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/CardiovascularandRenalDrugsAdvisoryCommittee/ucm094743.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: August 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19067 Filed 8–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3123]

Advisory Committee; Endocrinologic and Metabolic 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 Endocrinologic and Metabolic 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 Endocrinologic and Metabolic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until August 27, 2020.

DATES: Authority for the Endocrinologic and Metabolic Drugs Advisory Committee will expire on August 27, 2020, 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: *EMDAC@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 Endocrinologic and Metabolic 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 the Food and Drug Administration has regulatory responsibility.

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

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of endocrinology, metabolism, 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/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm100261.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: August 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19066 Filed 8–31–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3037]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quantitative Testing for the Development of FDA Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the creation of a new collection of information entitled ''Generic Clearance for Quantitative Testing for the Development of FDA Communications.''

DATES: Submit either electronic or written comments on the collection of information by November 5, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 5, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 5, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3037 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quantitative Testing for the Development of FDA Communications.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *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 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 *https://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: 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Generic Clearance for Quantitative Testing for the Development of FDA Communications

OMB Control Number 0910—New

This notice announces the FDA information collection request from OMB for a generic clearance that will allow FDA to use quantitative social/behavioral science data collection techniques (*i.e.,* surveys and experimental studies) to test consumers' reactions to FDA communications or educational messaging about FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. To ensure that communications activities and educational campaigns have the highest potential to be received, understood, and accepted by those for whom they are intended, it is important to assess communications while they are under development. Understanding consumers' attitudes, motivations, and behaviors in response to potential communications and education messaging plays an important role in improving FDA's communications.

If the following conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process:

• The collections are voluntary;

• The collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both the participants and the Federal Government;

• The collections are noncontroversial;

• Personally identifiable information (PII) is collected only to the extent necessary [1] and is not retained;

[1] For example, collections that collect PII to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All Privacy Act requirements will be met.

- Information gathered will not be used for the purpose of substantially informing influential policy decisions; [2] and
- Information gathered will yield qualitative findings; the collections will not be designed or expected to yield statistical data or used as though the results are generalizable to the population of study.

To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (*e.g.,* a copy of the survey or experimental design and stimuli for testing).

FDA will submit individual quantitative collections under this generic clearance to OMB. Individual quantitative collections will also undergo review by FDA's Research Involving Human Subjects Committee, senior leadership in the Center for Food Safety and Applied Nutrition, and PRA specialists.

Respondents to this collection of information may include a wide range of consumers and other FDA stakeholders such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN BY ANTICIPATED DATA COLLECTION METHODS [1]

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Total hours
Cognitive Interviews Screener	720	1	720	60
Cognitive Interviews	144	1	144	144
Pre-test Study Screener	2,400	1	2,400	199
Pre-testing Study	480	1	480	120
Self-administered Surveys/Experimental Studies Screener	75,000	1	75,000	6,225
Self-Administered Surveys/Experimental Studies	15,000	1	15,000	3,750
Total				10,498

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

The total estimated annual burden is 10,498 hours. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: August 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19088 Filed 8–31–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2700]

Food for Human Consumption; Export Certificates; Food and Drug Administration Food Safety Modernization Act of 2011; Certification Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fees we will assess for issuing export certificates for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use. The FDA Food Safety Modernization Act (FSMA) of 2011 authorizes us to charge fees to cover our costs associated with issuing export certificates for food. This notice provides the fee schedule for issuing these certificates and the basis for the fees. We have not previously exercised our FSMA authority to collect fees for export certificates issued for food for human consumption.

DATES: The fees described in this document for export certificates for food for human consumption, with the exception of dietary supplements, medical foods, and foods for special dietary use, will be effective October 1, 2018.

FOR FURTHER INFORMATION CONTACT: Kate Meck, International Affairs Staff, Center for Food Safety and Applied Nutrition (HFS–550), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2307, *CFSANExportCertification@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In April 1996, the ''FDA Export Reform and Enhancement Act of 1996'' (Pub. L. 104–134, amended by Pub. L. 104–180) amended sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381 and 382). As a result of the 1996 amendments, section 801(e)(4) of the FD&C Act provides that persons exporting a drug, animal drug, or device may request FDA to certify that the product meets the requirements of section 801(e)(1), section 802, or other applicable requirements of the FD&C Act. Upon a showing that the product meets the applicable requirements, the law provides that FDA shall issue export certification within 20 days of the receipt of a request for such certification. The law also authorizes us to charge up to $175 for each certification issued within the 20-day period.

In January 2011, section 801(e)(4) of the FD&C Act was further amended by FSMA (Pub. L. 111–353) to authorize FDA to issue, and charge fees for, export certificates for food. Under section 801(e)(4)(C) of the FD&C Act, an export certification can be made in such form (including a publicly available listing) as FDA determines appropriate.

This notice focuses on the fees to be assessed with respect to export certificates issued by the Center for Food Safety and Applied Nutrition (CFSAN) for food for human

[2] As defined in OMB and agency Information Quality Guidelines, ''influential'' means that ''an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.''