

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0543]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0575. 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 Rd., 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.

Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles—21 CFR 514.1(b)(7-8) (OMB Control Number 0910-0575)—Extension

The Center for Veterinary Medicine (CVM) issued guidance for industry (GFI) #171 entitled “Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles” to describe the procedures that the Agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

The Generic Animal Drug and Patent Term Registration Act (GADPTRA) of 1988 (Pub. L. 100-670) permitted generic animal drug manufacturers to copy those pioneer animal drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based, in part, upon a demonstration of bioequivalence between the generic product and pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies for soluble powder oral dosage form products and Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision. The requirement to establish bioequivalence through in vivo studies (blood level bioequivalence or

clinical endpoint bioequivalence) may be waived for soluble powder oral dosage form products or Type A medicated articles in either of two alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product’s formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in one of two ways: “USP definition” approach or “Dosage adjusted” approach. The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs. FDA estimates the burden for this collection of information as follows in Tables 1 and 2 of this document. The source of the above data is records of generic drug applications over the past 10 years.

In the **Federal Register** of January 12, 2015 (80 FR 1506), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, however it 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 FOR WATER SOLUBLE POWDERS ¹

CVM Guidance for industry #171	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Same formulation/manufacturing process approach	1	1	1	5	5
Same API/solubility approach	5	5	5	10	50
Total					55

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

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

CVM Guidance for industry #171	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Same formulation/manufacturing process approach	2	2	2	5	10

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