Products Inspection Act. The proposed rule had a 90-day comment period, which ended December 21, 2004. To discuss the proposed rule and solicit comments from interested stakeholders, FDA held three public meetings in 2004: October 28 in College Park, MD; November 9 in Chicago, IL; and November 16 in Los Angeles, CA.

II. Request for Comments

Based on comments received in response to the proposal, FDA is seeking further comment and information on industry practices and programs that prevent SE-monitored chicks from being infected by SE during the period of pullet rearing until placement into laying hen houses. Specifically, FDA seeks additional comment and supportive data or other information on the following questions:

1. How many pullet growing facilities are there in the United States? What is the range in the number of houses on those facilities?

• What percentage of pullet growers are under programs or have practices aimed at preventing SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into layer hen houses?

• Do State or regional Egg Quality Assurance Programs include provisions to prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into layer hen houses? How effective have the pullet programs (whatever the programs entail—cleaning, testing, etc.) been in reducing the prevalence of SE in layer flocks? How is effectiveness measured?

2. During pullet rearing, what programs or industry practices are currently taken to prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into layer hen houses?

• Are pullets, or their environment, tested for SE between the time they are procured as chicks and the time they enter layer houses? If so, when? When tested, approximately how often do pullets or pullet environments test positive? What happens after a positive test?

• Is vaccination used as a preventive measure, if so, when and how?

• What cleaning and disinfecting practices are common?

• Are measures taken to reduce the prevalence of rodents and pests in the pullet rearing houses?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. 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.

Dated: May 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9327 Filed 5–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 361

[Docket No. 2004N–0432]

Radioactive Drugs for Certain Research Uses; Public Meeting; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until July 11, 2005, the comment period on the questions raised and issues addressed in the notice of public meeting, published in the **Federal Register** of October 5, 2004 (69 FR 59569), on the use of certain radioactive drugs for research purposes without an investigational new drug application (IND) under the conditions set forth in FDA regulations. We are taking this action in response to requests to extend the comment period and to allow additional time to review agency guidance on a related matter.

DATES: Submit written or electronic comments on the notice and/or public meeting by July 11, 2005.

ADDRESSES: You may submit comments, identified by Docket No. 2004N–0432, by any of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

• Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

• E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0432 in the subject line of your e-mail message.

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier (for paper, disk, 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 number for this proceeding. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments, see the ''Comments'' heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert Docket No. 2004N–0432 into the ''Search'' box and follow the prompts, or go to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

A transcript of the public meeting is available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/ohrms/dockets*.

FOR FURTHER INFORMATION CONTACT: Maria R. Walsh, Center for Drug Evaluation and Research (HFD–103), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3139, FAX: 301–480–3761, e-mail: *walsh@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 5, 2004 (69 FR 59569), we announced a public meeting to be held on November 16, 2004, to discuss research on radioactive drugs that is conducted under § 361.1 (21 CFR 361.1). Under § 361.1, certain radioactive drugs (drugs that exhibit spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons) are considered generally recognized as safe and effective under specified conditions of use when administered to human research subjects for certain basic research uses. These uses include studies intended to obtain basic information regarding the metabolism (including pharmacokinetics, distribution, and localization) of a radioactive drug or regarding human physiology, pathophysiology, or biochemistry, but not studies intended for immediate therapeutic, diagnostic, or similar purposes or studies intended to determine the safety and effectiveness

of the drug. When conducted in accordance with § 361.1, clinical investigations of radioactive drugs are not subject to the requirements for INDs stated in 21 CFR part 312.

To facilitate discussion at the public meeting and assist us in our review of this matter, we invited comments on several questions we set forth in the **Federal Register** notice concerning the application of § 361.1. Interested persons were invited to present information at the public meeting and were given until January 16, 2005, to submit comments on the notice.

We held the public meeting on November 16, 2004. Subsequent to the public meeting, we received requests from the American College of Nuclear Physicists, the Society of Nuclear Medicine, and others that we extend the comment period on the notice on § 361.1 so that persons can consider the issues raised in the notice and at the public meeting in light of the information in the draft guidance on exploratory INDs that we expected to issue in the near future. We published a notice of availability of that draft guidance in the **Federal Register** of April 14, 2005 (70 FR 19764).

In response to these requests, we have decided to reopen the comment period on the questions and issues stated in the October 5, 2004, notice and discussed at the November 16, 2004, public meeting. This will allow interested persons more time to review and comment on these issues in light of the information in the draft guidance on exploratory INDs.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

III. Transcripts

You can examine a transcript of the November 16, 2004, public meeting on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm* or at the Division of Dockets Management (see **ADDRESSES**), Monday through Friday between 9 a.m. and 4 p.m. You may also request a copy of the transcript from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, at a cost of 10 cents per page or on CD at a cost of $14.25 each.

Dated: May 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9326 Filed 5–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD05–05–041]

RIN 1625–AA09

Drawbridge Operation Regulations; Atlantic Intracoastal Waterway (AICW), Elizabeth River, Southern Branch, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulations that govern the operation of the Dominion Boulevard (U.S. 17) Bridge across the Southern Branch of the Elizabeth River, at Atlantic Intracoastal Waterway (AICW) mile 8.8, at Chesapeake, Virginia. The proposal would change the morning rush hour closure period so that it starts at 7 a.m. and ends at 9 a.m., and also allow the bridge to open every hour from 9 a.m. to 4 p.m., Monday through Friday, except holidays. The proposed change is necessary to relieve vehicular traffic congestion and reduce traffic delays between weekday rush hours while still providing for the reasonable needs of navigation.

DATES: Comments and related material must reach the Coast Guard on or before June 24, 2005.

ADDRESSES: You may mail comments and related material to Commander (obr), Fifth Coast Guard District, Federal Building, 1st Floor, 431 Crawford Street, Portsmouth, VA 23704–5004. The Fifth Coast Guard District maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Commander (obr), Fifth Coast Guard District between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Waverly W. Gregory, Jr., Bridge Administrator, Fifth Coast Guard District, at (757) 398–6222.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking CGD05–05–041, indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like a return receipt, please enclose a stamped, self-addressed postcard or envelope. We will consider all submittals received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Commander (obr), Fifth Coast Guard District at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one public meeting at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Current regulations require the Dominion Boulevard (US 17) Bridge across the Southern Branch of Elizabeth River, at AICW mile 8.8, to open on signal at any time for commercial vessels carrying liquefied flammable gas or other hazardous materials and for commercial vessels that provide a two-hour advance notice. In addition, from Memorial Day to Labor Day, from 8:30 a.m. to 4 p.m., Monday through Friday, except Federal holidays, the draw is opened only every hour on the half-hour. From 6:30 a.m. to 8:30 a.m. and from 4 p.m. to 6 p.m., Monday through Friday, except Federal holidays, the draw need not open for the passage of recreational vessels and commercial vessels carrying non-hazardous material that do not provide a 2-hour advance notice.

On December 17, 2004, we published a notice of temporary deviation from the regulations and request for comments entitled ''Drawbridge Operation Regulations; Atlantic Intracoastal Waterway (AICW), Elizabeth River, Southern Branch, VA'' in the **Federal Register** (69 FR 75472). The temporary deviation was an effort to test an alternate drawbridge operation schedule for 90 days and to solicit comments from the public. In accordance with the temporary deviation, from December 13,