General advice is provided where modifications of the prescribing information for specific products are needed.

FDA previously issued draft guidance on the prescribing information for COCs in March 2004 and invited public comment. That draft guidance was withdrawn in July 2015. However, the development of the current draft guidance took into consideration public comments submitted to the 2004 draft guidance that were science-based and consistent with current PLR and PLLR labeling regulations. This draft guidance has been broadened to incorporate the more general class of CHCs.

FDA invites comments on the content of this draft guidance. In particular, FDA seeks comments on the proposed language under section 7.1 of labeling that identifies a drug interaction with all metabolic enzyme inducers. A variety of metabolic enzyme inducers have been reported to decrease the plasma concentration of the estrogen and/or progestin components of CHCs. FDA seeks comments and data regarding specific enzyme inducers or classes of inducers (*e.g.,* cytochrome p450 3A strong inducers) that interact with CHCs; in particular, comments are requested on whether the CHC labeling should include specific inducers or classes of inducers, or if it should remain broad and essentially cover all possible cytochrome p (CYP) enzyme inducers of any pathway and potency.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on labeling for CHCs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.56 and 201.57 (''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products'') are approved under OMB control number 0910–0572. The collections of information from the final rule entitled ''Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling'' are approved under OMB control number 0910–0624.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov/*.

Dated: December 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28252 Filed 12–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2347]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions associated with export certificate applications for FDA-regulated food and cosmetic products.

DATES: Submit either electronic or written comments on the collection of information by March 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 March 5, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 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–2014–N–2347 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Cosmetic Export Certificate Application Process.'' 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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, including each proposed extension of an existing 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.

Food and Cosmetic Export Certificate Application Process

OMB Control Number 0910–0793—Revision

Some countries may require manufacturers of FDA-regulated products to provide certificates for products they wish to export to that country. Accordingly, firms exporting products from the United States often ask FDA to provide such a ''certificate.'' In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States, or that they meet specific U.S. requirements. In some cases, review of an FDA export certificate may be required as part of the process to register or import a product into another country. An export certificate generally indicates that the particular product is marketed in the United States or otherwise eligible for export and that the particular manufacturer has no unresolved enforcement actions pending before, or taken by, FDA. FDA's Center for Food Safety and Applied Nutrition (CFSAN) issues export certificates for food and cosmetic products. Interested persons may request a certificate electronically via the Certificate Application Process (CAP), a component of the FDA Industry Systems, or by contacting CFSAN for assistance. To facilitate the application process we have eliminated paper-based forms. For food products, we have expanded the electronic options for providing facility and product information. Respondents will now be able to identify facilities based on a food facility registration number, FDA Establishment Identification (FEI) number, or Data Universal Numbering System (DUNS) number. The system uses these identifiers to locate and auto-populate name and address information, eliminating the need for users to manually enter this information and reducing the time to complete the application. Respondents can also upload product information via a spreadsheet, which reduces the time needed to enter product information, particularly for applications that include multiple products. All information is entered using electronic Forms FDA 3613d, 3613e, 3613g, and 3613l and used to evaluate certificate requests.

While burden associated with information collection activities for export certificates issued for other FDA-regulated products is approved under OMB control no. 0910–0498, this collection specifically supports export certificates issued by CFSAN. Also, because we have eliminated paper-based forms, respondents who require assistance with completing export certificate applications online may contact CFSAN directly by email (*CFSANExportCertification@fda.hhs.gov*) or telephone (240–402–2307). Instructions for Form FDA 3613d are available online at *https://www.fda.gov/cosmetics/internationalactivities/exporters/ucm353912.htm* and instructions for Form FDA 3613e are available online at *https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm260280.htm.* Draft screenshots of Form FDA 3613g and 3613l are available for comment online at *https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm.*

Description of Respondents: The respondents to this collection of information are firms interested in exporting U.S.-manufactured food and cosmetic products to foreign countries that require export certificates.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	FDA Form No.[2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Cosmetics	FDA 3613d	270	3	810	0.5	405
Food	FDA 3613e, 3613g, 3613l	881	5	4,405	0.5	2,203
Total						2,608

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] All forms are submitted electronically via the Certificate Application Process (CAP).

We have revised the currently approved burden estimate for the information collection to reflect the elimination of paper-based forms. Specifically, and based on our experience with the information collection, we have reduced the estimated time to prepare a submission from 1.5 hours to 0.5 hour. The previous estimate was based on the time necessary to prepare a paper submission, but all firms requesting export certificates now provide submissions electronically via CAP. We believe that the time to prepare an electronic submission is under 0.25 hour, but are estimating 0.5 hour as a conservative approach to address all scenarios. We base our estimates of the total annual responses on our experience with certificate applications received in the past 3 fiscal years.

We expect that most firms requesting export certificates in the next 3 years will choose to take advantage of the option of electronic submission via CAP. If a firm is unable to submit their information via CAP, they may contact CFSAN and request assistance. CFSAN will assist firms in entering their information into the electronic system so that the firm may receive their export certificates in a timely manner. Our burden estimates in Table 1 are based on the expectation of 100 percent participation in the electronic submission process. Providing the opportunity to submit the information in electronic format has reduced our previous estimates for the time to prepare each submission.

Dated: December 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28258 Filed 12–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroendocrinology, Neuroimmunology, Rhythms and Sleep Study Section.

Date: February 1–2, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: New Orleans Marriott, 555 Canal Street, New Orleans, LA 70130.

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *mselmanoff@csr.nih.gov*.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function A Study Section.

Date: February 1–2, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Dallas Downtown, 1015 Elm Street, Dallas, TX 75202.

Contact Person: David R. Jollie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, (301)–408–9072, *jollieda@csr.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Medical Imaging Study Section.

Date: February 1–2, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Catamaran Resort, 3999 Mission Boulevard, San Diego, CA 92109.

Contact Person: Xiang-Ning Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, 301–435–1744, *lixiang@csr.nih.gov*.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies A Study Section.

Date: February 1, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marines' Memorial Club & Hotel, 609 Sutter Street, San Francisco, CA 94102.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, *ryansj@csr.nih.gov*.

Name of Committee: Vascular and Hematology Integrated Review Group; Atherosclerosis and Inflammation of the Cardiovascular System Study Section.

Date: February 1–2, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–435–1206, *komissar@mail.nih.gov*.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Developmental Therapeutics Study Section.

Date: February 1–2, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Bayside, 4875 North Harbor Drive, San Diego, CA 92106.

Contact Person: Sharon K. Gubanich, Ph.D., Scientific Review Officer, Center for