collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 8, 2019.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2019–17398 Filed 8–13–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2374]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its intention to begin inactivating drug listing records that are improperly listed in accordance with FDA requirements because these drug listings are not certified as being active and up to date or are associated with a manufacturing establishment that is not currently registered with FDA. FDA's regulations governing drug establishment registration and drug listing require registrants to notify FDA if commercial distribution of a listed drug is discontinued. They also require firms to submit drug listing updates if any material changes are made to information previously submitted, including a change in manufacturing establishment(s). FDA has found that listings for many drug products do not comply with these regulations because they have not been updated in over a year, they have not been certified as being up to date, or they identify within the listing information at least one manufacturing establishment that is not currently registered with FDA. Many of the drugs that are the subject of these listings appear to no longer be in commercial distribution. The purpose of this notice is to remind registrants of their legal obligations and announce that, 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.

DATES: This notice is applicable September 13, 2019.

FOR FURTHER INFORMATION CONTACT: Paul Loebach, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2262, Silver Spring, MD 20993–0002, 301–796–2173, *Paul.loebach@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) and part 207 (21 CFR part 207) of FDA's regulations have long required owners or operators of drug manufacturing establishments to register their establishments with FDA. In this notice, the term ''manufacture'' refers to all activities that trigger the drug establishment registration obligation under part 207, including repacking, relabeling, and salvaging as defined in part 207. Registrants are also required by section 510 and part 207 to ''list'' each drug manufactured at their establishments for commercial distribution and submit updated drug listing information to FDA twice yearly, in June and December, notifying FDA if this information has changed. Specifically, section 510(i)(2) and (j) of the FD&C Act require registered establishments to report and periodically update, among other information, listing information for each drug manufactured, prepared, propagated, compounded, or processed by them for commercial distribution in the United States. Under 21 CFR 207.49, 207.53, and 207.54, registrants must provide listing information that corresponds to the activity or activities they engage in for that drug.

As part of the drug listing information they submit to FDA, registrants must identify all establishments where a ''listed drug'' (as the term used in the context of section 510 of the FD&C Act and part 207) is manufactured or provide a source NDC that enables FDA to identify such establishments. Registered establishments must also report to FDA the discontinuation of commercial distribution of a listed drug (section 510(j)(2)(B) of the FD&C Act) and any material change in drug listing information previously submitted, which includes any changes in the establishment(s) where the drug is manufactured (section 510(j)(2)(D) of the FD&C Act and 21 CFR 207.1). On August 31, 2016, FDA amended part 207 to require drug manufacturers and other registrants, at the time of registration renewal, to certify that no changes have occurred to their listings that were not submitted or updated during the current calendar year (81 FR 60170 and § 207.57 (21 CFR 207.57)). The first certifications under this new requirement were due during the registration renewal period from October 1 to December 31, 2017 (81 FR 60170 at 60201 and § 207.57). Establishments and labeler code holders are also required to update contact information (name, telephone number, and email) submitted to FDA within 30 calendar days of any changes (21 CFR 207.25(g), 207.29(a)(3), and 207.33(c)(2)).

Complete, accurate, and up-to-date establishment registration and drug listing information is essential to FDA's mission. FDA relies on establishment registration and drug listing information in administering several key programs, including drug establishment inspections, postmarketing surveillance, counterterrorism, recalls, drug quality reports, adverse event reports, monitoring of drug shortages and availability, supply chain security, and identification of products that are marketed without an approved application. If registration and listing information is outdated or otherwise unreliable (such as inaccurate, superfluous, incomplete, or missing), the integrity of the drug establishment registration and listing database—and FDA's ability to rely on the reported information for these programs—is compromised. Drug registration and listing information is also widely used outside FDA for several purposes, including electronic drug prescribing, prescription drug reimbursement, and patient education. A review of our data shows that the types of errors discussed in this notice affect tens of thousands of records. Therefore, the inclusion of such incorrect or outdated information in FDA's NDC Directory, the NSDE file, or other public drug listing databases can negatively affect public health.

