

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

comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

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-0722]

Draft Guidance for Industry: Implementation of Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Implementation of Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components" dated October 2011. The draft guidance document recognizes the abbreviated donor history questionnaire and accompanying materials (aDHQ documents), version 1.3 dated August 2011, as an acceptable mechanism for collecting blood donor history information from frequent donors of blood and blood components that is consistent with FDA's requirements and recommendations for collecting donor history information. The aDHQ documents will provide blood establishments that collect blood and blood components with a specific process for administering questions to frequent donors of blood and blood components to determine their eligibility to donate.

DATES: Although you can comment on any guidance at any time (see 21 CFR

10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 23, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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: Tami Belouin, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Implementation of Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components" dated October 2011. The draft guidance document recognizes the aDHQ documents, version 1.3 dated August 2011, prepared by the AABB Donor History Task Force, as an acceptable mechanism for collecting blood donor history information from frequent donors of blood and blood components that is consistent with FDA's requirements and recommendations. The aDHQ documents will provide blood establishments that collect blood and blood components with a specific process for administering questions to frequent donors of blood and blood components to determine their eligibility to donate. The guidance also advises licensed manufacturers who choose to implement the acceptable aDHQ documents on how to report the manufacturing change consisting of the

implementation of the aDHQ documents under 21 CFR 601.12.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 601.12 have been approved under OMB Control No. 0910-0338; the collections of information in 21 CFR 606.171 have been approved under OMB Control No. 0910-0458; and the collections of information in 21 CFR 640.3 have been approved under OMB Control No. 0910-0116.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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