

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 78

[Docket No. 02-070-2]

Official Brucellosis Tests

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would amend the brucellosis legislation by adding the fluorescence polarization assay to the list of official tests for determining the brucellosis disease status of test-eligible cattle, bison, and swine. This action will allow interested persons additional time to prepare and submit comments.

DATES: We will consider all comments that we receive on or before July 21, 2004.

ADDRESSES: You may submit comments by any of the following methods:

- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. 02-070-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 02-070-1.

- *E-mail:* Address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 02-070-1" on the subject line.

- *Agency Web Site:* Go to <http://www.aphis.usda.gov/ppd/rad/cominst.html> for a form you can use to submit an e-mail comment through the APHIS Web site.

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow

the instructions for locating this docket and submitting comments.

Reading Room: You may read any comments that we receive on Docket No. 02-070-1 in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Gertonson, National Center for Animal Health Programs, VS, APHIS, 2150 Centre Avenue, Bldg. B, MSC 3E20, Fort Collins, CO 80526-8117; (970) 494-7963.

SUPPLEMENTARY INFORMATION: On May 6, 2004, we published in the **Federal Register** (69 FR 25338-25340, Docket No. 02-070-1) a proposal to amend the brucellosis regulations in 9 CFR part 78 to add the fluorescence polarization assay to the list of official tests for determining the brucellosis disease status of test-eligible cattle, bison, and swine.

Comments on the proposed rule were required to be received on or before June 21, 2004. We are reopening the comment period on Docket No. 02-070-1 for an additional 30 days, ending July 21, 2004. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between June 22, 2004 (the day after the close of the original comment period) and the date of this notice.

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 29th day of June 2004.

W. Ron DeHaven,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04-15213 Filed 7-2-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 56

[Docket No. 2004N-0242]

Institutional Review Boards; Registration Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require institutional review boards (IRBs) to register at a site maintained by the Department of Health and Human Services (HHS). The registration information would include contact information, the number of active protocols involving FDA-regulated products reviewed in the previous calendar year, and a description of the types of FDA-regulated products involved in the protocols reviewed. The proposed IRB registration requirements would make it easier for FDA to inspect IRBs and to convey information to IRBs.

DATES: Submit written or electronic comments on this proposed rule by October 4, 2004. Submit written comments on the information collection provisions by August 5, 2004. See section III of this document for the proposed effective date of any final rule based on this document.

ADDRESSES: You may submit comments, identified by Docket No. 2004N-0242, 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-0242 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. 2004N-0242 for this rulemaking. All comments received will