II. Circumstances Under Which Certain Drug Listing Information Becomes Inaccurate

Each registrant must list all drugs it manufactures for commercial distribution within 3 days of initial

registration (21 CFR 207.45). Establishment registration must be renewed annually between October 1 and December 31 (21 CFR 207.29). Each registrant must in June and December each year: (1) Update its drug listing information to provide FDA with information about any drugs introduced for U.S. commercial distribution not previously listed, (2) report the discontinuation of any listed drug, and (3) report any material changes in drug listing information submitted previously (including any updates in the manufacturing establishments) (§ 207.57). If there are no changes to listing information to report in June or December, then the registrant must certify that there have been no changes to the listing information previously submitted, during the October 1 and December 31 registration renewal and listing certification period (§ 207.57). By December 31 of each calendar year, registrants should review their current files of listed human drugs to determine whether any data elements in their drug listing records are no longer accurate and submit updated listing files or listing certifications.

While a new drug listing submission transmitted to FDA electronically will not be accepted if the listing information identifies a manufacturing establishment that is not registered in accordance with FDA's requirements, previously submitted establishment and listing information may become outdated for a variety of reasons. In some cases, establishments that have discontinued manufacturing let their registration expire by not renewing their annual establishment registration at the end of the year but fail to update their drug listing information to report discontinuation of their listed drug(s). The result is that listing information for certain drugs may be certified to be current but potentially identifies one or more establishments that are not currently registered with FDA in accordance with FDA's requirements.

In other cases, registrants may incorrectly include additional establishments in their drug listing submissions (for example, in anticipation of a future business relationship with a contract manufacturer). Consistent with the applicable regulatory requirements in part 207, FDA expects all establishments identified in a drug listing submission to reflect current manufacturing facilities for the listed drug at the time of the listing submission or at the time of the update so that the Agency can rely on the information when submitted as an accurate picture of the supply chain. There are also cases in which a registrant fails to review and update its previously reported drug listing information as required in June and December of each year. Similarly, a registrant may neglect to certify to FDA that its listings are still up to date and accurate. (See section IV of this document for links to FDA's NDC Directory and other resources that may help registrants determine whether any data elements in their drug listing records are no longer accurate and correct inaccurate drug listings.)

III. FDA's Intended Response

To address the above registration and listing problems, FDA is encouraging firms that are required to register drug establishments and list human drugs under part 207 to review their currently listed human drugs and determine whether any information in their drug listings, including drug establishments identified, is no longer accurate. Any active drug listing submissions that are inaccurate should be updated as soon as possible.

Thirty days after publication of this notice, and every January thereafter, FDA will begin to inactivate human drug listings that remain uncertified from the previous renewal period of October 1 to December 31. In addition, every July thereafter, FDA will begin to inactivate human drug listings that remain active and certified after the June listing update, but still contain at least one establishment that is not currently registered in accordance with FDA's requirements. This action taken by FDA will include listings for finished drug products, as well as for active pharmaceutical ingredients and other unfinished drugs. These listing records, including their NDCs, will be inactivated and subject to immediate removal from FDA's NDC Directory and notification of each NDC's inactivation date will be included in FDA's NSDE file. NDCs that are inactivated by FDA may be reactivated with an updated and compliant drug listing submission as soon as the next business day. If activated again, the listing will again be included in the NDC Directory and the reactivation date will be included in the NSDE file. If a drug remains in commercial distribution after it has been inactivated and removed from the NDC Directory, the drug may be deemed misbranded for failure to fulfill registration or listing obligations under section 502(o) of the FD&C Act (21 U.S.C. 352(o)), and persons marketing the drug in the United States or offering it for import into the United States may be subject to enforcement.

