FDA-Industry Generic Drug User Fee (GDUF) Negotiations Meeting
June 24, 2011, 10:00-3:00pm
FDA White Oak Campus
Silver Spring, MD

Purpose

To discuss elements of a draft goals letter outlining agreements between FDA and industry and amendments to applications, in preparation of a final letter representing the parties' mutual agreement regarding goals and overall resource needs for the creation of a generic drug user fee program.

Participants

Generic Pharmaceutical Association (GPhA)

Debbie Jaskot	Teva North America
Gordon Johnston	GPhA
Marci McClintic-Coates	Mylan Labs
Tom Moutvic	Sagent Pharmaceuticals
Lara Ramsburg	Mylan Labs
Rich Stec	Perrigo

European Fine Chemicals Group (EFCG)

Guy Villax - Hovione

Bulk Pharmaceuticals Task Force (BPTF) of the Society of Chemical Manufacturers and Affiliates (SOCMA)

Alan Nicholls	Copperhead Chemical Company

FDA

Peter Beckerman	Office of the Commissioner (OC)
Donald Beers	Office of the Chief Counsel (OCC)
Rita Hassall (phone)	Center for Drug Evaluation and Research (CDER)
Brian Hasselbalch	Center for Drug Evaluation and Research (CDER)
Mike Jones	Center for Drug Evaluation and Research (CDER)
Brian Kehoe (via phone)	Office of the Commissioner (OC)
Anne Kirchner	Office of Regulatory Affairs (ORA)
Mari Long	Office of the Commissioner (OC)
Marie Angeline O'Shea	Center for Drug Evaluation and Research (CDER)
Suzanne Pattee	Center for Drug Evaluation and Research (CDER)
Edward Sherwood	Center for Drug Evaluation and Research (CDER)
Keith Webber	Center for Drug Evaluation and Research (CDER)
Russell Wesdyk	Center for Drug Evaluation and Research (CDER)

Discussion

FDA and industry discussed details of a proposed agreement to establish a generic drug user fee program. FDA discussed elements of a draft goals letter, including overall scope, assumptions and aspirations that underlie the agreement, major goals to be reached in the fifth year of the program, efficiency enhancements that FDA will implement at the program's start and interim goals to be achieved during years 3 and 4. Goals address performance metrics to: review ANDAs; examine DMFs referenced in ANDAs; inspect related facilities; review applications in the backlog; review amendments and prior approval supplements for generic drug applications; and increase and improve communication between FDA and industry, including first-cycle teleconferences and goals for controlled correspondence.

Many elements had been tentatively agreed to in advance of this meeting. Consequently, the discussion focused on ways to address areas still lacking in common understanding, particularly specific categories of amendments and FDA's desire to create a system that would discourage multiple amendments and "development on the clock" through repeated filing of amendments while an application is pending at FDA, but allowing submission of necessary amendments. Discussion focused on types of amendments, extensions of goals metrics, impact of amendments prior to and post complete response letters, solicited and unsolicited amendments and amendments that require additional inspections.

Amendments were divided into three categories, with tier 1 including all solicited first major and the first five minor amendments as well as all unsolicited amendments indicated by the sponsor and agreed to by FDA to be a result of certain external actions or that otherwise would eventually be solicited by FDA. Goals for tier 1 amendments would vary depending on year, type of amendment and whether the amendment necessitates an inspection. Tier 2 amendments, for review within 12 months, would include unsolicited amendments that do not result from particular actions, except those that remove information from the review package. Tier 3 amendments include any solicited amendments after the first major, and any solicited minor amendment subsequent to the fifth minor and would not be subject to performance goals.

FDA will prepare a draft goals letter with industry before the next meeting. Discussions will continue to ensure agreement on the goals letter.

Next Meeting

The next meeting will be held at FDA on Thursday, June 30. The types and structure of fees will be discussed, with industry providing FDA with its vision to kick off the meeting.