https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with§ 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product VIBERZI (eluxadoline). VIBERZI is indicated in adults for the treatment of irritable bowel syndrome with diarrhea. Subsequent to this approval, the USPTO received patent term restoration applications for VIBERZI (U.S. Patent Nos. 7,741,356; 8,344,011; and 8,609,709) from Janssen Pharmaceutica, N.V., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated August 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VIBERZI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for VIBERZI is 2,716 days. Of this time, 2,381 days occurred during the testing phase of the regulatory review period, while 335 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* December 21, 2007. FDA has verified the applicant's claim that December 21, 2007, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 27, 2014. The applicant claims June 26, 2014, as the date the new drug application (NDA) for VIBERZI was initially submitted. However, FDA records indicate that NDA 206940 was submitted on July 27, 2014, which is considered to be the NDA initially submitted date.

3. *The date the application was approved:* May 27, 2015. FDA has verified the applicant's claims that NDA 206940 was approved on May 27, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 428 days, 606 days, or 431 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket Nos. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02187 Filed 2–2–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0388]

Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Draft Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Hazard Analysis and Risk-

Based Preventive Controls for Food for Animals; Draft Guidance for Industry; Availability'' that appeared in the **Federal Register** of January 23, 2018. The document announced the availability of a draft guidance for industry #245 entitled ''Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.'' The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, January 23, 2018 (83 FR 3163), in FR Doc. 2018–01126, on page 3163, the following correction is made:

1. On page 3163, in the first column, in the header of the document, the docket number is corrected to read ''FDA–2018–D–0388''.

Dated: January 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02181 Filed 2–2–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2428]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug Adverse Event Reporting and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 March 7, 2018.

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 0910–0284. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Animal Drug Adverse Event Reporting and Recordkeeping—21 U.S.C. 360b(l), 21 CFR 510.301, and 514.80

OMB Control Number 0910–0284—Extension

With regard to adverse events and product/manufacturing defects associated with approved new animal drugs, section 512(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(l)) requires applicants with approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to establish and maintain records and reports of data relating to experience with uses of such drug, or with respect to animal feeds bearing or containing such drug, to facilitate a determination under section 512(e) as to whether there may be grounds for suspending or withdrawing approval of the NADA or ANADA under section 512(e) or 512(m)(4). Sections 571(e)(3) and 512(e)(2) of the FD&C Act (21 U.S.C. 360ccc(e)(3) and 360b(e)(2)) require that applicants with conditionally approved new animal drug applications (CNADAs) maintain adequate records and make reports in accordance with a regulation or order issued under section 512(l). Finally, section 512(m)(5) of the FD&C Act requires an applicant for a license to manufacture animal feeds bearing or containing new animal drugs to maintain adequate records and make reports ''as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine'' whether there may be grounds for suspending or withdrawing approval of the new animal drug under section 512(e) or a license to manufacture animal feeds bearing or containing new animal drugs under section 512(m)(4).

Section 514.80 of our regulations (21 CFR 514.80) sets forth the recordkeeping and reporting requirements for applicants and nonapplicants of approved NADAs and ANADAs. Section 510.301 of our regulations (21 CFR 510.301) sets forth the recordkeeping and reporting requirements for licensed medicated feed manufacturing facilities.

Recordkeeping and reporting requirements for applicants of approved NADAs and ANADAs. Section 514.80 requires applicants to keep records of and report to us data, studies, and other information concerning experience with new animal drugs for each approved NADA and ANADA. Following complaints from animal owners or veterinarians or following their own detection of a problem, applicants are required to submit adverse event reports and product defect reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) on Form FDA 1932. Form FDA 1932a (the voluntary reporting form) is used by veterinarians and the general public to submit adverse event reports, product defects, and lack of effectiveness complaints directly to FDA. Form FDA 2301 is used by applicants to submit the required transmittal of periodic reports (§ 514.80(b)(4)); special drug experience reports (§ 514.80(b)(5)(i)); promotional material for new animal drugs (§ 514.80(b)(5)(ii)); and distributor statements (§ 514.80(b)(5)(iii)). We review the records and reports required in § 514.80 and the voluntary reports to facilitate a determination under section 512(e) of the FD&C Act as to whether there may be grounds for suspending or withdrawing approval of the new animal drug. We have made minor editorial revisions to Form FDA 1932a to clarify how to report adverse drug events associated with compounded products using that form. Submitters are already reporting adverse drug events associated with compounded products on Form FDA 1932a. The clarifications include: the addition of a new question, ''Is this a compounded product?''; the addition of a new field to allow the submitter to provide product strength, ''Strength of Active Ingredient(s)''; modifying the title of the existing field requesting the name of manufacturer, so that it reads, ''Name of Manufacturer or Compounding Pharmacy/Compounder of Suspected Product''; and a request for contact information for the manufacturer or compounder. We estimate that the revisions will not change the average amount of time necessary to complete the form.