Burden Estimate: The table below provides an estimate of the annual reporting burden for notification of a product discontinuance and certification of good cause under §§ 314.81(b)(3)(iii) and 314.91, as amended by the interim final rule.

Notification of Discontinuance: Based on data collected from the CDER Drug Shortage Coordinator since December 17, 2007, when §§ 314.81(b)(3)(iii) and 314.91 went into effect, one manufacturer during each year reported to FDA a discontinuance of one drug product meeting the criteria of section 506C and its implementing regulations (i.e., the drug product was approved under section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act, the drug product was ''life-supporting, life-sustaining or intended for use in the prevention of a debilitating disease or condition,'' the drug product was produced by a sole manufacturer, and the drug product was permanently discontinued). CDER's Drug Shortages Coordinator tracked 220 drug shortages between January and October of 2011. The Agency estimates that 30 percent (66) of these shortages would relate to discontinuances subject to mandatory reporting under section 506C as a result of the interim final rule. Adjusting to include an additional two months of reporting (November and December), we estimate that FDA will receive a total of 80 notifications of a discontinuance per year under section 506C, as amended by the interim final rule. Based on experience, a manufacturer submits only one notification of a discontinuance per year, thus the total number of manufacturers who would be required to notify us of a discontinuance would be 80. Therefore, the number of respondents is estimated to be 80. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a notification of product discontinuance, including the time it takes to gather and copy the statement. Based on experience in working with manufacturers to submit notifications under § 314.81(b)(3)(iii), we estimate that approximately 2 hours on average are needed per response. We do not expect the changes in the interim final rule to affect the number of hours per response. Therefore, we estimate that respondents will spend 160 hours per year notifying us of a product discontinuance under these regulations.

Certification of Good Cause: Based on data collected from the CDER drug shortage coordinator since 2007, one manufacturer each year reported a discontinuance of one drug product under section 506C and its implementing regulations. Each manufacturer has the opportunity under § 314.91 to request a reduction in the 6-month notification period by certifying to us that good cause exists for the reduction. The Agency has received no certifications of good cause since 2007. Although we expect we will receive an increase in the number of reports of discontinuances as a result of the changes in the interim final rule, because of the limited circumstances under which good cause can be requested or would be appropriately granted, we do not expect a correspondingly large increase in the number of manufacturers requesting a certification of good cause. We estimate that only 5 manufacturers will request a certification of good cause each year. Therefore, the number of respondents is estimated to be 5. The total annual responses are the total number of certifications of good cause that are expected to be submitted to us in a year. We estimate that the total annual responses will remain small, averaging one response per respondent. The hours per response is the estimated number of hours that a respondent spends preparing the detailed information certifying that good cause exists for a reduction in the notification period, including the time it takes to gather and copy the documents. We estimate that approximately 16 hours on average are needed per response. Therefore, we estimate that 80 hours will be spent per year by respondents certifying that good cause exists for a reduction in the 6-month notification period under § 314.91.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification of Discontinuance (314.81(b)(3)(iii)	80	1	80	2	160
Certification of Good Cause (314.91)	5	1	5	16	80
Total					240

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

Dated: July 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18771 Filed 7–31–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0776]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Reclassification Petitions for Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On March 29, 2012, the Agency submitted a proposed collection of information entitled ''Reclassification Petitions for Medical Devices'' to OMB for review

and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0138. The approval expires on June 30, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18772 Filed 7–31–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0438]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 August 31, 2012.

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 0910–0583. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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