DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0715]

Acrylamide in Foods; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''Acrylamide in Foods.'' The guidance finalizes the ''Draft Guidance for Industry on Acrylamide in Foods,'' modified where appropriate in response to comments we received on the draft guidance dated November 2013. This guidance is intended to provide information that may help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods, which may mitigate potential human health risks from exposure to acrylamide.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2013–D–0715] for the guidance document. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to The Division of Plant Products and Beverages, Office of Food Safety, Center for Food Safety and Applied Nutrition, HFS–317, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Eileen Abt, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1529.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Guidance for Industry: Acrylamide in Foods.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of November 15, 2013, (78 FR 68852), we made available a draft guidance for Industry entitled ''Draft Guidance for Industry on Acrylamide in Foods'' and provided an opportunity for comment prior to our work on the final version of the guidance. The final guidance has been modified in response to comments. The guidance announced in this notice finalizes the draft guidance dated November 2013.

This guidance is intended to provide information that may help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods. Acrylamide is a chemical that can form in some foods during certain types of high-temperature cooking. Acrylamide is a concern because it can cause cancer in laboratory animals at high doses, and is reasonably anticipated to be a human carcinogen. Reducing acrylamide levels in foods may mitigate potential human health risks from exposure to

acrylamide. The guidance is intended to suggest a range of possible approaches to reducing acrylamide levels and not to identify specific recommended approaches.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: March 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05490 Filed 3–10–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0268]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Individual Patient Expanded Access Applications: Form FDA 3926

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 April 11, 2016.

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–New and title ''Individual Patient Expanded Access Applications: Form FDA 3926.'' 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 for Industry on Individual Patient Expanded Access Applications: Form FDA 3926—OMB Control Number 0910—NEW

I. Background

In the **Federal Register** of February 10, 2015 (80 FR 7318), FDA announced the availability of a draft guidance for industry entitled ''Individual Patient Expanded Access Applications: Form FDA 3926.'' In the draft guidance, FDA provided draft Form FDA 3926 (Individual Patient Expanded Access—Investigational New Drug Application (IND)) at Appendix 1 and described this draft form, which FDA stated it intended to make available for licensed physicians to use for expanded access requests for individual patient INDs as an alternative to Form FDA 1571 (Investigational New Drug Application (IND)).

As described in the final guidance, Form FDA 3926 provides a streamlined means to request expanded access to an investigational drug outside of a clinical investigation, or to an approved drug where availability is limited by a risk evaluation and mitigation strategy (REMS), for an individual patient who has a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition. Form FDA 3926 may also be used for certain followup submissions to an individual patient expanded access IND.

FDA may permit expanded access to an investigational new drug outside of a clinical investigation, or to an approved drug where availability is limited by a REMS, for an individual patient when the applicable criteria in § 312.305(a) (21 CFR 312.305(a)) (which apply to all types of expanded access) and the criteria in § 312.310(a) (21 CFR 312.310(a)) (which apply specifically to individual patient expanded access, including for emergency use) are met. The physician may satisfy some of the submission requirements by referring to information in an existing IND, ordinarily the one held by the investigational drug's manufacturer, if the physician obtains permission from that IND holder. If permission is obtained, the physician should then provide to FDA a letter of authorization (LOA) from the existing IND holder that permits FDA to reference that IND.

Section 312.305(b) sets forth the submission requirements for all types of expanded access requests. One of the requirements under § 312.305(b)(2) is that a ''cover sheet'' must be included ''meeting the requirements of § 312.23(a).'' This provision applies to several types of submissions under 21 CFR part 312, ranging from commercial INDs under § 312.23 that involve large groups of patients enrolled in clinical trials to requests from physicians to use an investigational drug for an individual patient. Form FDA 1571 is currently used by sponsors for all types of IND submissions to meet the requirements in § 312.23(a). FDA intends to accept submission of a completed Form FDA 3926 to comply with the IND submission requirements in §§ 312.23, 312.305(b), and 312.310(b). FDA intends to consider a completed Form FDA 3926 with the box in Field 10 checked and the form signed by the physician to be a request in accordance with § 312.10 for a waiver of any additional requirements in part 312 for an IND submission, including additional information currently provided in Form FDA 1571 and Form FDA 1572 (Statement of Investigator, which provides the identity and qualifications of the investigator conducting the clinical investigation).

Under § 312.310(d), in an emergency situation that requires the patient to be treated before a written submission can be made, the request to use the investigational drug for individual patient expanded access may be made by telephone (or other rapid means of communication) to the appropriate FDA review division. Authorization of the emergency use may be given by an FDA official over the telephone, provided the physician explains how the expanded access use will meet the requirements of §§ 312.305 and 312.310 and agrees to submit an expanded access application within 15 working days of FDA's initial authorization of the expanded access use (§ 312.310(d)). The physician may choose to use Form FDA 3926 for the expanded access application.

As explained in the instructions for Form FDA 3926, the following information would be submitted to FDA by those using Form FDA 3926:

- Initials for the patient and date of submission.
- Type of submission (initial or followup submission).
- Clinical information, including indication, brief clinical history of the patient (age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy), and the reason for