needed. In addition to this statutorily required annual notice, FDA intends to publish a **Federal Register** notice within the next few months to allow for public comment on the initial recognition of susceptibility test interpretive criteria.

Dated: December 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26790 Filed 12–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6352]

Gluten in Drug Products and Associated Labeling Recommendations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Gluten in Drug Products and Associated Labeling Recommendations.'' This draft guidance is intended to convey to drug manufacturers FDA's recommendations on how certain oral drug products should be labeled regarding gluten, a matter of interest to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. This draft guidance encourages drug manufacturers to have accurate information about their products' gluten content available so they can respond to questions from consumers and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.

DATES: Submit either electronic or written comments on the draft guidance by February 12, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–D–6352 for ''Gluten in Drug Products and Associated Labeling Recommendations.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Marci Kiester, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2258, Silver Spring, MD 20993–0002, 301–796–0600; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Gluten in Drug Products and Associated Labeling

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.

[FR Doc. 2017–26828 Filed 12–12–17; 8:45 am]

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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