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US FDA seeks inputs on its generic drug amendments

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US FDA seeks inputs on its generic drug fee amendments

Singapore: On July 9, 2012, the Generic Drug User Fee Amendments of 2012 (GDUFA) was enacted by the US. The Food and Drug Administration (FDA) has now called for an industry meet to gather input on the guidance documents, so as to ensure early and streamlined implementation of the same. The FDA has also issued a guidelines with queries and responses for industry to ensure transparency and facilitate compliance by companies.

The guidance will provide answers to the expected questions from participants (from the generic drug industry) regarding the implementation of GDUFA. The format of the guidance has been grouped under several categories, including fees, review of generic drug submissions, compliance and inspections among others.

GDUFA is designed to speed access to safe and effective generic drugs for the public and reduce costs to industry and requires generic drug manufacturers to pay user fees in order to finance critical and measurable program enhancements. GDUFA also requires that generic drug facilities, sites and organizations located around the world, to provide identification information annually to the FDA. It is based on an agreement negotiated by FDA and representatives of the generic drug industry to address a growing number of regulatory challenges.

GDUFA not only enables the FDA to evaluate user fees (in order to aid in critical and measurable enhancements to the performance of its generic drugs programme), but also enhance the its ability to protect the industry in the global supply environment by making it mandatory for companies to identify their facilities that are involved in the manufacture of generic drugs and other associated active pharmaceutical ingredients (API).

GDUFA will help to ensure that foreign and domestic firms in the US generic drug domain are scrutinized to consistent, high-quality standards and are evaluated twice-a-year, using a risk-based approach.