Generic Pharmaceutical Association

July 25, 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 on Establishment of Public Docket for Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format.

The Generic Pharmaceutical Association (GPhA) acknowledges the efforts of the FDA in requesting comments from Industry on ***Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format.*** We would like to thank you for giving us the opportunity to share our thoughts on this important public health issue.

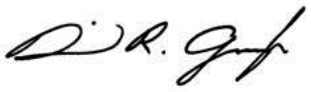
GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Our members manufacture more than 90% of all generic pharmaceuticals dispensed in the U.S., and their products are used in more than one billion prescriptions every year. Generics represent greater than 80% 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 and our members disagree with the FDA on the amount of time it takes applicants to convert content of labeling to Structured Product Labeling (SPL) formats. It has been the experience of our membership that conversions take more than the approximately 1.25 hours estimated in the notice. Additional time also translates into additional labor costs. The cost incurred particularly for smaller generic companies could be substantial. The staffing and expertise necessary to independently determine the need for a labeling change would be costly. This could result in fewer generics for certain types of products where the Adverse Drug Events (ADE) profile is high to start with (such as anti-depressants or oral contraceptives) or even fewer generic manufacturers in general due to the additional costs of supporting commercial product. While FDA provides technical assistance and other resources, including code sets and data standards regarding SPL files, we believe industry will also need to devote additional resources for technical support as well.

GPhA would like to request clarification concerning the type of filing needed or anticipated by FDA to make an appropriate labeling decision. The notice is not clear about what type of filing is needed other than a CBE, which will not allow the Agency adequate time to review if the label change is solely linked to one manufacturer or if it is indeed a product related safety concern applicable to an entire class of pharmaceuticals.

Finally, we believe the FDA is the only regulatory body qualified to make the public health decision on Labeling for Human Prescription Drugs and Biologics in Electronic Format, and we support FDA's efforts to work towards the development of a clear and proven Guidance.

Sincerely,



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