

Recommendations.” This draft guidance is intended to convey to drug manufacturers FDA’s recommendations on how certain drug products should be labeled regarding gluten, a matter of interest to individuals with celiac disease. Some individuals with celiac disease have faced difficulty when trying to determine whether specific drug products contain gluten. Confronted by uncertainty, some patients may forego important medication rather than risk an adverse reaction to gluten. Thus, even if gluten is not present at levels that would harm a typical individual with celiac disease, that individual may be harmed through uncertainty and lack of information.

Celiac disease is an immune-based reaction to dietary gluten that primarily affects the small intestine in susceptible individuals; unmanaged celiac disease can lead to serious health complications. Approximately 1 percent of the U.S. population has celiac disease (Binder, 2015, “Disorders of Absorption,” in *Harrison’s Principles of Internal Medicine*, 19th ed.). It is characterized by ongoing inflammation of part of the lining of the small intestine that generally heals if foods containing gluten are excluded from the diet and returns if they are reintroduced. This guidance encourages drug manufacturers to have accurate information about their products’ gluten content available so they can respond to questions from consumers and health care professionals. Manufacturers should pay attention to possible sources of gluten in their products, consider specifications when appropriate, and consider the impact of changes in ingredient sources or formulations on gluten content.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Gluten in Drug Products and Associated Labeling Recommendations. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information discussed in

the draft guidance have been approved by OMB under the following control numbers:

OMB control number 0910–0001: Submitting to FDA labeling in NDAs and ANDAs, including amendments to pending NDAs and ANDAs, supplements to approved NDAs and ANDAs, and annual reports; OMB control number 0910–0572: Designing, testing, and revising prescription drug product labeling; OMB control number 0910–0340: Designing, testing, and revising Drug Facts labeling for OTC drugs, including submitting labeling to FDA for OTC monograph drugs; OMB control number 0910–0139: Recordkeeping requirements in CGMPs; OMB control number 0910–0393: Preparing and revising Medication Guides; and OMB control number 0910–0338: Submitting to FDA labeling in BLAs, including amendments to pending BLAs, supplements to approved BLAs, and annual reports.

The recommended labeling statement in this draft guidance, “Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)” is information provided by FDA to applicants and manufacturers for disclosure to the public and therefore does not constitute a collection of information under 5 CFR 1320.3(c)(2).

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: December 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6455]

Agency Information Collection Activities; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 consultation procedures for foods derived from new plant varieties, including the information collection provisions in the guidance entitled, “Guidance on Consultation Procedures: Foods Derived From New Plant Varieties,” and in Form FDA 3665 entitled, “Final Consultation For Food Derived From a New Plant Variety (Biotechnology Final Consultation),” which developers may use to prepare the final consultation in a standard format.

DATES: Submit either electronic or written comments on the collection of information by February 12, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 12, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of February 12, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-N-6455 for “Guidance on Consultation Procedures: Foods Derived from New Plant Varieties.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila 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: 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.

Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

OMB Control Number 0910-0704—Extension

This information collection supports the above captioned Agency guidance document. 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 Derived From New Plant Varieties,” which is available on our website at <https://www.fda.gov/Food/Guidances>. 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 Federal Food, Drug, and Cosmetic Act (the FD&C Act).

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 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 in compliance with all requirements of the FD&C Act (57 FR 22984 at 22985).

Description of Respondents: Respondents to this collection of information include 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

Activity	FDA Form No.	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial consultation	None	20	2	40	4	160
Final consultation	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.

We have retained the currently approved burden estimate for this information collection and discuss the information collection activities below.

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.

We base our estimate of the average time to prepare a submission on informal contact with firms that made one or more biotechnology consultation submission under the voluntary biotechnology consultation process. As such, we estimate the average time to prepare a submission for final consultation to be 150 hours.

Dated: December 5, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0345]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Drug Product Communications as Used by the Food and Drug Administration

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 January 12, 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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0695. 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, 301-796-7729, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed