

FDA-Industry Generic Drug User Fee (GDUF) Negotiations Meeting
August 31, 2011, 9:00-3:00pm; and various teleconferences up to and including
September 1, 2011
FDA White Oak Campus
Silver Spring, MD

Purpose

To confirm agreement and plans to recommend and seek formal ratification by September 9; to finalize Goals Letter; and to edit legislative language, for the generic drug user fee act (GDUFA) program.

Participants

Generic Pharmaceutical Association (GPhA)

Debbie Jaskot	Teva North America
Gordon Johnston	GPhA
Charlie Mayr (phone)	Watson Pharmaceuticals
Marci McClintic-Coates	Mylan Labs
Tom Moutvic (phone)	Sagent Pharmaceuticals
Lara Ramsburg	Mylan Labs
Rich Stec (phone)	Perrigo

European Fine Chemicals Group (EFCG)

Carla Vozzone (phone)	Hovione
Guy Villax (phone)	Hovione

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

John DiLoreto	BPTF
Alan Nicholls	Copperhead Chemical Company, Inc.
Brant Zell (phone)	Polypeptide Laboratories

FDA

Peter Beckerman	Office of the Commissioner (OC)
Don Beers	Office of Chief Counsel (OCC)
Lisa Berry	Office of Financial Management (OFM)
Rita Hassall	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)
Mari Long	Office of the Commissioner (OC)
David Miller	Office of Financial Management (OFM)
Marie Angeline O'Shea	Center for Drug Evaluation and Research (CDER)
Suzanne Pattee	Center for Drug Evaluation and Research (CDER)
Lynnette Riggio	Office of Regulatory Affairs (ORA)

Ted Sherwood
Russell Wesdyk

Center for Drug Evaluation and Research (CDER)
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Discussion

The groups met on August 31th and in various teleconference discussions to make final changes to the Goals Letter on performance commitments, discuss the draft legislative language for the congressional proposal for generic drug user fees act (GDUFA) program, and to confirm agreement and plans to recommend and seek formal ratification by September 9.

The groups finalized the Goals Letter with only minor formatting and conforming (to legislative language) matters remaining prior to ratification.

The group completed a second cycle review of the legislative language. There was agreement on all open issues and a third revision was circulated. Open items include:

- Direct hire authority insert
- ANDA completeness assessment pre and post 20 day grace period insert

The respective group representatives plan to present the final documents to their respective members and seek formal ratification by COB September 9th.

Broad outlines of the agreement are as follows:

To help FDA ensure that participants in the U.S. generic drug system comply with U.S. quality standards, and to increase the likelihood that American consumers get timely access to low cost, high quality generic drugs, FDA and industry have jointly agreed to a comprehensive human generic drug user fee program, to be supplemental to traditional appropriated funding, that is focused on three key aims:

Safety – Ensure that industry participants, foreign or domestic, who participate in the U.S. generic drug system are held to consistent high quality standards and are inspected biennially, using a risk-based approach, with foreign and domestic parity.

Access – Expedite the availability of low cost, high quality generic drugs by bringing greater predictability to the review times for abbreviated new drug applications, amendments and supplements, increasing predictability and timeliness in the review process.

Transparency – Enhance FDA’s ability to protect Americans in the complex global supply environment by requiring the identification of facilities involved in the manufacture of generic drugs and associated active pharmaceutical ingredients, and improving FDA’s communications and feedback with industry in order to expedite product access.

Recognizing the critical role generic drugs play in providing more affordable, therapeutically equivalent medicine, the Generic Drug User Fee program is designed to keep individual fee amounts as low as possible to supplement appropriated funding to ensure that consumers continue to receive the significant benefits offered by generic drugs which provided more than \$824 billion dollars in savings to the nation's health care system in the last decade alone. The additional resources called for under the agreement, an inflation adjusted \$299 million annually for each of the five years of the program, will provide FDA with the ability to perform critical program functions that could not otherwise occur. This program is not expected to add significantly to the cost of generic drugs: given that a reported 3.99 billion retail prescriptions per year were dispensed in the United States in 2010¹, and assuming that 78% of these prescriptions were filled by generic drugs,² if the entire cost of the program were passed through to U.S. retail consumers (although this is not the intent), the average cost of a prescription filled by a generic drug in the United States would rise less than a dime per prescription. Moreover, with the adoption of user fees and the associated savings in development time, the overall expense of bringing a product to market may decline and result in reduced costs.

