FDA-Industry Generic Drug User Fee (GDUF)
Announcement of Ratification; Next Steps
September 9, 2011

Announcement of Ratification

The Food and Drug Administration is pleased to announce the ratification by FDA and each of the three industry trade associations participating in the generic drug user fee negotiations of a goals letter and proposed legislative language. These documents have been carefully negotiated between FDA, the Generic Pharmaceutical Association, the Bulk Pharmaceutical Task Force of the Society of Chemical Manufacturers and Affiliates, and the European Fine Chemicals Group, in a series of negotiation sessions over the last six months.

As is the case in the reauthorization process for FDA's other, already existing, user fee programs, the negotiated documents are not being publicly released at this time, as they now need to undergo review by the Department of Health and Human Services and the White House prior to their public release and their eventual presentation to Congress. However, general outlines of the negotiated program are available from the meeting minutes that have been regularly posted during the negotiations.

Minutes of negotiation sessions can be found at the following webpage:
http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm256662.htm

Additional information on the need for and process of negotiating a generic drug user fee program, and materials from FDA's public meetings and stakeholder updates on the process can be found at the following webpage:
http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm

Next Steps

The goals letter and proposed legislative language will now be provided to the Department of Health and Human Services for review, and will thereafter be provided to the Office of Management and Budget for review. The agency will post the final cleared goals letter and proposed legislative language for the generic drug user fee program upon receiving clearance from OMB, as the agency does in its other user fee negotiations. FDA anticipates providing a generic drug user fee package to congress in January, accompanying the reauthorization packages for FDA's other user fees.