believe that these plant-based products are nutritionally equivalent to their dairy counterparts and can replace them as a food choice? Are expectations of nutritional equivalency a factor in parents' and caregivers' decisions to purchase these plant-based products as part of young children's or other family members' balanced diet? Please provide any data or evidence to support your answer.

3. Do these plant-based products vary in nutrient composition, even when manufactured using the same type of plant ingredients (*e.g.,* soy or almond)? If so, how? What are consumers' expectations regarding the nutrient compositions of different brands of each subclass (*e.g.,* soy or almond) of plant-based products? What impact, if any, does the compositional variation have on purchase and consumption decisions? Please provide any data or evidence to support your answer.

4. We are aware that the United States Department of Agriculture's National Nutrient Database for Standard Reference (USDA Nutrient Database) provides information about the nutritional content of dairy foods as well as some plant-based products that resemble dairy foods (Ref. 2). However, we believe the USDA Nutrient Database may not be a full representation of all the varieties of dairy foods, including milk, cultured milk, yogurt, cheese, and of the plant-based products manufactured to resemble these dairy foods, currently in the United States marketplace. We are interested in any data regarding the nutritional profiles of different dairy foods, such as, for example, milk, modified milk, cultured milk, yogurt, and cheese products, and any data regarding the nutritional profiles of the various plant-based products that resemble dairy foods, including fortified versions of those plant-based products. We are particularly interested in obtaining data that compares the amounts of protein, calcium, vitamin D, and potassium in these plant-based products and their dairy counterparts.

5. How do the protein qualities of plant-based products compare to their dairy counterparts? How does the variation, if any, impact consumer perception, and purchasing and consumption decisions? Please provide any data or evidence to support your answer.

E. The Role of Plant-Based Products and Dairy Foods in Meeting the Recommendations in the Dietary Guidelines

The Dietary Guidelines contain nutritional and dietary information and guidelines for the public. The Dietary Guidelines are based on the preponderance of current scientific and medical knowledge and are intended to help individuals ages 2 years and older consume a healthy, nutritionally adequate diet. As part of these recommendations, the Dietary Guidelines refer to several ''food groups,'' including a ''dairy group,'' which includes fortified soy beverages. [*Note:* Although the Dietary Guidelines refer to a ''dairy group,'' as indicated in section I.A., by ''dairy foods,'' FDA is referring to foods such as milk, cheese, and yogurt, and not to their plant-based counterparts.]

The Dietary Guidelines state that healthy eating patterns in the dairy group include fat-free and low-fat (1 percent) dairy, including milk, yogurt, cheese, or fortified soy beverages (see Ref. 1 at page 23). The Dietary Guidelines explain that soy beverages fortified with calcium, vitamin A, and vitamin D, are included as part of the dairy group because they are similar to fortified low- and non-fat milk based on nutrient composition and in their use in meals. The Dietary Guidelines also state that other plant-based beverages sold as ''milks'' (such as almond, rice, coconut, and hemp ''milks'') are not included as part of the dairy group because their overall nutritional content is not similar to that of milk and fortified soy beverages (id.).

According to the Dietary Guidelines, the key nutrient contributions in the dairy group include calcium, phosphorus, vitamin A, vitamin D (in products fortified with vitamin D), riboflavin, vitamin B12, protein, potassium, zinc, choline, magnesium, and selenium (id.).

1. Do consumers understand that certain plant-based products might have a nutritional content that is not adequate to place them in the dairy group as described in the Dietary Guidelines? How does this influence their purchasing behavior with respect to plant-based products and dairy foods? Please provide any data or evidence to support your answer.

2. Do consumers who purchase or consume plant-based products instead of dairy foods, such as yogurt or cheese, believe that these plant-based products meet the dairy group recommendation described in the Dietary Guidelines? Please provide any data or evidence to support your answer.

III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture. ''Dietary Guidelines for Americans, 2015–2020.'' Eighth Edition. December 2015. Accessed online at *https://health.gov/dietaryguidelines/2015/guidelines/.*

2. U.S. Department of Agriculture. National Nutrient Database for Standard Reference (Release 23), Food items with NDB Numbers: 01077, 01079, 01082, 01085, 16222, 16229, 16230, 14091, and 14639 accessed online at *http://www.nal.usda.gov/fnic/foodcomp/search* on August 1, 2018.

Dated: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21200 Filed 9–27–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–N–0073; FDA–2018–N–0074; FDA–2010–N–0155; FDA–2014–N–0987; FDA–2016–D–1164; FDA–2014–N–2029; FDA–2012–N–0369; FDA–2017–N–6730; FDA–2009–N–0025; FDA–2014–N–2294; and FDA–2018–N–1129]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for

each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Irradiation in the Production, Processing, and Handling of Food	0910–0186	7/31/2021
State Enforcement Notifications	0910–0275	7/31/2021
Veterinary Feed Directive	0910–0363	7/31/2021
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications	0910–0796	7/31/2021
Quality Facility Attestation	0910–0854	7/31/2021
Administrative Practices and Procedures; Formal Evidentiary Public Hearing	0910–0191	8/31/2021
Regulations Under the Federal Import Milk Act	0910–0212	8/31/2021
Medical Device Reporting	0910–0437	8/31/2021
Animal Food Labeling; Declaration of Certifiable Color Additives	0910–0721	8/31/2021
Evaluation of the Food and Drug Administration's Fresh Empire Multicultural Youth Tobacco Prevention Campaign	0910–0788	8/31/2021
National Agriculture and Food Defense Strategy Survey	0910–0855	8/31/2021

Dated: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21209 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–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 or we) 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, 2018.

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 Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 FDA issued a policy statement on foods derived from new plant varieties, including those varieties that are developed through biotechnology, we have encouraged developers of new plant varieties 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,'' (available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm096156.htm*) 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 recommended 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),'' (*https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM350010.pdf*) 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 an 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