

operating school days. For student transfers between local educational agencies, the free meals may be offered for up to 10 operating school days at the discretion of the receiving local educational agency.

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Dated: October 24, 2013.

Audrey Rowe,

Administrator, Food and Nutrition Service.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 51

[NRC-2012-0246]

RIN 3150-AJ20

Proposed Waste Confidence Rule and Draft Generic Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Rescheduling of public meetings.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has rescheduled the Waste Confidence public meetings it initially planned to hold in Perrysburg, Ohio, and Minnetonka, Minnesota, on October 15 and October 17, 2013, respectively. The NRC postponed these meetings as a result of lapsed appropriations. The Waste Confidence public meeting in Perrysburg will now be held on December 2, 2013. The Waste Confidence public meeting in Minnetonka will now be held on December 4, 2013. In addition to these rescheduled meetings, the NRC has also scheduled an additional, teleconference-only public meeting on December 9, 2013, that is accessible from anywhere in the United States. The meetings will allow the NRC to receive public comments on proposed amendments to the NRC's regulations pertaining to the environmental impacts of the continued storage of spent nuclear fuel beyond a reactor's licensed life for operation and prior to ultimate disposal (the proposed Waste Confidence rule) and the draft generic environmental impact statement (DGEIS), NUREG-2157, "Waste Confidence Generic Environmental Impact Statement," that forms a regulatory basis for the proposed rule. The meetings are open to the public, and anyone may participate. The NRC has now rescheduled all Waste Confidence public meetings that were affected by the lapse in governmental appropriations.

DATES: The NRC plans to hold a rescheduled Waste Confidence public meeting in Perrysburg Ohio, on December 2, 2013. The NRC plans to hold a rescheduled Waste Confidence public meeting in Minnetonka, Minnesota, on December 4, 2013. The NRC has scheduled a new public teleconference meeting on December 9, 2013. This document contains specific meeting information in the **SUPPLEMENTARY INFORMATION** section. **ADDRESSES:** Please refer to Docket ID NRC-2012-0246 when contacting the NRC about the availability of information for the proposed Waste Confidence rule and DGEIS. You may access publicly available information related to these documents by any of the following methods:

- Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for Docket ID NRC-2012-0246.

- NRC's Waste Confidence Web site: Go to <http://www.nrc.gov/waste/spent-fuel-storage/wcd.html>.

- NRC's Agencywide Documents Access and Management System (ADAMS): You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. The DGEIS is available in ADAMS under Accession No. ML13224A106.

- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT:

Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-287-0675; email: Sarah.Lopas@nrc.gov.

SUPPLEMENTARY INFORMATION: The NRC published the proposed Waste Confidence Rule in the **Federal Register** on September 13, 2013 (78 FR 56776). On the same day, the NRC and the U.S. Environmental Protection Agency issued notices of availability for the DGEIS (78 FR 56621; 78 FR 56695).

Prior to the lapse in appropriations in October 2013, the NRC staff held two Waste Confidence public meetings (one in Rockville, Maryland, on October 1, and one in Denver, Colorado, on October 3). The NRC postponed five meetings (in San Luis Obispo and Carlsbad, California; Perrysburg, Ohio;

Minnetonka, Minnesota; and Oak Brook, Illinois) as a result of lapsed appropriations. The NRC rescheduled the meeting in Oak Brook, Illinois, on November 12; in Carlsbad, California, on November 18; and in San Luis Obispo, California, on November 20. Five additional Waste Confidence public meetings remain scheduled as publicized in 78 FR 54789: Chelmsford, Massachusetts, on October 28; Tarrytown, New York, on October 30; Charlotte, North Carolina, on November 4; Orlando, Florida, on November 6; and Rockville, Maryland, on November 14. The December 9 meeting is a new meeting that the NRC has added to allow interested groups and individuals an additional opportunity to present oral comments.

