

FDA-Industry Generic Drug User Fee (GDUF) Negotiations Meeting
April 14, 2011, 10:00-3:00pm
FDA White Oak Campus
Silver Spring, MD

Purpose

To provide opportunity for exchange of information on goals for review of applications; and legal, technical and post-market goals; and to provide detailed information on FDA resource needs on review of applications to meet projected performance goals for a generic drug user fee program.

Participants

Industry

<u>Name</u>	<u>Company</u>
<u>Generic Pharmaceutical Association (GPhA)</u>	
Beth Brannan (phone)	Watson Pharmaceuticals
Debbie Jaskot	Teva North America
Charlie Mayr	Watson Pharmaceuticals
Marcie McClintic-Coats	Mylan Labs
Tom Moutvic	Sagent Pharmaceuticals
Molly Rapp	Ben Venue Laboratories
Lara Ramsburg	Mylan Labs
Richard Stec	Perrigo

European Fine Chemicals Group (EFCG)

Guy Villax	Hovione
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Society of Chemical Manufacturers and Affiliates (SOCMA)

John DiLoreto	BPTF
Alan Nicholls	Copperhead Chemical Company
Joel Carpenter	Albemarle Corporation

FDA

<u>Name</u>	<u>Center</u>
Leslie Ball	Center for Drug Evaluation and Research (CDER)
Peter Beckerman	Office of the Commissioner (OC)
Don Beers	Office of the Chief Counsel (OCC)
Boris Brodsky	Center for Drug Evaluation and Research (CDER)
Gerald Dal Pan	Center for Drug Evaluation and Research (CDER)
Mike Jones	Center for Drug Evaluation and Research (CDER)
Rita Hassall (phone)	Center for Drug Evaluation and Research (CDER)
Brian Hasselbalch	Center for Drug Evaluation and Research (CDER)

Brian Kehoe (phone)	Office of the Commissioner (OC)
Adam Kroetsch	Center for Drug Evaluation and Research (CDER)
Kevin Laser	Center for Drug Evaluation and Research (CDER)
Deborah Livornese	Center for Drug Evaluation and Research (CDER)
Mari Long	Office of the Commissioner (OC)
David Miller	Office of the Commissioner (OC)
Jacqueline O'Shaughnessy	Center for Drug Evaluation and Research (CDER)
Angeline O'Shea	Center for Drug Evaluation and Research (CDER)
Suzanne Pattee	Center for Drug Evaluation and Research (CDER)
David Roeder	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)
Russ Wesdyk	Center for Drug Evaluation and Research (CDER)
Marta Wosinska	Center for Drug Evaluation and Research (CDER)

Discussion

The FDA presented its perspective on goals related to bioequivalence inspections and answered questions on the same. FDA provided information on technical, legal, and postmarketing activities and their importance to generic drugs. Items covered included responding to citizen petitions, providing technical consults on applications, and working on risk evaluation and mitigation strategies (REMS). FDA provided an opportunity for questions as the agency envisions these areas being additionally funded by a generic user fee program.

Goals for review of abbreviated new drug applications (ANDAs), as well as related filings such as drug master files (DMFs) submitted by active pharmaceutical ingredient (API) manufacturers, were discussed. This was followed by FDA presenting a detailed overview of the resources needed to review ANDAs currently pending and those to be submitted in order to meet proposed review goal timeframes. Also discussed was the need for the agency to ramp up to provide personnel and expertise to meet performance goals, and the challenges involved in such hiring.

Representatives from the Generic Pharmaceutical Association (GPhA), the Society of Chemical Manufacturers and Affiliates (SOCMA) and the European Fine Chemicals Group (EFCG), asked questions to further explore these aspects of FDA's broad scope of work in the generic drug program.

Industry and FDA agreed that the parties are in alignment on key goals necessary to implement a workable user fee program. Such goals include the prospective size of the program, general target of timeframes for complete review of ANDAs and supplements, the need to reduce the queue of pending applications so that applications can be processed within the agreed time frames by the end of the first cycle of the program, as well as biennial inspections goals for domestic and foreign programs while maintaining critical review policies.

Specifically, the parties plan on conducting negotiations within industry's and FDA's proposed metaphorical "four walls and a roof," namely:

- FDA must continue to adhere to a general first-in-first-reviewed application review policy, with no separation of the currently pending application queue (the so-called "backlog");
- A goal to reduce the queue to a steady state level, where applications coming in can go out within the goal times, by the end of year 5 of the program;
- A primary application review goal of 10 months in year 5 of the program;
- User fee resources not exceeding \$250-\$300 million annually, as a basis for discussion; and
- Commitment by FDA to a risk-adjusted biennial surveillance inspection model with foreign and domestic parity in year 5.

There was mutual recognition that the parties still need to find solutions and make additional changes to accommodate all the factors above (i.e. "to stay within the four walls and roof of the house.")

The FDA docket remains open throughout the generic drug user fee discussions and FDA welcomes comments from all stakeholders. A public stakeholder meeting is planned for May and will be announced in the Federal Register.

Next Meeting

The next meeting will be held on Thursday, April 28, at the FDA. At this meeting, FDA will address inspectional resource needs for a generic drug user fee program as well as resource needs related to legal, technical and postmarketing activities.