

FDA-Industry Generic Drug User Fee (GDUF) Negotiations Meeting
August 18, 2011, 9:00-3:00pm
FDA White Oak Campus
Silver Spring, MD

Purpose

To finalize changes to a draft letter of performance commitments and goals, discuss operationalizing fee structures for the generic drug user fee act (GDUFA) program, and discuss legislative language.

Participants

Generic Pharmaceutical Association (GPhA)

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

European Fine Chemicals Group (EFCG)

Carla Vozzone (phone)	Hovione
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Bulk Pharmaceutical Task Force (BPTF) of the Society of Chemical Manufacturers and Affiliates (SOCMA)

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

FDA

Leslie Ball	Center for Drug Evaluation and Research (CDER)
Peter Beckerman	Office of the Commissioner (OC)
Lisa Berry	Office of Commissioner (OC)
Hilmar Hamann	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)
Kevin Laser	Center for Drug Evaluation and Research (CDER)
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)
Lynnette Riggio	Office of Regulatory Affairs (ORA)
Edward Sherwood	Center for Drug Evaluation and Research (CDER)

Adam Southers
Keith Webber
Russell Wesdyk

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Discussion

The groups met on August 18, 2011 to make final changes to the goals letter on performance commitments, to discuss the draft legislative language for the statutory proposal that will accompany the goals letter for generic drug user fees act (GDUFA) program, and to learn more about FDA user fee payment mechanisms through iStore and iReceivables. The groups discussed recent press coverage of the negotiations and the need to finalize the goals letter and legislative language.

In reviewing the final draft of the goals letter, the parties discussed overview language explaining that fees under GDUFA are expected to be reasonably low because of the industry's mission to provide consumers access to lower cost drugs. The parties discussed mechanisms to explain to the public and industry that fees are expected to be orders of magnitude lower than application fees under the PDUFA program. GPhA discussed the interaction between complete response letters and citizen petitions, particularly with regard to citizen petitions submitted prior to legislation in 2007 establishing response timelines under Section 505(q) of the Federal Food, Drug and Cosmetic Act (FDCA); this was noted to be a small number of petitions existing at the agency. FDA indicated that it will strive to address issues raised in citizen petitions in complete response letters where possible.

In response to industry's request for more information on payment mechanisms, the agency presented its procedures for user fee electronic payment systems to industry. iStore enables the user fee payor to create an invoice with a cover sheet, add specific identifying information, such as abbreviated new drug application (ANDA) or drug master file (DMF) number, payment ID number, confirmation number and a cover sheet number. Using this information, the payor will then pay the fees via bank checks, Fedwire, or pay.gov to the US Treasury. Payors can use iReceivables to obtain information similar to a receipt, which has information on transactions, account balances including any overdue payments.

The FDA shared with industry draft legislative language necessary for Congress to implement the program for generic drugs. The draft legislative language, once enacted, will provide authority for FDA to collect a fee, definitions of the types of applications and facilities that will be subject to fees, and mechanisms by which FDA will notify industry of fee amounts, among other things. Some elements, such as an inflation adjuster, from the prescription drug user fee act (PDUFA) are included and the overall statutory structure is similar to PDUFA.

FDA explained its concerns regarding industry's suggestion the prior week of a possible "trigger" or "overflow mechanism" in which fees from a stable funding source (e.g., facilities) would be paid through an additional "spillover" fee source that is variable (e.g.,

submissions) and explained that the agency could only consider such a mechanism if the fees “spilled over” into equally stable, non-variable funding sources. FDA also voiced concern that such a mechanism could increase the cost of administering the program. In light of these considerations, and the late date at which this proposal arose, the parties agreed not to incorporate a “spillover” fee. The parties reiterated their agreement regarding previously discussed fee distributions, with API manufacturers providing 20 percent of overall program funds, and finished dosage form manufacturers providing 80 percent. They also reaffirmed that 30 percent of fees will come from ANDA and DMF fees, with 70 percent of fees coming from facility fees. In order to provide more certainty about the typical types of fees to be collected from facilities, the groups urged FDA to take whatever steps are possible prior to the program’s implementation to identify the number of facilities subject to fees.

The groups also discussed the relative break out of fees that will be included in the GDUFA statute. The statute will not include specific fee amounts, as that must be calculated annually, based on then current available information. This mirrors the fee setting process for other user fees. It was stressed that the size of the fees will not be comparable to PDUFA application fees. Rather, the industry found that the potential fees that were discussed were reasonable for both large and small manufacturers, and well worth the investment given the certainty of timing that will arise from the performance goals from FDA. In identifying which facilities would be subject to DMF fees, the group talked about ways the FDA and industry associations can work to communicate about the program prior to and during its implementation.

The groups will continue to work through the draft of legislative language, will finalize the goals letter on performance commitments in continuing discussions before the next face-to-face meeting on August 31, 2011. The parties are working toward a Sept. 9th deadline to provide the final goals letter and legislative language for internal administration review. All groups indicated a willingness to conduct additional discussions by telephone before the deadline.

Next Meeting

The next meeting will be held at FDA on Wednesday, August 31st where FDA and industry hope to finalize the performance goals letter and the draft legislation regarding fee structure to operationalize the program.