The December 2 public meeting will take place at the Hilton Garden Inn Toledo/Perrysburg, 6165 Levis Commons Boulevard, Perrysburg, Ohio. The December 2 meeting will start at 7:00 p.m. Eastern Standard Time and will continue until 10:00 p.m. Eastern Standard Time. The December 4 public meeting will take place at the Minneapolis Marriott Southwest, 5801 Opus Parkway, Minnetonka, Minnesota. The December 4 meeting will start at 7:00 p.m. Central Standard Time and will continue until 10:00 p.m. Central Standard Time. Additionally, the NRC staff will host informal discussions during an open house one hour prior to the start of the Perrysburg and Minnetonka meetings. The open houses will start at 6:00 p.m. local time.

The December 9 public meeting will take place via teleconference only. The teleconference meeting will start at 1:00 p.m. Eastern Standard Time and will end at 4:00 p.m. Eastern Standard Time. To participate in the December 9 teleconference public meeting, dial 1-888-603-9749, and provide the operator with passcode 5132332. Interested groups and individuals may participate in the December 9 teleconference public meeting from anywhere in the United States.

The NRC staff will accept comments from the public during the comment-period portion of the meetings. The public meetings will be transcribed and will include: (1) a presentation on the contents of the DGEIS and proposed Waste Confidence rule; and (2) the opportunity for government agencies, organizations, and individuals to provide comments on the DGEIS and proposed rule. No oral comments on the DGEIS or proposed Waste Confidence rule will be accepted during the open house sessions at the December 2 and December 4 meetings (the December 9 meeting does not have an open house

session). To be considered, oral comments must be presented during the transcribed portions of the public meetings. The NRC staff will also accept written comments at any time during the public meetings.

Persons interested in presenting oral comments at the December 2, December 4, or December 9 public meetings are encouraged to pre-register. Persons may pre-register to present oral comments at either meeting by calling 301-287-9392 or by emailing WCRegistration@nrc.gov no later than 3 days prior to the meeting. Members of the public may also register in-person to provide oral comments at each meeting. Individual oral comments may be limited by the time available, depending on the number of persons who register.

If special equipment or accommodations are needed to attend or to present information at either public meeting, then the need should be brought to the NRC's attention no later than 10 days prior to the meeting to provide the NRC staff adequate notice to determine whether the request can be accommodated. The meeting agenda and participation details for each meeting will be available on the NRC's Public Meeting Schedule Web site at <http://www.nrc.gov/public-involve/public-meetings/index.cfm> no later than 10 days prior to each meeting.

Dated at Rockville, Maryland, this 29th day of October 2013.

For the Nuclear Regulatory Commission.

Carrie M. Safford,

Deputy Director, Waste Confidence Directorate, Office of Nuclear Material Safety and Safeguards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 310, 314, and 600

[Docket No. FDA-2011-N-0898]

RIN 0910-AG88

Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulations to implement certain drug shortages

provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). The proposed rule would require all applicants of covered approved drugs or biological products—including certain applicants of blood or blood components for transfusion and all manufacturers of covered drugs marketed without an approved application—to notify FDA electronically of a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply (or a significant disruption in supply for blood or blood components) of the product in the United States.

DATES: Submit either electronic or written comments on the provisions of this proposed rule by January 3, 2014. Submit comments on the information collection requirements under the Paperwork Reduction Act of 1995 (the PRA) by December 4, 2013 (see the "Paperwork Reduction Act of 1995" section).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0898 by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions:

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. 2011-N-0898 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or

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.

FOR FURTHER INFORMATION CONTACT: Kalah Auchincloss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993, 301-796-0659; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

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SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Proposed Rule

FDASIA (Pub. L. 112-144) significantly amended provisions in the FD&C Act related to drug shortages. Among other things, FDASIA amended section 506C of the FD&C Act (21 U.S.C. 356c) to require all manufacturers of certain drugs to notify FDA of a permanent discontinuance or an interruption in manufacturing of these drugs 6 months in advance of the permanent discontinuance or interruption in manufacturing, or as soon practicable. FDASIA also added section 506E to the FD&C Act (21 U.S.C. 356e) requiring FDA to maintain a current list of drugs that are determined by FDA to be in shortage in the United States, and to include on that public list certain information about those shortages. Finally, FDASIA permits FDA to apply section 506C to biological products by regulation, and requires FDA to issue a final rule implementing