November 8, 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Comments of the Generic Pharmaceutical Association for Docket No. FDA–2012-D-0880-0006, Draft Guidance for Industry Generic Drug User Fee Amendments of 2012: Questions and Answers.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Generic Pharmaceutical Association (GPhA) acknowledges the efforts of the FDA on **Docket Number FDA–2012-D-0880-0006, Draft Guidance for Industry Generic Drug User Fee Amendments of 2012: Questions and Answers**. 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.

GPhA has reviewed the questions identified in the above referenced Federal Register Notice. Please note that GPhA is providing comment for only those questions for which our member companies have specific recommendations.

GPhA would like to request rewording Q75 & Q76 in order to clarify the language. We recommend revision to read:

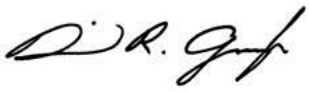
> "What is the reporting period for a facility to self-identify for the very first time if the facility has been referenced or is intended to be referenced in either a pending generic drug submission or a supplement to an approved generic drug submission?

Q87 also requires some clarification. Please consider dividing the question into two separate questions to allow the appropriate answer to be provided. The first part of the question asks what the goal date adjustment would be for an amendment that requires an inspection. The answer

depends on whether the amendment was a Tier 1 unsolicited amendment agreed by FDA to be a result of either delaying actions as determined by OGD that otherwise would eventually be solicited (review cohort equal to 10 months) or a Tier 2 unsolicited amendment not arising from delaying actions as determined by OGD (review cohort equal to 12 months). The response that the application's review may extend by up to 10 months is incorrect and not consistent with the GDUFA Commitment Letter (pages 10-11). The second part of the question asks what the goal date adjustment would be for submission of a major amendment. The response that the application's review may extend by up to 10 months is correct and consistent with the GDUFA Commitment Letter (pages 10-11).

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,



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