

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0747]

Agency Information Collection Activities; Proposed Collection; 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 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, 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 current burden hours on regulated industry of complying with the guidance underlying this collection of information.

DATES: Submit either electronic or written comments on the collection of information by December 23, 2011.

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: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, PI50-400B, 1350 Piccard Dr., Rockville, MD 20850, 301-796-7651, juanmanuel.vilela@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.

Agency Information Collection Activities; Proposed Collection; Comment Request; 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) and (b)(8) (OMB Control Number 0910-0575)—Extension

The Center for Veterinary Medicine has written this guidance to address a perceived need for Agency guidance in its work with the animal health industry. This guidance describes 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 of 1988 (Pub. L. 100-670) permitted generic drug manufacturers to copy those pioneer 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR WATER SOLUBLE POWDERS ¹

	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 Burden Hours					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

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Same Formulation/Manufacturing Process Approach	2	2	2	5	10
Same API/Solubility Approach	10	10	10	20	200
Total Burden Hours					210

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

Dated: October 18, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0733]

Guidance for Industry on Evaluating the Safety of Flood-Affected Food Crops for Human Consumption; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “Guidance for Industry: Evaluating the Safety of Flood-Affected Food Crops for Human Consumption.” Flooding events can present a potentially hazardous public health risk. Flood waters may have been exposed to sewage, chemicals, heavy metals, pathogenic microorganisms, or other contaminants. The growers are responsible to ensure the safety of the flood-affected food crops. The guidance is intended to provide growers information on how to evaluate the safety of flood-affected food crops for human consumption.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Plant and Dairy Food Safety,

Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Yingqing Ma, Center for Food Safety and Applied Nutrition/Office of Food Safety, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 240-402-2479.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Evaluating the Safety of Flood-affected Food Crops for Human Consumption” This guidance is being issued consistent with FDA’s good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because the guidance deals with highly time-sensitive issues and requires immediate implementation for public health reasons. Although this guidance document is immediately in effect, it remains subject to comment in

accordance with the Agency’s GGP’s regulation.

The guidance is intended to provide growers information on how to evaluate the safety of flood-affected food crops for human consumption. The recommendations in this guidance are consistent with existing FDA’s positions on the safety of flood-affected food crops. This guidance reiterates FDA’s positions and includes additional information to help growers assess the safety of food from flood-affected crops for human consumption. Specifically, the guidance addresses: (1) Safety of food crops when flood waters contacted the edible portions of the crops, (2) safety of food crops when flood waters did not contact the edible portions of the crops, (3) assessment of flood-affected fields before replanting, and (4) additional controls to avoid cross-contamination after flooding.

The guidance represents the Agency’s current thinking on the safety of flood-affected food crops for human consumption. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received