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Client Alert

FDA & Life Sciences Practice Group

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Reminder To Update or Certify "No Changes" to Drug Listings Before the End of 2017

Failure To Maintain Listings May Affect Operations and Coverage for Reimbursement

The Federal Food, Drug, and Cosmetic Act ("FDCA") has long required pharmaceutical manufacturers, repackers, relabelers, and salvagers to register their production facilities, and to list each drug product currently manufactured there for commercial distribution.[i] In the past, registrants were required to revise drug listings, as needed, at least twice per year (e.g., to note discontinued products, or to update previously submitted information). Revised Food and Drug Administration ("FDA") regulations added a new requirement, effective for 2017, that registrants not only update changed information in drug product listings on a periodic basis, but also that they certify annually (when applicable) that unchanged, previously submitted listing information has been reviewed and remains up-to-date (i.e., no changes required).[ii] The purpose is to enhance the overall accuracy of the FDA database. FDA intends to purge information that was not updated or certified "no changes" during 2017 from the NDC Directory and other drug listing publications in 2018.

The failure to fulfill listing obligations under the FDCA is a prohibited act, and can render a drug product misbranded.[iii] FDA has cited both a failure to fulfill listing requirements, and also high error rate in listings in recent Warning Letters.[iv] Failure to properly list can also impact import entry in the United States.

Most recently, the Centers for Medicare and Medicaid Services ("CMS") notified manufacturers participating in the Medicaid Drug Rebate Program ("MDRP") to take necessary listing action by December 31, 2017. That agency noted that it uses FDA's databases to verify that products meet the definition of a "covered outpatient drug" under Section 1927(k) of the Social Security Act. If a drug is not found in FDA's NDC Structured Product Labeling Data Elements ("NSDE") file – for example, if the information has been purged as part of FDA's upcoming clean-up process – a drug's status in the MDRP may be affected.

It is possible to reactivate certain drug listings that expire and are removed from FDA's databases. However, in order to avoid potential coverage gaps

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or other problems, it is recommended to confirm that appropriate listing updates and certifications have been made at this time.

Please contact us if you require assistance with drug registration and listing, MDRP, or other issues.

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[i] 21 U.S.C. § 360(a) and (j).
[ii] 21 C.F.R. § 207.57.
[iii] 21 C.F.R. § 21 U.S.C. § 331(p).
[iv] E.g., https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm562143.htm and https://www.fda.gov/iceci/enforcementactions/warningletters/2017/ucm588722.htm.