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Issued in Kansas City, Missouri, on December 27, 2012.

John Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2012-N-1148]

Food and Drug Administration Actions Related to Nicotine Replacement Therapies and Smoking-Cessation Products; Report to Congress on Innovative Products and Treatments for Tobacco Dependence; Public Hearing; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; Extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of public hearing that appeared in the **Federal Register** of November 28, 2012 (77 FR 70955). In the public hearing notice, FDA requested comments on FDA consideration of applicable approval mechanisms and additional indications for nicotine replacement therapies (NRTs), and input on a report to Congress examining the regulation and development of innovative products and treatments for tobacco dependence. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by January 16, 2013.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ayanna Augustus, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, Rm. 3219, Silver Spring, MD 20993, 301-796-3980, FAX: 301-796-2310, email: Section918PublicMeeting@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 28, 2012, FDA published a document announcing a public meeting on December 17, 2012, and the opening of a public docket to receive comments related to the implementation of section 918 of the FD&C Act (21 U.S.C. 387r), as amended by the Tobacco Control Act (Pub. L. 111-31). Under Section 918(a), the Secretary of the Department of Health and Human Services (the Secretary of HHS) is required to consider certain new approval mechanisms and additional indications for NRTs. Several NRTs, including nicotine-containing gums, patches, and lozenges, are already marketed for smoking cessation. Section 918(b) requires that the Secretary of HHS, after consultation with recognized scientific, medical, and public health experts, submit a report to Congress examining how best to regulate, promote, and encourage the development of “innovative products and treatments (including nicotine-based and non-nicotine-based products and treatments)” to better achieve the following three goals: (1) Total abstinence from tobacco use, (2) reductions in consumption of tobacco, and (3) reductions in the harm associated with continued tobacco use. FDA will consider the information it obtains from the public hearing and related docket submissions in its implementation of the requirements of section 918, including in drafting the report to Congress required by section 918(b).

II. Submission of Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: December 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 63, 80, 85, 122, 123, and 412

[EPA-HQ-OW-2012-0813, FRL-9764-8]

Section 610 Review of NPDES Permit Regulation and Effluent Limitations Guidelines Standards for Concentrated Animal Feeding Operations (CAFOs); Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of public comment period.

SUMMARY: On October 31, 2012 the EPA published a request for comments on a Regulatory Flexibility Act section 610 review titled, Section 610 Review of NPDES Permit Regulation and Effluent Limitations Guidelines Standards for Concentrated Animal Feeding Operations (CAFOs). As initially published in the **Federal Register**, written comments were to be submitted to the EPA on or before December 31, 2012 (a 60-day public comment period). Since publication, the EPA has received a request for additional time to submit comments. Therefore, the EPA is extending the public comment period for 60 days until March 1, 2013.

DATES: The public comment period for the review published October 31, 2012 (77 FR 65840) is being extended for 60 days to March 1, 2013 in order to provide the public additional time to submit comments and supporting information.

ADDRESSES:

Comments: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2012-0813, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.
- **Email:** rfa-sbrefa@epa.gov, Attention Docket ID No. EPA-HQ-OW-2012-0813.
- **Fax:** (202) 566-9744.
- **Mail:** Water Docket, Environmental Protection Agency, Mailcode: 28221T, Attention Docket ID No. EPA-HQ-OW-2012-0813, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- **Hand Delivery:** EPA Docket Center, EPA West, Room 3334, 1301

Constitution Avenue NW., Washington, DC, Attention Docket ID No. EPA-HQ-OW-2012-0813. Such deliveries are accepted only during the Docket Center's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OW-2012-0813. The EPA's policy is that all comments received will be included in the public docket without change and could be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or email. The www.regulations.gov Web site is an "anonymous access" system, which means that the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through www.regulations.gov your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If the EPA cannot read your comment because of technical difficulties and cannot contact you for clarification, the EPA might not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>. For additional instructions on submitting comments, go to the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave.

NW., Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

FOR FURTHER INFORMATION CONTACT: For additional information contact, Hema Subramanian, Office of Wastewater Management (4203M), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564-5041; fax number: (202) 564-6384; email address:

subramanian.hema@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

Section 610 of the Regulatory Flexibility Act requires that an agency review, within 10 years of promulgation, each rule that has or will have a significant economic impact on a substantial number of small entities (SISNOSE). The EPA undertakes section 610 reviews to decide whether the agency should continue a rule unchanged, amend it, or withdraw it. We encourage small entities to provide comments on the need to change these rules, and in particular, how the rules could be made clearer, more effective, or if there is need to remove conflicting or overlapping requirements with other Federal or State regulations.

The EPA promulgated revised regulations for CAFOs on February 12, 2003 (68 FR 7175). The "2003 CAFO Rule" expanded the number of operations covered by the CAFO regulations and included requirements to address the land application of manure from CAFOs. The 2003 CAFO Rule required all CAFOs to seek NPDES permit coverage. The EPA developed a Final Regulatory Flexibility Analysis (FRFA) for the 2003 CAFO Rule. In the 2003 CAFO Rule, the EPA took several steps to minimize its impacts on small businesses, including regulatory revisions designed to focus on the largest producers, eliminating the "mixed" animal calculation for operations with more than a single animal type for determining which AFOs are CAFOs, raising the duck threshold for dry manure handling duck operations, and adopting a dry-litter chicken threshold higher than proposed.

Subsequently, a series of court decisions based on legal challenges to the rulemaking have limited the requirement for NPDES permit coverage specifically to CAFOs that discharge. In response to these court decisions, the

EPA made revisions to the CAFO regulations in 2008 (73 FR 70418) and 2012 (77 FR 44494). In promulgating the 2008 regulatory revision, the EPA certified that the 2008 rule would not have a significant adverse economic impact on a substantial number of small entities. In promulgating the 2012 regulatory revision, the 2012 rule was not subject to the RFA because the RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute, and the 2012 rule was not subject to notice and comment requirements. Both rules reduced the potential impact of the EPA's CAFO regulations on small entities by reducing the universe of CAFOs that must apply for NPDES permits. Although the EPA has made these subsequent revisions to the CAFO regulations, the scope of this 610 review is limited to the impacts on small entities of the 2003 CAFO Rule as amended.

II. Extension of Comment Period for the Section 610 Review of the 2003 CAFO Rule

The EPA is extending the deadline for submitting comments on the section 610 review of the CAFO Rule to March 1, 2013. The original deadline for comments, based on a 60-day comment period, was December 31, 2012. The EPA's decision responds to a request to extend the comment deadline. The EPA believes that this 60-day extension will assist in providing an adequate amount of additional time for the public to review the action and to provide written comments.

Dated: December 19, 2012.

Alexander Cristofaro,

Director, Office of Regulatory Policy and Management.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R4-ES-2012-0020; 92220-1113-0000-C6]

RIN 1018-AX60

Endangered and Threatened Wildlife and Plants; Reclassification of the Continental United States Breeding Population of the Wood Stork From Endangered to Threatened; Correction

AGENCY: Fish and Wildlife Service, Interior.