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

be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see section IX of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may submit comments on the information collection provisions to the Office of Management and Budget (OMB) by the following method:

• FAX: 202–395–6974. OMB is still experiencing significant delay in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Introduction

IRBs are boards, committees, or groups formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. (See § 56.102(g) (21 CFR 56.102(g)).) An IRB's primary purpose during such reviews is to assure the protection of the rights and welfare of human subjects (§ 56.102(g)). FDA's general regulations pertaining to IRBs are in part 56 (21 CFR part 56). (While section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) refers to ''institutional review committees'' rather than IRBs, FDA considers institutional review committees to be IRBs and to be subject to the IRB regulations.)

Even though IRBs play an important role in the conduct of clinical investigations regulated by FDA, FDA has never compiled a comprehensive list of IRBs involved in reviewing clinical investigations regulated by FDA. Existing FDA regulations have required some, but not all, clinical investigators or sponsors of clinical investigations to provide IRB names and addresses to FDA, and the requirements differ slightly. For example, for human drug products, the sponsor must disclose the name and address of ''each reviewing'' IRB. (See 21 CFR 312.23(a)(6)(iii)(*b*).) For medical devices, the sponsor must disclose the names and addresses of IRBs that have ''been asked *or will be asked*'' to review the investigation (see 21 CFR 812.20(b)(6)) (emphasis added). For other types of clinical investigations regulated by FDA (such as food additive studies involving human subjects), the regulations do not expressly require the sponsor or the clinical investigator to disclose or keep records showing an IRBs name and address, and they make no distinction between ''reviewing IRBs'' and IRBs that have been asked or will be asked to review a study.

In 1998, HHS's Office of Inspector General (OIG) issued several reports on IRBs. OIG sought to identify the challenges facing IRBs and to make recommendations on improving Federal oversight of IRBs. One recommendation was that all IRBs should register with the Federal Government on a regular basis as part of an effort to develop more streamlined, coordinated, and probing means of assessing IRB performance and to enhance the Federal Government's ability to identify and respond to emerging problems before they result in ''serious transgressions'' (Ref. 1, pp. 20 and 21).

After reviewing the OIG's recommendation, FDA has concluded that IRB registration would serve several important goals. IRB registration would:

• Enable FDA to identify more precisely those IRBs reviewing clinical investigations regulated by FDA. At present, much of FDA's knowledge about the identities and numbers of IRBs reviewing clinical investigations regulated by FDA is based on information from persons conducting or sponsoring clinical investigations rather than from IRBs themselves. This information may be obsolete (because there may be no obligation to update the information) or incomplete (because the requirements to report the names and addresses of IRBs are not uniform across all FDA-regulated products);

• Enable FDA to send educational information and other information to IRBs. Because FDA lacks an accurate list of IRBs, FDA's outreach and educational efforts are not as efficient as they might be. Changes in IRB addresses result in returned mail, and newly-formed IRBs may not appear on FDA's mailing lists; and

• Help FDA identify IRBs for inspection, because the agency would have a more accurate list of IRBs.

FDA, in conjunction with HHS' Office for Human Research Protection (OHRP), is developing an Internet site for IRB registration purposes. The goal is to create a simple, electronic registration system that all IRBs, regardless of whether they review clinical investigations regulated by FDA or research conducted or supported by HHS, can use. (FDA discusses the Internet site in greater detail later in this document.)

Elsewhere in this issue of the **Federal Register**, OHRP has published a proposed rule to require IRB registration of IRBs that review research that is conducted or supported by HHS and that are designated under an assurance of compliance with HHS human subjects protection regulations. FDA and OHRP proposed rules would create a single HHS IRB registration system. Information regarding public disclosure of IRB registration information, the Freedom of Information Act (FOIA), and the Privacy Act of 1974 may be found in the OHRP proposed rule. However, insofar as IRB registration information required by FDA's proposed rule is concerned, the name of the institution operating the IBR, as well as the IRB's name, will be publicly accessible. All other IRB registration information that would be required by FDA under this proposal would be subject to public disclosure under FOIA and FDA's public information regulations at 21 CFR part 20.

II. Description of the Proposed Rule

The proposed rule would amend the IRB regulations at part 56 to require IRB registration. The proposed rule would also delete an obsolete cross-reference to a nonexistent FDA regulation.

A. IRB Registration (Proposed § 56.106)

1. Who Must Register? (Proposed § 56.106(a))

The proposal would create a new § 56.106, entitled ''Registration'' to require IRBs to register at a site maintained by HHS. In brief, proposed § 56.106(a) would require registration of:

• Each IRB in the United States that reviews clinical investigations regulated by FDA under section 505(i) or 520(g) of the act (21 U. S. C. 355(i)). A research permit under section 505(i) of the act is usually known as an investigational new drug application (IND), and a research permit under section 520(g) of the act is usually known as an investigational device exemption (IDE); and

• Each IRB in the United States that reviews clinical investigations that support applications for research or marketing permits for FDA-regulated products.

FDA requests comment on whether there are circumstances in which foreign IRBs should be required or invited to register.

Proposed § 56.106(a) would also specify that an individual authorized to act on the IRB's behalf must submit the registration information. The individual may be an IRB member or any other person authorized by the IRB to submit the registration information.

FDA considered requiring sponsors or clinical investigators to submit IRB registration, but rejected such an approach because it created the potential for multiple IRB registrations for the same IRB. For example, if two sponsors used a particular IRB and the proposed rule would require sponsors to submit IRB registration information, the result would be two registrations for the same IRB. Thus, it would be more practical and efficient to require the IRBs themselves to register.

2. What Information Must an IRB Provide When Registering? (Proposed § 56.106(b))

Proposed § 56.106(b) would describe the information to be submitted as part of the registration process. In brief, the proposal would require IRBs to provide:

- The name and mailing address of the institution operating the IRB and the name, mailing address, phone number, fax number, and e-mail address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB. The senior officer must not be an IRB member, IRB staff, or a sponsor or investigator participating in an investigation under review by that IRB. This information would enable FDA to identify the institution with which the IRB is affiliated. Information on the institution would also enable FDA to determine, if there are problems with an IRB, whether similar problems exist at other IRBs affiliated with that institution. Information on the senior officer of the institution would enable FDA to contact that person directly if significant issues or problems arose that involved or could involve the institution;
- The IRB's name, the IRB chairperson's name, the name of the contact person for the IRB (if different from the IRB chairperson), and the mailing addresses and street addresses (if different from the mailing address), phone numbers, fax numbers, and e-mail addresses for the IRB chairperson and contact person (if different from the IRB chairperson). This information would enable FDA to contact an IRB contact person on routine issues and to contact an IRB chairperson quickly, if necessary, on important issues and to send electronic mail to the IRB chairperson and contact person;
- The number of active protocols involving FDA-regulated products reviewed (both initial reviews and continuing reviews). In this case, ''active protocol'' would mean any protocol for which an IRB conducted an initial review or a continuing review during the preceding calendar year. The proposal would not require an IRB to report a specific number of protocols; instead, IRBs would indicate the range of the numbers of protocols they had reviewed in the preceding calendar year. The proposal would consider a ''small'' number of protocols to be 1 to 25 protocols; ''medium'' would be 26 to 499, and ''large'' would be 500 protocols or more. This information would enable FDA to determine how active an IRB is and to assign its inspection resources based on an IRB's activity level;
- A description of the types of FDA-regulated products, such as human drugs, biological products (which include, but are not limited to, vaccines, blood, blood products, and tissues), medical devices, food additives, and/or color additives involved in the protocols that the IRB reviews. This information would allow FDA to send appropriate information (such as information pertaining to the product or a class of products, new regulatory requirements, or new guidance documents) to the IRB and to assign appropriate personnel to conduct IRB inspections; and
- An indication as to whether the IRB is accredited and, if it is accredited, the date of its last accreditation and the name of the accrediting body or organization. FDA recognizes that IRB accreditation is a developing concept, so information on IRB accreditation will help FDA evaluate the extent and value of IRB accreditation and help identify the accrediting bodies or organizations. FDA specifically solicits public comment related to the perceived value of collecting information on the accreditation status of IRBs.

Due to statutory and regulatory differences between FDA and OHRP, the Internet registration site may request more information from IRBs reviewing research conducted or supported by HHS than those reviewing clinical investigations regulated by FDA that are not conducted or supported by HHS. For example, OHRP may request information concerning the IRB chairperson's status (e.g., physician-scientist, other scientist, or nonscientist) and educational degrees and also ask for a list of IRB members and alternates. In those instances where the Internet registration site would seek more information than FDA would require under this proposal, the site would clarify that IRBs regulated solely by FDA may, but are not required to, provide the additional information.

3. When Must an IRB Register? (Proposed § 56.106(c))

Proposed § 56.106(c) would require IRBs to register once and to renew their registrations every 3 years. The proposal would require initial IRB registration within 30 days before the date when the IRB intends to review clinical investigations regulated by FDA. To show how this would work, assume that a newly formed IRB has been asked to review a protocol for a clinical investigation regulated by FDA under section 505(i) of the act. The IRB would then be subject to FDA's IRB regulations (§ 56.101(a)), and the IRB, under proposed § 56.106(c), would submit its initial registration 30 days before the date the IRB intends to review the protocol. (If the IRB declined to review the protocol, the IRB would not necessarily be subject to FDA regulation and would not have to register under this proposal.) Requiring IRBs to renew their registrations periodically would help ensure that FDA's list of IRBs remains current. (See section III of this document regarding the rule's implementation for IRBs already reviewing clinical investigations when FDA issues a final rule.)

