



U.S. Food and Drug Administration

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Generic Drug User Fee (GDUF) Meeting Summary
Tuesday, May 10, 2011 2:00 – 3:30 PM
FDA White Oak, Building One

FDA Attendees:

Peter Beckerman, FDA
Kevin Bugin, FDA
Megan Clark Velez, FDA

Mari Long, FDA
Ted Sherwood, CDER
Russell Wesdyk, FDA

Public Attendees:

Bernadette Attinger, Sandoz, Inc.
Paul Brown, National Research Center for
Women & Families
Rebecca Dandeker, K & L Gates, LLP
Edward Eichmann, BD Medical
Elizabeth Ernst, Roxane Laboratories
Paul Feuerman, Attorney for Agvar
Chemicals, Inc.
Derrick Gingery, The Pink Sheet
Laura Helbling The RPM Report
Janette Merrill, SNM, Advancing
Molecular Imaging & Therapy

Nirmal Mulye, Nostrum Laboratories, Inc.
David Pittman, FDAnews
Marvin Samson, Advisor to Agvar
Chemicals, Inc.
Mark Sebree, BD Medical
Dennis Strickland, Pfizer
Randall Wilson, Roxane Laboratories, Inc.
Nik Johnson, AMCP
Mark Vonderhaar, Consultant
Carol Patterson, Endo Pharmaceuticals,
Inc.

FDA Presentation: Peter Beckerman, J.D., Policy Advisor, FDA/OC Office of Policy;
Russell Wesdyk, FDA/CDER Office of Pharmaceutical Science

- FDA is engaged in the effort to strengthen the generic drug program..
- The Process for a New User Fee
 - See the GDUF Web site for additional information:
<http://www.fda.gov/Drugs/NewsEvents/ucm224121.htm>.
 - The GDUF docket will remain open throughout the duration of the negotiations (Docket number FDA-2010-N-0381, visit www.regulations.gov to submit comments electronically).
- Activities to Date
 - Public meetings held: September 17, 2010, February 23, 2011, and May 10, 2011.
 - Negotiations began February 28, 2011 (five meetings held to date) and are scheduled through June 2011.
- Transparency and Inclusion
 - Formal negotiations are held with trade associations, not individual companies. FDA is aware that company positions may differ from that of trade associations and to ensure all opinions are heard, individual companies or persons may provide input through the docket.
- FDA/Industry Goals
 - First-in-first-reviewed policy, with no separation of the backlog
 - Queue to steady state by the end of year five.

- The primary application review goal is 10 months in year five.
- Commitment to risk-adjusted biennial surveillance inspection model with foreign and domestic frequency parity in year five.
- Ensuring that FDA has adequate resources to ensure FDA is able to meet agreed upon goals.
- FDA is aggressively seeking process efficiencies and has analyzed the review process, inspection process, and has improved knowledge about the processes to improve efficiency.

Public and Stakeholder Presentations:

Paul Feuerman, representing Agvar Chemicals

- Founders of the generic drug industry had the goal of protecting consumer rights with respect to access to affordable medicines.
- GDUF program must have committed timelines for review and approval of applications to ensure U.S. citizens have access to a competitive flow of generic prescription drugs.
- Review of drug master files: A company permitted to submit a master file and should pay a fee and have timelines associated with the review of the DMF. Recommend that fees for the review of drug master files be at a reduced rate (suggest this fee be 50% of any agreed upon ANDA application fee)
- Want DMFs reviewed even if not referenced
- Will submit comments to the docket.

Paul Brown, National Research Center for Women and Families

- Supports user fees as appropriations are inadequate to support FDA work; however support is contingent on part of the user fees funding post-market surveillance of generic drugs.
- Comments on types of fees:
 - Emphasize that foreign drug manufacturers must pay fair share due to the increased number of generic drugs being manufactured abroad;
 - Support the use of a sliding fee scale for smaller companies; and,
 - Express concern that user fees be tied to broad, agreed upon goals to ensure there is not the appearance that the FDA is there to serve the generic industry. User fees must support the program and not give special treatment to the industry.
- Suggested changes to the negotiating process:
 - Suggest a consumer group be at the negotiating table so that these groups can ensure patients are protected.
 - User fees should not be tied to specific approval numbers, timelines for individual drugs, etc. rather they should be tied to broad, agreed upon goals.
 - Review staff should publicly sign off on the approval process.
 - Portion of the fees should fund post-market surveillance of generic drugs.
 - This surveillance will benefit both the industry and patients. Adverse events or issues with safety or efficacy could be investigated by FDA when reported.

- Concern with lack of firewall between performance goals and industry demands.

Nirmal Mulye, Nostrum Pharmaceuticals, LLC

- Does not support generic drug user fees. FDA does not have a resource problem, rather the issue lies with the needed reform of the generic drug review process. Currently the review process lacks accountability which leads to a significant waste of resources.
- Lack of harmonization between regulatory review and compliance branches require additional post-approval regulatory filings.
- User fees are an additional tax on businesses which will lead to increased product costs.
- FDA must recognize role and limitations.
- Suggest FDA be cautious with creating additional regulatory burdens, and if it must do so, remove redundant or meaningless regulations.
- If reviewers are properly trained and with accountability built in would allow for timely and effective review of applications.
- Suggested reforms needed:
 - Clearly defined regulations and guidance and administering these in a transparent way;
 - Open and efficient communication with the industry, building in accountability for decisions made by FDA reviewers and management;
 - Streamlining processes to free resources; and,
 - Harmonizing and/or integrating various FDA branches.

Questions and Answers

- Have the findings from the study commissioned by FDA examining efficiencies been published?
 - A final report has not been issued, however FDA is committed to considering and implementing any recommendations that will be made.
- Will there be an opportunity to share the findings from the efficiencies study with the industry?
 - When a final report is issued and accepted, FDA has an obligation to make it available.
 - P. Beckerman will look into report status and will take the expression of interest in the report back to OGD.
- This report is part of an ongoing effort to look at processes both in OGD and throughout the Agency to improve efficiencies.
- The generic industry is handicapped by the inability to simply call and discuss issues with respect to reviews and individual reviewers with FDA supervisors. Access and communication processes need to be built into the system to improve efficiency.
- Once the negotiations are concluded, will the proposal be published for comment prior to being sent to Congress?
 - Concurrent review may occur due to timelines; however, the opportunity for public comment will be provided.

- Foreign inspection parity: Has communication with inspectors occurred?
 - Yes –FDA is committed scaling up inspections in an efficient manner. This will require significant hiring and training and FDA’s generic drug negotiating team includes members from ORA and CDER Office of Compliance, the FDA divisions that conduct inspections, so the field investigators’ perspective is being considered.