Manufacturers and repackagers of products subject to the new product identification requirement (see section 582(b)(2) and (e)(2) of the FD&C Act, respectively (21 U.S.C. 360eee–1(b)(2) and (e)(2))), and who have incorporated the new product identifier (serialization) into their labeling, must submit such updated labeling with listing updates (§ 207.57) and not merely certify that affected listings are up to date via ''no changes'' certifications during the registration renewal period. Such a change requires that a new and representative sample of labeling incorporating the new product identifier requirements be submitted as an update to listing (§ 207.57). Note that such an update would satisfy the annual certification requirement for the drug listing and not require an additional ''blanket no changes'' submission to maintain the listing's active status.

Firms are required by law to update their drug listings when they discontinue marketing their listed drugs (§ 207.57). To properly discontinue a listed drug, the listing record must be updated to include an accurate marketing end date that corresponds with the last lot expiration date of the drug (§ 207.57(b)(ii)). If the listing record expires without an update, certification, or discontinuance submitted, the process described above will assign an inactivation date that is different from the actual date of discontinuance and may have unintended consequences for dispensing and reimbursement. Rather than explicitly discontinuing certain listings, some firms have notified FDA that they do not intend to certify or update those listings. However, listing certification is a separate requirement and should not be treated as a mechanism to discontinue the drug listing record.

IV. Resources Available To Assist With Updating or Certifying Drug Listings

The NDC Directory (available at: *https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm*) currently identifies all active, but uncertified, listings. The online search marks uncertified listings with a ''(U)'' in red font. The online search also marks active but otherwise deficient or erroneous listing records with an ''(E)''. Listing records marked with an ''(E)'' have been identified by FDA as having an error or deficiency associated with the submission. These include, but are not limited to, records with at least one establishment that is not registered in accordance with FDA's requirements. All listing records should be reviewed for accuracy at least biannually,

regardless of whether they have been marked as deficient or not. Within the download files for the NDC Directory, uncertified listings may be identified using the LISTING CERTIFIED THROUGH DATE column. Any value that appears in this date field occurring in the past identifies a product listing that has not been certified. Erroneous or deficient listings are identified by a value of ''E'' in the EXCLUDE FLAG column.

Updates and certifications to listing information must be provided electronically in Structured Product Labeling (SPL) format. Anyone seeking information on how to update listing information may visit *www.fda.gov/edrls* or contact *edrls@fda.hhs.gov.* Additionally, FDA offers two SPL authoring tools for use in the creation and submission of SPL: Xforms and CDER Direct. Xforms is available from FDA's SPL web page at: *https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm.* CDER Direct is available at: *https://direct.fda.gov.*

Dated: August 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17436 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0520]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 13, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0339. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—21 CFR 589.2000(e)(1)(iv)

OMB Control Number 0910–0339—Extension

Section 701(a) (21 U.S.C. 371(a)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act. Our regulation at 21 CFR 589.2000 provides that animal protein derived from mammalian tissue (with some exclusions) is not generally recognized as safe (GRAS) for use in ruminant feed and is a food additive subject to certain provisions of the act (62 FR 30936, June 5, 1997).

This information collection was established because epidemiological evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. This regulation places general requirements on persons that manufacture, blend, process, and distribute products that contain, or may contain, protein derived from mammalian tissue, and feeds made from such products.

Specifically, this regulation requires renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution to maintain written procedures specifying the cleanout procedures or other means and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment. These written procedures are intended to help the firm formalize their processes, and then to help inspection personnel confirm that the firm is operating in compliance with the regulation. Inspection personnel will evaluate the written procedure and confirm it is being followed when they are conducting an inspection.

These written procedures must be maintained as long as the facility is operating in a manner that necessitates the record, and if the facility makes changes to an applicable procedure or process the record must be updated. Written procedures required by this section shall be made available for inspection and copying by FDA.

Description of Respondents: Respondents include renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution.

In the **Federal Register** of December 21, 2018 (83 FR 65681), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received in support of the collection of information.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
589.2000(e)(1)(iv); written procedures	320	1	320	14	4,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.