James Seligman, Co-Chair
Irma Arispe
Janet Collins
Hazel Dean
Joseph Henderson
Christine Kosmos
Alan Kotch
Jennifer Parker
Judith Qualters
Kalwant Smagh

Dated: September 24, 2015.

Veronica Kennedy,

Acting Director, Division of the Executive Secretariat, Office of the Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2015–24650 Filed 9–28–15; 8:45 am]

BILLING CODE 4163–18–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 October 29, 2015.

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: 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.

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

Since May 29, 1992, when we issued a policy statement on foods derived from new plant varieties, we have encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with us 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 us 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 the new protein.

We believe 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 produced by new plant varieties, including bioengineered food plants, and the procedures for communicating with us about the safety evaluation.

Interested persons may use Form FDA 3666 to transmit their submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition. Form FDA 3666 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 our 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, or may be submitted in paper format, or as electronic files on physical media with paper signature page. The information is used by us to evaluate the food safety of a specific new protein produced by a new plant variety.

In the **Federal Register** of June 19, 2015 (80 FR 35370), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Category	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
First four data components	3666	6	1	6	4	24
Two other data components	3666	6	1	6	16	96
Total						120

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

The estimated number of annual responses and average burden per response are based on our experience with early food safety evaluations. 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). 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 us about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop.

For purposes of this extension request, we are re-evaluating our estimate of the annual number of responses that we expect to receive in the next 3 years. We received 12 NPCs during the 5-year period from 2005 through 2009, for an average of 2.4 NPCs per year. However, during the last extension period, we saw a decrease in the number of NPCs submitted by developers, with no NPCs submitted in 2010 through 2014. More recently, we received four NPCs in the first 4 months of 2015. Based on an approximate average from the years 2005 through 2009, and our experience in 2015, we are revising our estimate of the annual number of NPCs submitted by developers to be six or fewer.

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. We estimate that completing these data components will take about 4 hours per NPC. We estimate the reporting burden for the first four data components to be 24 hours (4 hours × 6 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. We estimate that completing these data components will take about 16 hours per NPC. We estimate the reporting burden for the two other data components to be 96 hours (16 hours × 6 responses). Thus, we estimate the total annual hour burden for this collection of information to be 120 hours.

Dated: September 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24620 Filed 9–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–M–2375, FDA–2015–M–0909, FDA–2015–M–0199, FDA–2015–M–0200, FDA–2015–M–0201, FDA–2015–M–0228, FDA–2015–M–0266, FDA–2015–M–0267, FDA–2015–M–0431, FDA–2015–M–0502, FDA–2015–M–0690, FDA–2015–M–0738, FDA–2015–M–0910]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Melissa Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–5576.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2015, through March 31, 2015. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2015, THROUGH MARCH 31, 2015

PMA No., Docket No.	Applicant	Trade name	Approval date
P980040/S049, FDA–2014–M–2375	Abbott Medical Optics, Inc.	TECNIS® multifocal 1-piece intraocular lens.	12/17/2014
P140010, FDA–2015–M–0199	Medtronic, Inc.	IN.PACT™ Admiral™ Paclitaxel-coated Percutaneous Transluminal Angioplasty Balloon Catheter.	12/30/2014
P130019, FDA–2015–M–0201	EnteroMedics, Inc.	Maestro® Rechargeable System	1/14/2015
P130025, FDA–2015–M–0200	Koning Corp.	Koning Breast CT (Model CBCT 1000)	1/14/2015
P060001/S020, FDA–2015–M–0228	ev3, Inc.	Protégé™ GPS Self-Expanding Peripheral Stent System.	1/21/2015
H140001, FDA–2015–M–0267	ABIOMED, Inc.	Impella RP System	1/23/2015