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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

February 21, 2014

Re: Submission of Comments to Docket No. FDA-2013-N-1615; Food and Drug Administration;
Draft GDUFA Information Technology Plan

By way of introduction, the Bulk Pharmaceuticals Task Force (BPTF), an affiliate of the Society of Chemical Manufacturers and Affiliates (SOCMA), is an association for manufacturers of active pharmaceutical ingredients, excipients and intermediates. Our primary objective is to seek clarification of the current regulatory requirements for our products and to interact with government agencies on emerging issues that may impact SOCMA members. SOCMA is the leading trade association of the specialty batch and custom manufacturing chemical industry in the United States representing approximately 300 member companies with more than 2,000 manufacturing sites and over 100,000 employees.

The BPTF is respectfully asking the FDA to consider the following comments from its membership on the December 2013 publication titled *GDUFA Information Technology Plan (Draft)*:

Section 3.0 Electronic Regulatory Submissions

The BPTF requests inclusion of some guidance and clarity from the agency as to its expectation for the submission of Type II DMFs in electronic format.

Whereas in the GDUFA Confirmation Letter, in section 2.B. titled DMF Review Efficiency Enhancements, the FDA states: “*Review metric goal (described below) will only apply to Type II DMFs submitted after the program’s implementation date, if they are submitted electronically.*”; in the Draft Guidance for Industry titled Generic Drug Fee Amendments of 2012: Questions and Answers, the agency replied “*Yes*” to the question: “*If an ANDA is submitted electronically, but one or more of its referenced DMFs was submitted in paper format, will the ANDA be included as part of GDUFA performance metrics?*”. The BPTF considers the above statements by the agency to be contradictory, and the outcome from submission of Type II DMFs in paper format on the review time for the referencing ANDA to be unclear.



Line 120 of the Draft Information Technology (IT) Plan provides a timetable that requires NDA, BLA and ANDA submissions to be in eCTD format in 2016 and commercial INDS in 2017, but no reference is made to the agency's expectation or timeline for the formatting of DMFs in this or any other section of the IT Plan.

Section 4.3 Efficiency Enhancements

BPTF wholeheartedly supports the intent expressed in Line 294 of the IT Plan that the FDA will make system enhancements to provide improvements in the completeness assessment process for Type II API DMFs and efficiencies fostering inspection parity among foreign and domestic facilities. However, no outline or timetable has been provided for industry stakeholders to determine how the agency intends to enhance these programs. We believe that a written outline and a timetable for starting these activities should be included in the IT Plan.

In addition, the BPTF would like the IT Plan to contain a commitment by the FDA to continuous improvement with respect to efficiency enhancements. The Draft Plan lists no specific enhancement projects after 2015, although funding will continue to be provided annually by industry in the form of inflation adjusted GDUFA fees. We consider that going forward it is important the GDUFA IT systems are kept current as technology progresses.

BPTF appreciates the opportunity to submit these comments, and thanks the agency for its attention to our request for clarification and revision.

Sincerely,

A handwritten signature in black ink, appearing to read "John DiLoreto". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

John DiLoreto
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