Total Annual Responses: 166,140.
Total Burden Hours: 782,520.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Frequency: Variable, depending on the collection.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0107, Federal Acquisition Regulation Part 23 Requirements, in all correspondence.

Dated: October 3, 2018.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2018–22030 Filed 10–10–18; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3343]

Advisory Committee; Dermatologic and Ophthalmic Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Dermatologic and Ophthalmic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Dermatologic and Ophthalmic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until October 7, 2020.

DATES: Authority for the Dermatologic and Ophthalmic Drugs Advisory Committee will expire on October 7, 2018, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *DODAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Dermatologic and Ophthalmic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of nine voting members including two Chairpersons. Members and the Chairpersons are selected by the Commissioner or designee from among authorities knowledgeable in the fields of dermatology, ophthalmology, internal medicine, pathology, immunology, epidemiology or statistics, and other related professions. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DermatologicandOphthalmicDrugsAdvisoryCommittee/ucm094782.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**).

In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: October 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22183 Filed 10–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–N–0341; FDA–2012–N–0115; FDA–2018–N–1011; FDA–2010–N–0110; FDA–2012–N–0547; FDA–2014–N–2347; FDA–2016–D–2285; FDA–2016–D–1307; FDA–2016–D–4318; FDA–2016–N–0407; and FDA–2018–N–0270]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control number	Date approval expires
New Animal Drugs for Investigational Use	0910–0117	8/31/2021
Guidance for Industry and FDA Staff, Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle	0910–0594	8/31/2021
Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements	0910–0608	8/31/2021
Prescription Drug Advertisements	0910–0686	8/31/2021
Survey of the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types	0910–0744	8/31/2021
Permanent Discontinuation or Interruption in Manufacturing of Certain Drug and Biological Products	0910–0759	8/31/2021
Food and Cosmetic Export Certificate Applications Process	0910–0793	8/31/2021
Guidance for Industry: Medical Product Communications That are Consistent With the Food and Drug Administration Required Labeling—Questions and Answers	0910–0856	8/31/2021
Guidance for Industry: Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities Questions and Answers	0910–0857	8/31/2021
Guidance for Industry: Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities	0910–0858	8/31/2021
Drug Supply Chain Security Act Pilot Program	0910–0859	8/31/2021
Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional and Retail Food Stores and Facility Types (2015–2025)	0910–0799	9/30/2021

Dated: October 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22101 Filed 10–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3323]

Advisory Committee; Antimicrobial Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Antimicrobial Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Antimicrobial Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until October 7, 2020.

DATES: Authority for the Antimicrobial Drugs Advisory Committee will expire on October 7, 2018, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Lauren Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *AMDAC@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Antimicrobial Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Antimicrobial Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 13 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/ucm094132.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check *https://www.fda.gov/AdvisoryCommittees/default.htm*.

Dated: October 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22098 Filed 10–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the