CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. section	Former maximum penalty amount (in dollars)	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
360pp(b)(1)	355,000	For any related series of violations	2013	375,000
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000
300aa–28(b)(1)	120,000	Per occurrence	2013	130,000

[1] Not adjusted.

■ 3. In § 17.5, revise paragraph (a) to read as follows:

§ 17.5 Complaint.

(a) The Center with principal jurisdiction over the matter involved shall begin all administrative civil money penalty actions by serving on the respondent(s) a complaint signed by the Office of the Chief Counsel attorney for the Center and by filing a copy of the complaint with the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For a civil money penalty action against retailers of tobacco products, the complaint may be signed by any Agency employee designated by the Chief Counsel.

* * * * *

Dated: January 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02149 Filed 1–31–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 507

[Docket No. FDA–2013–N–1043]

Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for a document we made available for public comment in the **Federal Register** of October 29, 2013 (78 FR 64428) (the draft RA). We are taking this action to make the comment period for the draft RA conform to the comment period for proposed rule entitled ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals'' (the proposed preventive controls rule for food for animals).

DATES: FDA is extending the comment period on the draft RA. Submit either electronic or written comments by March 31, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–1043 by any of the following methods:

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 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. FDA–2013–N–1043. 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 ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION**.

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: Kim Young, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–2207.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 29, 2013, we published a notification with a 120-day comment period announcing the availability of, and requesting comment on, a document entitled ''Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm'' (the draft RA). The purpose of the draft RA is to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk.

We conducted this draft RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA.

In the **Federal Register** of October 29, 2013, we announced that we had used the results of the draft RA to propose to exempt certain animal food facilities (i.e., those that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/animal food combinations) from the proposed requirements of the Federal Food, Drug, and Cosmetic Act for hazard analysis and risk-based preventive controls (the proposed preventive controls rule). Interested persons were originally given until February 26, 2014, to comment on the proposed preventive controls rule.

FDA has received requests for an extension of the comment period on the proposed preventive controls rule for

food for animals to allow interested persons an opportunity to consider the interrelationship between this proposed rule and the proposed rules entitled ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals'' (78 FR 45729, July 29, 2013) and ''Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications'' (78 FR 45782, July 29, 2013). We have considered the requests, and elsewhere in this issue of the **Federal Register**, we are granting an extension of the comment period to March 31, 2014, for the proposed preventive controls rule. We are extending the comment period for the draft RA to March 31, 2014, to continue to make the comment period for the draft RA conform to the comment period for the proposed preventive controls rule.

II. Request for Comments

Interested persons may submit either electronic comments regarding the proposed rule 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: January 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02112 Filed 1–31–14; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF DEFENSE

40 CFR Part 1700

[EPA–HQ–OW–2013–0469; FRL–9903–49–OW]

RIN 2040–AD39

Uniform National Discharge Standards for Vessels of the Armed Forces—Phase II

AGENCY: Environmental Protection Agency and Department of Defense.

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) and the U.S. Department of Defense (DoD) are proposing performance standards for certain discharges incidental to the normal operation of a vessel of the Armed Forces into the navigable waters of the United States, the territorial seas, and the contiguous zone. The proposed standards would reduce the adverse environmental impacts associated with the discharges, stimulate the development of improved pollution control devices, and advance the development of environmentally sound ships by the Armed Forces. The proposed standards are designed to be consistent with the effluent limitations included in the recently issued National Pollutant Discharge Elimination System (NPDES) general permit for discharges incidental to the normal operation of a non-military vessel.

DATES: Comments must be received on or before April 4, 2014.

ADDRESSES: Submit your comments, identified by Docket No. EPA–HQ–OW–2013–0469, by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow on-line instructions for submitting comments.

Mail: Send an original and one copy of your comments and enclosures (including references) to EPA Water Docket, U.S. Environmental Protection Agency, Mail Code: 2822–IT, 1200 Pennsylvania Avenue NW., Washington, DC 20460, Attention Docket No. EPA–HQ–OW–2013–0469.

Hand Delivery: EPA Water Docket, EPA Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004, Docket No. EPA–HQ–OW–2013–0469. Deliveries to the docket are accepted only during their normal hours of operation: 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. For access to docket materials, call (202) 566–2426, to schedule an appointment.

Email: ow-docket@epa.gov; Attention Docket No. EPA–HQ–OW–2013–0469. To ensure that EPA can properly respond to comments, commenters should cite the paragraph(s) or section(s) in the proposed rule to which each comment refers. Commenters should use a separate paragraph for each issue discussed, and must submit any references cited in their comments. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment. Electronic files should avoid any form of encryption and should be free of any defects or viruses.

Instructions: Direct your comments to docket ID number EPA–HQ–OW–2013–0469. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://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 *http://www.regulations.gov*. The Federal *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means 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 EPA without going through *http://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, 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 EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid any form of encryption and should be free of any defects or viruses. For additional instructions on submitting comments, go to the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: The electronic version of the public docket is available through the Federal Docket Management System (FDMS) found at *http://www.regulations.gov*. You may use the FDMS to view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once at the Web site, enter the appropriate Docket ID No. in the ''Search'' box to view the docket. Certain types of information will not be placed in the EPA dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in hard copy in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available