4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0073]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

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 [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

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 0910-0704. 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.

Guidance on Consultation Procedures: Foods Derived From New Plant Varieties--(OMB Control No. 0910-0704)--(Extension)

Since 1992, when FDA issued its "Statement of Policy: Foods Derived from New Plant Varieties" (the 1992 policy) (57 FR 22984, May 29, 1992), FDA has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA during the plant development process to discuss possible scientific and regulatory issues that might arise. In the 1992 policy, FDA explained that, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), developers of new foods (in this document food refers to both human food and animal feed) have a responsibility to ensure that the foods they offer to consumers are safe and are in compliance with all requirements of the FD&C Act (57 FR 22984 at 22985).

FDA recommends that producers who use biotechnology in the manufacture or development of foods and food ingredients work cooperatively with FDA to ensure that products derived through biotechnology are safe and comply with all applicable legal requirements, and has instituted a voluntary consultation process with industry. To facilitate this process the Agency has issued a guidance entitled, “Guidance on Consultation Procedures: Foods From New Plant Varieties,” which is available on FDA’s website at http://www.fda.gov/FoodGuidances. The guidance describes FDA’s consultation process for the evaluation of information on new plant varieties provided by developers. The Agency believes this consultation process will help ensure that human food and animal feed safety issues or other regulatory issues (e.g. labeling) are resolved prior to commercial distribution. Additionally, such

communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development, and will help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the standards of the FD&C Act.

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

In the Federal Register of December 11, 2014 (79 FR 73590), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, it was not responsive to the information collection topics solicited in the notice and is not, therefore, addressed in this document.

FDA estimates the burden of this collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	FDA Form No.	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial consultation	None	20	2	40	4	160
Final consultation	FDA 3665	12	1	12	150	1,800
Total						1,960

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

Initial Consultations

Initial consultations are generally a one-time burden, although a developer might return more than once to discuss additional issues before submitting a final consultation. As noted in the guidance, FDA encourages developers to consult early in the development phase of their products, and as often as necessary. Historically, firms developing a new bioengineered plant variety intended for food use have generally initiated consultation with FDA early in the process of developing such a variety, even though there is no legal obligation for such consultation. These consultations have served to make FDA aware of foods and food ingredients before these

products are distributed commercially, and have provided FDA with the information necessary to address any potential questions regarding the safety, labeling, or regulatory status of the food or food ingredient. As such, these consultations have provided assistance to both industry and the Agency in exercising their mutual responsibilities under the FD&C Act.

FDA estimates that its Center for Veterinary Medicine and its Center for Food Safety and Applied Nutrition jointly received an average of 40 initial consultations per year in the last 3 years via telephone, email, or written letter. Based on this information, we expect to receive no more than 40 annually in the next 3 years.

Final Consultations

Final consultations are a one-time burden. At some stage in the process of research and development, a developer will have accumulated the information that the developer believes is adequate to ensure that food derived from the new plant variety is safe and that it demonstrates compliance with the relevant provisions of the FD&C Act. The developer will then be in a position to conclude any ongoing consultation with FDA. The developer submits to FDA a summary of the safety and nutritional assessment that has been conducted about the bioengineered food that is intended to be introduced into commercial distribution. FDA evaluates the submission to ensure that all potential safety and regulatory questions have been addressed. FDA has developed a form that prompts a developer to include certain elements in the final consultation in a standard format: Form FDA 3665, entitled, "Final Consultation for Food Derived From a New Plant Variety (Biotechnology Final Consultation)." The form, and elements that would be prepared as attachments to the form, can be submitted in electronic format.

Upon implementation of the collection, FDA contacted five firms that had made one or more biotechnology consultation submissions. We asked each of these firms for an estimate of the hourly burden to prepare a submission under the voluntary biotechnology consultation process. Based on information provided by the three firms who responded, we estimate the average time to prepare a submission for final consultation to be 150 hours.

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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