identity tests exist to differentiate between all products manufactured at the facility; and

CDMOs routinely manufacture same products/molecular entities (i.e., innovator and generic product; competing biosimilars, etc.) for more than one license holder within a single multi-product manufacturing site. As written the above draft guidance language could restrict multi-product manufacturing facilities from producing same products for more than one license holder. Other applicable controls which are used in conjunction with identity testing to confirm the identity of the product to be manufactured should be included in the draft guidance. These controls include, and are not limited to, the following: labeling, manufacturing site of API/BDS, packaging configuration, and inspection.

CDMOs who manufacture clinical and commercial programs often support clinical programs with identity methods that are less discriminating in early phase. License holders often develop identity tests specific to their product compared to other products within their own suite of products. A confirmation of the specificity of a new

product's identification test to all products manufactured at a CDMO is not a feasible exercise, as license holders may not be willing or able to supply material for testing, and the number of products manufactured at a single site can be extensive. Therefore, CDMOs routinely utilize multiple controls in addition to analytical testing to control the identity of each product manufactured.

Line 263-265:
Replacement of a nonspecific identity test with a discriminating identity test that includes a change in acceptance criteria (e.g., replacing SDS-PAGE13 with peptide mapping).

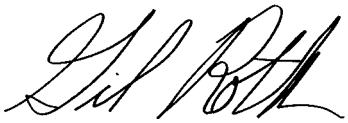
We thank FDA for the inclusion of the above as it will encourage industry to develop discriminating identity tests.

Line 281:
Use of a contract manufacturing organization for the washing of a drug product stopper, provided the applicant certifies that the organization's washing process has been validated and its site has been audited by the applicant (or by another party sponsored by the applicant) and found CGMP compliant.

We ask the FDA to clarify if sterilization is out of scope.

The Pharma & Biopharma Outsourcing Association appreciates this opportunity to submit our comments.

Sincerely,



Gil Roth
President
Pharma & Biopharma Outsourcing Association

PBOA

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