Attention Pharma Industry: Update your Drug Product Listings Now (FDA will begin to deactivate old and outdated listings soon)

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FDA recently reminded pharmaceutical manufacturers and other registered drug establishments to confirm that all product listing records are current and to remove outdated listings. The agency will soon begin deactivating old drug listing records; those not updated as of September 12, 2019 (and each January thereafter) may be deemed inactive and removed from FDA's databases. FDA has noted that drugs with inactivated listing records may not be legally marketed in the U.S. until the records are brought up to date. Deactivation may also pose issues for reimbursement or supply chain tracking. We briefly discuss key points below.

Summary of Background and Action Needed

On August 13, 2019, FDA announced that it will deactivate drug listing records that: (i) have not been updated or certified as required by regulation, or (ii) include an establishment with an expired registration.[1] These listings are required by law, and databases that include the information are used for a number of purposes by FDA, as well as other stakeholders, such as public and private insurers (e.g., FDA's National Drug Code Directory). The agency has found thousands of drug listings that have not been updated or certified, which affects database integrity and post-market surveillance, for example.

Drug manufacturing establishments must be registered with FDA. For purposes of registration, the term "manufacture" also includes activities such as repacking, relabeling, and salvaging. Registrants must list each drug manufactured at their establishments, and renew the registration each year. Registrations must be updated to reflect changes in material information, including changes in manufacturing establishment(s) and discontinuation of drug products. As part of the annual renewal, all registrants must certify that no changes have occurred to their listings that were not submitted or updated during the calendar year. FDA noted in its August announcement that some facilities were not currently registered.

FDA has urged registrants to review all drug listings as soon as possible. As of September 12, 2019 (for current information), and each January going forward, the agency plans to take the following action:

> …if drug listings are not appropriately updated, certified, or associated with a registered establishment, they will be marked by FDA as 'inactive,' and the date of inactivation will be added to the listing record. This process will result in the closure of drug records in all public drug listing databases maintained by FDA, including the National Drug Code (NDC) Directory and the NDC SPL Data Elements (NSDE) file, until corrections to the relevant listings are made.[2]

1 See FDA press release, *FDA In Brief: FDA takes new steps to improve drug supply chain integrity and patient safety by announcing its intention to begin deactivating outdated drug listing records in its database* (Aug. 13, 2019), available at https://www.fda.gov/news-events/fda-brief/fda-brief-fda-takes-new-steps-improve-drug-supply-chain-integrity-and-patient-safety-announcing-its see also FDA *Federal Register* notice, *Drugs Intended for Human Use That Are Improperly Listed Due to Lack of Annual Certification or Identification of a Manufacturing Establishment Not Duly Registered with the Food and Drug Administration; Action Dates* ("FDA Drug Listing Notice"), 84 Fed. Reg. 40417 (Aug. 14, 2019).

2 See FDA Drug Listing Notice, *supra* note 1, at 40417.

At minimum, registrants should review their own drug establishment registration and product listings, as well as reviewing related information in FDA's NDC Directory.

AGG Observations

- Drug manufacturers and other registrants (e.g., relabelers) should review establishment registration and product listings as soon as possible to confirm that all information is up-to-date.
    - Any old or incorrect information should be updated or corrected right away; this should be done before September 12, 2019.
    - Going forward, companies should ensure that their policies incorporate this review each December as part of the annual registration renewal and certification.
        - To the extent that material changes occur in the first half of the year, updates should be made by June.
- If drug products are manufactured or otherwise handled by contracted companies (e.g., a contract manufacturing organization or CMO), product sponsors should confirm with contractors (or independently confirm) that all relevant entities are registered with FDA, if required, and have up-to-date product listings.
- In addition to compliance with FDA requirements and related legal obligations, it is important that product listings are up-to-date for other reasons as well. For example, product listing information may be used in prescription drug payment systems, and related information (e.g., NDC codes) may be embedded in drug "track-and-trace" or other supply chain systems.

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