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) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 invites 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 10, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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 Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	FDA form number [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, and 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] Form FDA 3613d and Form 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: January 5, 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–2258]

Determination That TAGAMET (Cimetidine) Tablets and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6223, Silver Spring, MD 20993–0002, 301–796–5418, *Amy.Hopkins@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.