September 9, 2011
From GPhA Board of Directors Chairman Paul Bisaro

Dear GPhA Member,

RE: *Generic Drug User Fee Program*

I am pleased to announce that we have completed the negotiating phase of a generic drug user fee program (GDUFA). Yesterday, GPhA formally ratified the documents outlining the agreed upon performance goals letter and the proposed legislative language needed to authorize GDUFA. And today, we received word from both the European API industry and from the Bulk Pharmaceuticals Task Force of SOCMA that they also have ratified the documents. These documents now head to the Office of Management and Budget and to the Department of Health and Human Services for review, and then are sent to Congress for enactment.

Before sharing with you the highlights of GDUFA, let me thank the GPhA negotiating team for their diligent work over the past several months on this critical issue: team leader Gordon Johnston of GPhA; Debbie Jaskot, Teva; Charlie Mayr; Watson; Marci McClintic-Coates, Mylan; Tom Moutvic, Sagent; Lara Ramsburg, Mylan; and Rich Stec, Perrigo. We also thank Carla Vozone and Guy Villax, representing the European Fine Chemicals Group, and John DiLoreto, Alan Nicholls and Brant Zell, representing the Bulk Pharmaceutical Task Force of SOCMA. Finally, we sincerely thank the FDA for its substantial commitment in collaborating with all industry stakeholders to assure that we reached a successful and mutually acceptable outcome. The entire generic industry owes all of these stakeholders its sincere gratitude.

GDUFA Highlights

Until full details of the program are submitted to Congress and become public, we remain under a confidentiality agreement with other stakeholders. But we are free to share several of the program highlights, which also are provided in the negotiating minutes at fda.gov.

The purpose of GDUFA is to provide additional funds to FDA to supplement the traditional annual funding appropriated by Congress. The three key aims of GDUFA are:

- **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 ANDAs, 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 APIs, and improving FDA's communications and feedback with industry in order to expedite product access.

The additional funding called for under GDUFA is an inflation-adjusted $299 million annually for each of the five years of the program. This amount will be split between finished dosage form manufacturers and active pharmaceutical ingredient manufacturers (see below). The GDUFA program is expected to provide significant value to all industry participants—particularly smaller companies and first time entrants in the generic market—who will benefit from the certainty associated with the new performance review metrics. GDUFA metrics and fees are not expected to competitively disadvantage any company regardless of size or location. Further, given that outstanding inspections result in delays of ANDA approvals, the goal of ensuring FDA has necessary resources to conduct needed inspections and achieve parity of GMP inspections for foreign and domestic facilities will provide significant value to all participants.

Overview of Performance Goals

We are pleased to report that overall the agreed upon performance metrics are right in line with what we requested. The metrics for the first five years are designed to clear up the current application backlog and ensure timely approvals of future submissions. Major program goals can be summarized as follows:

- **Application Metrics** – By year five, 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, upon enactment of the program (e.g., use of complete review/response letters; completeness assessment for DMFs intending to be referenced by ANDA sponsors; division level deficiency review; and first cycle deficiency meetings for 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.

Overview of Fees

Fees will be derived from both applications and facilities in a 30%-70% split. Fees will be split between finished dosage form manufacturers and active pharmaceutical ingredient manufacturers 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 finished dosage form manufacturers and API facilities with a modest fee differential reflecting the added costs of overseas inspection.

- **Source of Fees** – The percentage to be obtained from different industry segments and types of fees are estimated below. Please note that these are estimates based on current projections and will be subject to minor changes based on annual updated data. However, this provides a general outline of expected fees.

    - First year only: 17% (in the first year only) from ANDA submissions pending on Oct. 1, 2012 (the backlog); 5% from DMF submissions; 20% from ANDAs and supplements (with individual PAS fee amount being half the fee for ANDAs); 46% from generic drug finished dosage form facilities; 12% from API facilities

    - Subsequent years: 6% from DMF submissions; 24% from ANDAs and supplements (with individual PAS fee amounts being half the fee amount for ANDAs); 56% from generic drug finished dosage form facilities; 14% from API facilities.

Again, we thank all GPhA member companies for your support during this process. This represents a major milestone for our industry…one that will benefit us and the consumers we serve for years to come.

Regards,
Paul Bisaro