

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES ¹—Continued

| CVM Guidance for industry #171 | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|------------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Same API/solubility approach | 10 | 10 | 10 | 20 | 200 |
| Total | | | | | 210 |

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

Dated: April 8, 2015.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2347]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Cosmetic Export Certificate Application Process

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 May 15, 2015.

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-NEW and title “Food and Cosmetic Export Certificate Application Process (21 U.S.C. 381(e)).” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road; COLE-14526, Silver Spring, MD 20993-0002 *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.

Food and Cosmetic Export Certificate Application Process (21 U.S.C. 381(e)) (OMB Control Number 0910-NEW)

Some foreign countries require manufacturers of FDA-regulated products to provide an export certificate for the products they wish to export to that country. A Certificate of Free Sale is a certificate (not pertaining to a particular production lot or export consignment) that indicates that the particular product is marketed in the United States or 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 such certificates for food, food additives, seafood, dietary supplements, and cosmetics. Interested persons may request a certificate by using the electronic CFSAN Certificate Application Process, which is part of FDA Unified Registration and Listing System, or by submitting a paper Form FDA 3613d for cosmetic products or a paper Form FDA 3613e for food products. We use the information submitted to determine whether to issue the requested certificate.

OMB has approved the submission of requests for export certificates on paper Forms FDA 3613d and FDA 3613e and, electronically, via the CFSAN Certificate Application Process under OMB control number 0910-0498. This notice announces that, to ensure the efficient review of the information collection by OMB under the PRA, we are seeking to obtain a new OMB Control Number for Forms FDA 3613d and FDA 3613e and the CFSAN Certificate Application Process to reflect that the electronic submission system for food and cosmetic export certificates is separate from the electronic submission system associated with export certificates for other FDA-regulated products approved under OMB control number 0910-0498. Upon OMB approval of this information collection request, we will adjust the burden hours associated with Forms

FDA 3613d and FDA 3613e and the CFSAN Certificate Application Process approved under OMB control number 0910-0498.

We request the following information on Form FDA 3613d and the CFSAN Certificate Application Process, as currently approved by OMB: The name of and contact information for the requester; the name of and contact information for the exporting company (if different from requester); a designation of the type of certificate requested (“general” or “product-specific”); if product-specific, a list of the exact brand names of the products; the contact person, company name and address where the requested certificate should be sent; and, the name and account number (if applicable) of the requester’s preferred carrier for delivery of the certificate. Finally, Form FDA 3613d and the CFSAN Certificate Application Process requires the requester’s signature, the name and title of the person signing the form, as well as the date signed.

We request the following information on Form FDA 3613e and the CFSAN Certificate Application Process, as currently approved by OMB: The name of and contact information for the manufacturer, as well as the manufacturer’s state license or registration number; the name of and contact information for the exporting company (if different from manufacturer), as well as the exporting company’s state license or registration number; a description of the shipment including the product, the common name, the manufacturer, and a description or additional comments; the name of the country to which the requester of the certificate intends to ship the product; the contact person, firm name and address where the requested certificate should be sent; and, the name and account number (if applicable) of the requester’s preferred carrier for delivery of the certificate. Form FDA 3613e and the CFSAN Certificate Application Process requires the requestor to submit an original or copy of the applicable product label or labels. Finally, Form FDA 3613e and the CFSAN Certificate Application Process

requires the submitter's signature, the name and title of the person signing the form, as well as the date signed.

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.

In the **Federal Register** of January 9, 2015 (80 FR 1422), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received four comments in response to the notice. The comments generally supported the necessity and practical utility of the information collected during the export certificate application process for food, however no comments were received regarding the export certificate application process for cosmetics. Our responses to the comments are discussed below.

One comment had concerns about our request for the manufacturer's (and exporter's, if different from manufacturer) state license or registration number on Form FDA 3613e, stating that doing so could allow third parties unnecessary and/or

unauthorized access to confidential commercial information. We appreciate this comment and note that we do not place the firm's state license or registration numbers on the certificates we issue. In addition, confidential commercial information is protected from disclosure under the Freedom of Information Act under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and under our regulations at 21 CFR part 20. At the same time, the state license or registration number is necessary for our review of the application. We verify the license or registration and investigate inspection data on the listed products.

One comment suggested ways we might modify the electronic submission system, including expanding the number of characters that may be entered per data field; developing corporate identification numbers and passwords, permitting a product label to be submitted electronically through the CFSAN Certificate Application Process; and, permitting a submitter to pay the application fees electronically within the CFSAN Certificate Application Process. Similarly, another comment discussed possible changes to the content of the Export Certificates or the

Certificates of Free Sale that we issue for food, including incorporating pagination to indicate the number of sequential pages that would be part of the certificate; adding statements that the product is fit for human consumption, may be freely sold or exported in the United States, and, is produced in a manner consistent with good manufacturing practice; and providing the applicant the ability to request the type of certificate referenced on the header of the document and to request additional services, such as a notarized certificate document or expedited processing. While we are not able to accommodate the suggested modifications at this time, we will consider them as we contemplate future revisions to the relevant forms and solicit additional comments at that time through a notice published in the **Federal Register**.

Finally, one comment was received that did not respond to any of the four information collection topics solicited and is therefore not addressed by the Agency.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| Category | FDA form No. ² | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|---------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|--------------|
| Cosmetics | 3613d | 600 | 1 | 600 | 1.5 | 900 |
| Conventional Food (Including Seafood) .. | 3613e | 398 | 1 | 398 | 1.5 | 597 |
| Dietary Supplements, Food for Special Dietary Use, Infant Formula, & Medical Foods | 3613e | 2,129 | 4 | 2,129 | 1.5 | 3,194 |
| Food Additives and Food Contact Substances | 3613e | 167 | 1 | 167 | 1.5 | 251 |
| Total | | | | | | 4,942 |

¹ There are no operating and maintenance costs associated with this collection of information.

² Forms FDA 3613d and FDA 3613e may be submitted electronically via the Certificate Application Process.

For the purpose of this information collection request, we are basing our estimate of the average burden per response in column 6 of table 1 on the estimates previously submitted to and approved by OMB under control number 0910-0498. Our estimate of the average burden per response in column 6 of table 1 varies according to the product category for which the certificate is requested. We base our estimates of the total annual responses in column 5 of table 1 on our experience with certificate applications received in the past 2 fiscal years. Some respondents send in requests as often as three or four times a month while others may submit only periodic requests.

We expect that most if not all firms requesting export certificates in the next 3 years will choose to take advantage of the option of electronic submission via the CFSAN Certificate Application Process. Thus, our burden estimates in table 1 are based on the expectation of 100 percent participation in the electronic submission process. The opportunity to provide the information in electronic format could reduce the Agency's previous estimates for the time to prepare each submission. However, as a conservative approach for the purpose of this analysis, we are assuming that the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission.

Dated: March 8, 2015.

Leslie Kux,
Associate Commissioner for Policy.
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