



December 6, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Comments of the Generic Pharmaceutical Association for Docket No. FDA–2012-D-0880-0006, Draft Guidance for Industry Generic Drug User Fee Amendments of 2012: Questions and Answers.

The Generic Pharmaceutical Association (GPhA) acknowledges the efforts of the FDA on **Docket Number FDA–2012-D-0880-0006, Draft Guidance for Industry Generic Drug User Fee Amendments of 2012: Questions and Answers.** Upon review GPhA and our members crafted several additional questions for consideration following the submission of our initial comments on November 8, 2013. We would also like to thank you for giving us the opportunity to share our thoughts on this important public health issue.

GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Our members manufacture more than 90% of all generic pharmaceuticals dispensed in the U.S., and their products are used in more than one billion prescriptions every year. Generics represent greater than 84% of all prescriptions dispensed in the U.S., but only 27% of expenditures on prescription drugs. GPhA is the sole association representing America's generic pharmaceutical sector in the U.S., while this response letter represents the views of the association these comments may not reflect all member company positions.

GPhA has reviewed the questions identified in the above referenced Federal Register Notice and has additional questions to pose to FDA:

- The FDA commitments letter talks about expediting PIV (day 1 submissions). What is happening to PIV, FTF applications in the backlog? Will they continue to be expedited to permit timely, day 1 approval of quality generic drugs?
- Will enhanced collaborations with foreign regulators result in FDA relying on a foreign regulators report in order to provide clearance to a site?
- Under the risk-based inspection program, will ANDAs be able to get approved if their sites have a clean compliance history, but have not been inspected within the last 2 years?



- Is it still possible to self-identify for this fiscal year or does an applicant have to wait for the upcoming self-identification period?
- Is a manufacturer who manufactures a drug-device combination product required to self-identify?
- How does the agency interpret the facility fee policy for multiple sites of a company located on one campus? What are the criteria and requirements for making such a decision? In FDAMA legislation there was a 5 mile limit applied to distance between buildings in terms of sameness of site. In GDUFA there is a vague statement regarding geographical closeness. Can you comment on this disparity?

Thank you for your continued guidance of the Generic Drug User Fee program. We appreciate the opportunity to provide our comments and support FDA's efforts to work towards the development of a clear and proven Guidance.

Sincerely,

A handwritten signature in black ink, appearing to read "D.R. Gaugh". The signature is fluid and cursive.

David R. Gaugh, R.Ph.
Senior Vice President for Sciences and Regulatory Affairs