any report containing information which is determined to be necessary to carry out the surveys and studies provided for by the Act; and

(c) Persons not notified in writing of their filing obligation by the Bureau of Economic Analysis are not required to complete the survey.

■ 3. Add § 801.10 to read as follows:

§ 801.10 Rules and regulations for BE–12, Benchmark Survey of Foreign Direct Investment in the United States—2017.

A BE–12, Benchmark Survey of Foreign Direct Investment in the United States, will be conducted covering 2017. All legal authorities, provisions, definitions, and requirements contained in §§ 801.1 through 801.2 and §§ 801.4 through 801.6 are applicable to this survey. Specific additional rules and regulations for the BE–12 survey are given in paragraphs (a) through (e) of this section. More detailed instructions are given on the report forms and instructions.

(a) *Response required.* A response is required from persons subject to the reporting requirements of the BE–12, Benchmark Survey of Foreign Direct Investment in the United States—2017, contained in this section, whether or not they are contacted by BEA. Also, a person, or their agent, contacted by BEA about reporting in this survey, either by sending them a report form or a written inquiry, must respond in writing pursuant to this section. This may be accomplished by filing a properly completed BE–12 report (BE–12A, BE–12B, BE–12C, or BE–12 Claim for Not Filing);

(b) *Who must report.* A BE–12 report is required for each U.S. affiliate (except certain private funds as described below), that is, for each U.S. business enterprise in which a foreign person (foreign parent) owned or controlled, directly or indirectly, 10 percent or more of the voting securities in an incorporated U.S. business enterprise, or an equivalent interest in an unincorporated U.S. business enterprise, at the end of the business enterprise's fiscal year that ended in calendar year 2017. Certain private funds are exempt from reporting on the BE–12 survey. If a U.S. business meets ALL of the following 3 criteria, it is not required to file any BE–12 report except to indicate exemption from the survey if contacted by BEA: (1) The U.S. business enterprise is a private fund; (2) the private fund does not own, directly or indirectly through another business enterprise, an ''operating company''—*i.e.,* a business enterprise that is not a private fund or a holding company—in which the foreign parent owns at least 10 percent of the voting interest; AND (3) if the foreign parent owns the private fund indirectly (through one or more other U.S. business enterprises), there are no U.S. ''operating companies'' between the foreign parent and the indirectly-owned private fund.

(c) *Forms to be filed.* (1) Form BE–12A must be completed by a U.S. affiliate that was majority-owned by one or more foreign parents (for purposes of this survey, a ''majority-owned'' U.S. affiliate is one in which the combined direct and indirect ownership interest of all foreign parents of the U.S. affiliate exceeds 50 percent) if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the following three items for the U.S. affiliate (not just the foreign parent's share) was greater than $300 million (positive or negative) at the end of, or for, its fiscal year that ended in calendar year 2017:

(i) Total assets (do not net out liabilities);

(ii) Sales or gross operating revenues, excluding sales taxes; or

(iii) Net income after provision for U.S. income taxes.

(2) Form BE–12B must be completed by:

(i) A majority-owned U.S. affiliate if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the three items listed in paragraph (c)(1) of this section (not just the foreign parent's share), was greater than $60 million (positive or negative) but none of these items was greater than $300 million (positive or negative) at the end of, or for, its fiscal year that ended in calendar year 2017.

(ii) A minority-owned U.S. affiliate (for purposes of this survey, a ''minority-owned'' U.S. affiliate is one in which the combined direct and indirect ownership interest of all foreign parents of the U.S. affiliate is 50 percent or less) if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, any one of the three items listed in paragraph (c)(1) of this section (not just the foreign parent's share), was greater than $60 million (positive or negative) at the end of, or for, its fiscal year that ended in calendar year 2017.

(3) Form BE–12C must be completed by a U.S. affiliate if, on a fully consolidated basis, or, in the case of real estate investment, on an aggregated basis, none of the three items listed in paragraph (c)(1) of this section for a U.S. affiliate (not just the foreign parent's share), was greater than $60 million (positive or negative) at the end of, or for, its fiscal year that ended in calendar year 2017.

(4) BE–12 Claim for Not Filing will be provided for response by persons that are not subject to the reporting requirements of the BE–12 survey but have been contacted by BEA concerning their reporting status.

(d) *Aggregation of real estate investments.* All real estate investments of a foreign person must be aggregated for the purpose of applying the reporting criteria. A single report form must be filed to report the aggregate holdings, unless written permission has been received from BEA to do otherwise. Those holdings not aggregated must be reported separately on the same type of report that would have been required if the real estate holdings were aggregated.

(e) *Due date.* A fully completed and certified Form BE–12A, BE–12B, BE–12C, or BE–12 Claim for Not Filing is due to be filed with BEA not later than May 31, 2018 (or by June 30, 2018 for reporting companies that use BEA's eFile system).

[FR Doc. 2017–26887 Filed 12–12–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA–2017–N–6379]

Advisory Committee; Food Advisory Committee; Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the Food Advisory Committee. This document removes the Food Advisory Committee from the Agency's list of standing advisory committees.

DATES: This rule is effective December 13, 2017.

FOR FURTHER INFORMATION CONTACT: Karen Strambler, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5001 Campus Dr., Rm. 1C–008, College Park, MD 20740, 240–402–2589, Fax: 301–436–2637, *karen.strambler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Food Advisory Committee (the Committee) was established on March 6, 1992 (57 FR 8064). The Committee provides advice to the Commissioner of Food and

Drugs and other appropriate officials on emerging food and cosmetic safety, food science, nutrition, and other food-related health issues that FDA considers of primary importance for its food and cosmetics programs. The Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

The Committee is no longer needed and will be terminated on December 12, 2017. Over the past several years, the Committee has met very infrequently, and the effort and expense of maintaining the Committee are no longer justified. Any relevant food issues in the future could be addressed by FDA's Science Board and/or FDA's Risk Communication Advisory Committee, with additional augmentation of expertise by appropriate subject matter experts serving as temporary members on either of those committees. In addition, CFSAN will continue to hold workshops, meetings, conferences, and webinars to engage with its stakeholders.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary because the Committee is not being adequately used, and the final rule merely removes the name of the Food Advisory Committee from the list of standing advisory committees in § 14.100 (21 CFR 14.100).

Therefore, the Agency is amending § 14.100(f) as set forth in the regulatory text of the document.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committee, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155; Pub. L. 113–54.

§ 14.100 [Amended]

■ 2. Section 14.100 is amended by removing paragraph (f).

Dated: December 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26829 Filed 12–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, and 558

[Docket No. FDA–2017–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for a new animal drug application (NADA) and abbreviated new animal drug applications (ANADAs) during May and June 2017. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to make technical amendments to improve the accuracy of the regulations.

DATES: This rule is effective December 13, 2017.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for a NADA and ANADAs during May and June 2017, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING MAY AND JUNE 2017

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
May 23, 2017	055–099	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	CLAVAMOX (amoxicillin and clavulanate potassium tablets) Chewables.	Dogs and cats	Supplemental approval of a chewable tablet form of the approved tablet.	FOI Summary.
June 21, 2017	141–338	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	INTERCEPTOR SPECTRUM (milbemycin oxime/ praziquantel) Chewable Tablets.	Dogs	Supplemental approval for the treatment and control of adult tapeworm (*Dipylidium caninum*) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older.	FOI Summary.