FDA Expands Scope of Reporting for Discontinued Drugs

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The FDA has published an interim final rule amending definitions related to required notifications regarding drug shortages. 21 C.F.R. 314.81(b)(3)(iii) requires an applicant who is the sole manufacturer certain approved drug products to notify FDA in writing at least 6 months prior to discontinuing manufacture of the drug product. 21 C.F.R. 314.81(b)(3)(iii) now refers to "discontinuance of manufacture" rather than "discontinuing manufacture," and defines "discontinuance" as "any interruption in manufacturing of a drug product described in paragraph (b)(3)(iii)(a) of this section for sale in the United States that could lead to a potential disruption in supply of the drug product, whether the interruption is intended to be temporary or permanent" and "sole manufacturer" as "an applicant that is the only entity currently manufacturing a drug product of a specific strength, dosage form, or route of administration for sale in the United States, whether the product is manufactured by the applicant under contract with one or more different entities."

These changes broaden the scope of reporting required under § 314.81(b)(3) and are intended to help FDA provide better information to physicians and patient organizations and to work with stakeholders to respond to potential drug shortages. Under § 314.81(b)(3)(iii)(a), the reporting requirements apply to drug products that are "life supporting, life sustaining, or intended for use in the prevention of a serious disease or condition" and "w[ere] not originally derived from human tissue and replaced by a recombinant product." All drug manufacturers should review the revised regulation to determine if their products now fall within the scope of § 314.81(b)(3).

The interim final rule is effective January 18, 2012, and comments are due by February 17, 2012.