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FDA Announces Proposals for Biosimilars User Fees and Performance Review Goals

December 9, 2011 by Peter Reichertz

FDA has at last began formal implementation of the Biologics Price Competition and Innovation Act of 2009 ("BPCI Act"), by announcing the proposal it will send to Congress to implement user fees for "generic" copies of biologics, called biosimilars in the BPCI Act. A biosimilar is a product approved under Section 351(k) of the Public Health Service Act ("PHSA"); approvals are not Federal Food, Drug and Cosmetic Act ("FFDCA") approvals. Under the proposal, the user fees for biosimilars - including the product application fee, the annual product fee and the annual establishment fee - would be identical to the fees established for human drug products approved under Section 505(b) of the FFDCA with one significant difference.[1]

Because there are currently no biosimilars approved, FDA expects to expend significant resources upfront in evaluating research and protocols for biosimilar applications. As a result, it is proposing to assess a Biological Product Development ("BPD") Fee for review of Investigational New Applications ("INDs") submitted for biosimilar products. The fee would be due at the time of submission of an IND for a biosimilar product or, if requested, within five (5) days of FDA granting a request for a BPD meeting. In addition, a BPD fee would be assessed to any IND filed for a biosimilar product before any biosimilars user fee legislation is enacted. The BPD fee would be ten percent (10%) of the application fee established for a 505(b) application for the year submitted.

In addition, the fee would be assessed on an annual basis until the applicant either submits a marketing application, or withdraws the IND.[2] The BPD fees would be subtracted from the application user fee due when a biosimilars application is filed under Section 351(k) of the PHSA. There is also a reactivation fee if one withdraws an IND and reactivates subsequently. That fee would be in amount equal to twice the BPD user fee for fiscal year the IND is reactivated, and would be due upon reactivation of the IND, or within five (5) days of FDA granting a request for a BPD meeting.[3]

In addition, FDA has announced proposed review performance goals. The full description of the proposed performance goals and procedures for the biosimilars user fee program can be found in the draft biosimilars user fee commitment letter (draft commitment letter) posed on FDA's Web site at:

FDA: Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 Through 2017

In brief FDA proposes to review 70% of 351(k) application within 10 months of receipt in fiscal 2013 and 2014, 80% in fiscal 2015, 85% in fiscal 2016 and 90% in fiscal 2017. There are other performance goals for review of supplements, review of proprietary names, clinical hold responses, meeting requests, and the like.

FDA is holding a public hearing on these proposals on December 16, 2011, and is requesting comments - which are due by January 6, 2011. FDA's proposal can be found at 76 Fed. Reg. 76, 424 (December 7, 2011).

These proposals are just the first in a series of proposals on the regulation of biosimilars expected to be announced in the near future. Other expected proposals include proposals on generic names of biosimilars, clinical trial requirements and ability to rely upon foreign approvals, implementation of the "interchangeability" provision and characterization of molecules. It has been almost twenty months since the BCPI Act was enacted. At last manufacturers are being provided some formal notice on how FDA intends to approve biosimilars.

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[1]The 2012 user fees for human drug products approved under Section 505(b) are currently as follows: - NDA - $1,841,500 - Supplements - $920,750 - Establishment - $520,100 (after approval) - Product - $98,970 (after approval) These fees, as well as the user fees for medical devices, are up for renewal. A comprehensive bill establishing new conditions for these fees - and new fees for generic human drug products approved under Section 505(j) of the FFDCA - is expected to be enacted during the next year (prior to September 30, 2012).

[2] A sponsor would need to withdraw the IND by August 1 to avoid paying a fee that would be due on each October 1.

[3]If fees are not paid, FDA would not grant BPD meetings or not consider IND's as submitted. If annual BPD fees were not paid, FDA would place by investigation on "financial hold".