In addition to the public health benefits outlined above, the GDUFA program is expected to provide significant value to small companies and first time entrants in the generic market who will benefit significantly from the certainty associated with performance review metrics that offer the potential to dramatically reduce the time needed to commercialize a generic drug when compared to pre-GDUFA review times.

In addition, the variety of funding sources for the program will assure that participants in the generic drug industry, whether finished dosage form (FDF) manufacturers or Active Pharmaceutical Ingredient (API) manufacturers appropriately share the financial expense and benefits of the program. Given that the total amount of annual user fee funding is expected to be derived from a broad funding sources, and any individual fee is expected to be approximately an order of magnitude of lower than PDUFA application fees, generic drug user fees are expected to provide a measurable return on investment related to predictability of inspection, and review timelines. The program's goals of ensuring FDA has necessary resources to conduct needed inspections as part of the complete review framework and achieve parity of GMP inspections for foreign and domestic facilities by the 5th year of the user fee program will also provide significant value to industry participants given that outstanding inspections can result in delays of ANDA approvals.

Taken collectively, the user fee program and associated performance metrics and fee are expected to provide measurable public health benefits and are not expected to competitively disadvantage any company or business sector regardless of size or location.

¹ Source: "The Use of Medicines in the United States: Review of 2010", Report by the IMS Institute for Healthcare Informatics, slide 8, available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII_UseOfMed_report.pdf.

² Ibid, slide 22.

Major program goals can be summarized as follows:

Application metrics – For Abbreviated New Drug Applications (ANDAs) in the year 5 cohort, FDA will review and act on 90 percent of complete electronic ANDAs within 10 months after the date of submission. There are various interim year metrics as well as quality metrics designed to enhance the quality of applications and limit the number of review cycles. DMF and inspection matters are subsumed in the application goals.

Backlog metrics – FDA will review and act on 90 percent of all ANDAs, ANDA amendments and ANDA prior approval supplements regardless of current review status (whether electronic, paper, or hybrid) pending on October 1, 2012 by the end of FY 2017.

CGMP Inspection metrics – FDA will conduct risk-adjusted biennial CGMP surveillance inspections of generic API and generic FDF manufacturers, with the goal of achieving parity of inspection frequency between foreign and domestic firms in FY 2017.

Efficiency Enhancements – FDA will implement various efficiency enhancements impacting review of both ANDAs and DMFs as well as inspection on October 1, 2012 or upon enactment of the program. Some examples include:

- Use of complete review/response letters (ANDAs and DMFs)
- DMF completeness assessment (for DMFs intending to be referenced by ANDA sponsors)
- Division level deficiency review (ANDAs and DMFs)
- Rolling review (ANDAs and DMFs)
- First cycle deficiency meetings (ANDAs and DMFs)

Regulatory Science – FDA will undertake various initiatives designed to enhance post-market safety, to develop guidance to industry, and to mitigate regulatory science gaps in select generic regulatory pathways.

The fee structure can be summarized as follows:

Fees will be derived from both applications and facilities in a 30:70 split. Fees will be split across industry segments (FDF and API) in an 80:20 split.

Application fees – Include backlog fees in year 1, and ANDA and PAS fees, as well as DMF first reference fees, in all years.

Facility fees – Will be paid by both FDF and API facilities with a modest fee differential reflecting the added costs of overseas inspection.

The percentage to be obtained from different industry segments and types of fees are estimated to be in the range of:

First year

- 17 percent from ANDA submissions pending on Oct. 1, 2012 (e.g., backlog) (first year only)
- 5 percent from DMF submissions
- 20 percent from ANDAs and supplements (with individual PAS fee amount being half the fee for ANDAs)
- 46 percent for generic drug finished dosage form facilities
- 12 percent for active pharmaceutical ingredient facilities

In subsequent years, the fee estimates are to be:

- 6 percent from DMF submissions
- 24 percent from ANDAs and supplements (with individual PAS fee amounts being half the fee amount for ANDAs)
- 56 percent from generic drug finished dosage form facilities
- 14 percent from active pharmaceutical ingredient facilities

Next Meeting

If necessary, the next and final meeting will be held at FDA on Wednesday, September 7 where FDA and industry will finalize the draft legislation to operationalize the program.