

Dated: May 9, 2012.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0438]

Agency Information Collection Activities; Proposed Collection; Comment Request; Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

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 information collection provisions of FDA's procedures for early food safety evaluation of new non-pesticidal proteins produced by new plant varieties intended for food use, including bioengineered food plants; new Form FDA 3666, which may be submitted electronically via the Electronic Submission Gateway (ESG); and the guidance document entitled, "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use."

DATES: Submit either electronic or written comments on the collection of information by July 16, 2012.

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:

Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, 301-796-5733, domini.bean@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.

Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (OMB Control Number 0910-0583)—Revision

I. Background

Since May 29, 1992, when FDA issued a policy statement on foods derived from new plant varieties, FDA has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA early in the development process to discuss possible scientific and regulatory issues that might arise (57 FR 22984). The guidance entitled, "Recommendations for the

Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use," continues to foster early communication by encouraging developers to submit to FDA their evaluation of the food safety of their new protein. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of material from that plant variety.

FDA believes that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. The guidance describes the procedures for early food safety evaluation of new proteins in new plant varieties, including bioengineered food plants, and the procedures for communicating with FDA about the safety evaluation.

FDA has recently developed a form that interested persons may use to transmit their submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition. New Form FDA 3666, a draft of which is available at <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/RegulatorySubmissions/UCM199325.pdf>, is entitled, "Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation)" and may be used in lieu of a cover letter for a New Protein Consultation (NPC). Form FDA 3666 prompts a submitter to include certain elements of a NPC in a standard format and helps the respondent organize their submission to focus on the information needed for FDA's safety review. The form, and elements that would be prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway (ESG), or may be submitted in paper format, or as electronic files on physical media with paper signature page. The information is used by FDA to evaluate the food safety of a specific new protein produced by a new plant variety.

II. NPC Information Submitted on Form FDA 3666

The NPC submitted to FDA includes the following information on Form FDA 3666 and in attachments to the form:

A. Introductory Information About the Submission

- Whether the NPC submission is a new submission, or an amendment or supplement to a previously established NPC;
- Whether the submitter has determined that all files provided in an electronic transmission are free of computer viruses;
- The date of the submitter’s most recent meeting (if any) with FDA before transmitting a new NPC submission; and
- The date of any correspondence, sent to the submitter by FDA, relevant to an amendment or supplement the submitter is transmitting.

B. Information About the Submitter

- The name of and contact information for the submitter, including the identity of the contact person and the company name (if applicable); and
- The name of and contact information for any agent or attorney who is authorized to act on behalf of the submitter.

C. General Administrative Information

- The title of the submission;
- The format of the submission (i.e., paper, electronic, or electronic with a paper signature page);
- The mode of transmission of any electronic submission (i.e., ESG or transmission on physical media such as CD-ROM or DVD);
- Whether the submitter is referring us to information already in our files;
- Whether the submitter has designated in its submission any information as trade secret or as confidential commercial or financial information; and
- Whether the submitter has attached a redacted copy of some or all of the submission.

D. Information About the New Protein

- The name of the new protein;
- Any requested registry designations for the new protein; and
- The purpose or intended technical effect of the new protein.

E. Information About Genetic Material

- Information about the introduced genetic material (including identity and source).

F. The Scientific Evaluation of the Food Safety of the New Protein

The submitter indicates:

- Whether there is a history of safe use of the new protein in food or feed;
- Whether the submitter has included an assessment of the amino acid similarity between the new protein and known allergens and toxins;
- Whether the submitter has included information about the overall stability of the protein, and the resistance of the protein to enzymatic degradation using appropriate *in vitro* assays; and
- Whether the submitter has included any other information for FDA to consider in evaluating a NPC.

Form FDA 3666 also requires the signature of a responsible official (or agent or attorney) and a list of attachments.

III. Burden Estimates

Description of Respondents: The respondents to this collection of information are developers of new plant varieties intended for food use.

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
First four data components	Form FDA 3666	20	1	20	4	80
Two other data components	Form FDA 3666	20	1	20	16	320
Total						400

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

² Form FDA 3666 may be submitted electronically via the ESG.

The estimated number of annual responses and average burden per response are based on FDA’s experience with early food safety evaluations submitted in the past 3 years. Completing an early food safety evaluation for a new protein from a new plant variety is a one-time burden (one evaluation per new protein). Based on its experience over the past 3 years, FDA estimates that approximately 20 developers will choose to complete an early food safety evaluation for their new plant protein, for a total of 20 responses annually. Many developers of novel plants may choose not to submit an evaluation because the field testing of a plant containing a new protein is conducted in such a way (e.g., on such a small scale, or in such isolated conditions, etc.) that cross-pollination with traditional crops or commingling of plant material is not likely to be an issue. Also, other developers may have

previously communicated with FDA about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop. The early food safety evaluation for new proteins includes six main data components. Four of these data components are easily and quickly obtainable, having to do with the identity and source of the protein. FDA estimates that completing these data components will take about 4 hours per NPC. FDA estimates the reporting burden for the first four data components to be 80 hours (4 hours × 20 responses). Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis which can be performed using publicly available databases. The other data component involves “wet” lab work to assess the new protein’s

stability and the resistance of the protein to enzymatic degradation using appropriate *in vitro* assays (protein digestibility study). The paperwork burden of these two data components consists of the time it takes the company to assemble the information on these two data components and include it in a NPC. FDA estimates that completing these data components will take about 16 hours per NPC. FDA estimates the reporting burden for the two other data components to be 320 hours (16 hours × 20 responses). Thus, FDA estimates the total annual hour burden for this collection of information to be 400 hours. FDA expects that most if not all businesses filing NPCs in the next 3 years will choose to take advantage of the option of electronic submission via the ESG. Thus, the burden estimates in Table 1 are based on the expectation of one hundred percent (100%)

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, FDA is assuming that the availability of new Form FDA 3666 and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission. While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from \$20 to \$30.

Dated: May 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0454]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

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 guidance solicits comments on "Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and

Nonprescription Drug Consumer Protection Act."

DATES: Submit either electronic or written comments on the collection of information by July 16, 2012.

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, 1350 Piccard Dr., PI50-400B, 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.

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Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act—(OMB Control Number 0910-0640)—Extension

On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application.

Section 502(x) of the FD&C Act (21 U.S.C. 352(x)), which was added by Public Law 109-462, requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a responsible person may receive a report of a serious adverse event associated with the product. The guidance document contains questions and answers relating to this labeling requirement and provides guidance to industry on the following topics: (1) The meaning of "domestic address" for purposes of the labeling requirements of section 502(x) of the FD&C Act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or phone number that is required to appear on the product label under section 502(x) of the FD&C Act; and (3) FDA's intent regarding enforcing the labeling requirements of section 502(x) of the FD&C Act. Separate guidance, issued by the Center for Food Safety and Applied Nutrition on reporting for dietary supplements, is announced elsewhere in the **Federal Register**.

Title: Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (pursuant to section 502(b)(1) of the FD&C Act) appears on the label of a nonprescription drug product marketed in the United States without an approved application.