Under the proposal, IRB registration would become effective when HHS posts that information on its Web site. FDA also recognizes that some IRBs may have voluntarily registered under the OHRP system, and OHRP will continue to recognize such registrations.

4. Where Can an IRB Register? (Proposed § 56.106(d))

Proposed § 56.106(d) would direct IRBs to register at a specific Internet address (which FDA will provide when it issues any final rule) or, if an IRB lacks the ability to register electronically, to send its registration information to a specific mail address (which FDA will provide in a final rule). Although electronic registration may be easier and faster than written registration, FDA cannot determine how widespread Internet access is among IRBs. Thus, the agency will allow for written registration as an alternative to electronic registration, but invites comment on whether it should discontinue written IRB registration procedures after some time period has elapsed.

5. How Does an IRB Revise Its Registration Information? (Proposed § 56.106(e))

Under proposed § 56.106(e), if an IRB's contact registration information changes, the IRB must revise its registration information within 90 days of the change. All information involving changes other than changes in an IRB contact or an IRB chairperson only need to be updated at the time of the 3- year renewal under proposed § 56.106(c). For example, if an IRB selects a new chairperson, the IRB would, under proposed § 56.106(e), revise its registration information within 90 days of the new chairperson's selection. If an IRB reviews new types of FDA-regulated products, the IRB, under proposed § 56.106(e), would revise its registration information to reflect this change within 30 days.

Proposed § 56.106(e) would also consider an IRB's decision to disband or stop reviewing clinical investigations regulated by FDA to be a change that must be reported. Requiring IRBs to report when they have disbanded or stopped reviewing clinical investigations regulated by FDA will enable FDA to stop sending educational information to the IRB and also forego inspecting the IRB.

Revised registration information would be submitted electronically at the Internet address (which FDA will identify by the time it issues a final rule). If an IRB lacks Internet access, it would submit any revised registration information, in writing, to a specific mail address (which FDA will identify by the time it issues a final rule).

6. What Happens if an IRB Does Not Register?

As stated earlier, requiring IRBs to register will help FDA send educational information to IRBs and identify IRBs for inspection. If sponsors of clinical investigations or marketing applications and investigators could use unregistered IRBs, those IRBs would not have had the benefit of receiving educational materials from FDA and would not have been identified on an FDA IRB registration list for future inspection. Therefore, to the extent that any existing FDA regulation requires a sponsor or investigator to comply with part 56 or to use an IRB that complies with part 56, FDA will consider sponsors and investigators using an unregistered IRB to be in conflict with their regulatory obligations. For example, the IND regulations in § 312.66 (21 CFR § 312.66), require an investigator to use an IRB that complies with part 56. If the investigator uses an unregistered IRB, FDA would consider the sponsor or investigator to be in violation of its obligations under § 312.66. (See also § 312.53(c)(1)(vii) (IND sponsor must obtain a commitment by the investigator that an IRB that complies with part 56 will be responsible for the initial and continuing review and approval of the clinical investigation); 21 CFR 361.1(d)(5) (investigators studying radioactive drugs must obtain review and approval by an IRB that complies with part 56); § 812.42 (21 CFR 812.42) (sponsor shall not begin a device investigation until an IRB and FDA have approved the application or supplemental application relating to the investigation); § 812.60 (IRB reviewing and approving device investigations must comply with part 56 in all respects)). An IRB that refuses to register may be subject to administrative action for noncompliance (see, e.g., §§ 56.120, 56.121, and 56.124). FDA believes that the proposed registration requirement is both simple and straightforward and beneficial to IRBs, so the agency does not expect that many IRBs will refuse or fail to register.

FDA considered other options to require sponsors and investigators to use only registered IRBs. For example, one option would be to refuse to consider information from an application for a research permit for a clinical investigation that is reviewed or is to be reviewed by an unregistered IRB. This would have given sponsors and investigators a strong incentive to use only registered IRBs and would have been similar to § 56.121(d) (which describes FDA's actions if a clinical investigation is reviewed by a disqualified IRB). However, the agency did not consider an IRB's failure to reregister to be comparable to an IRB's status as disqualified, so FDA did not include such a provision in the proposed rule. FDA invites comments on how it could best ensure that all sponsors and investigators involved in clinical investigations using human subjects use only registered IRBs to review and approve those clinical investigations. The agency is particularly interested in the following issues:

- What sanctions or administrative mechanisms, if any, should be or might be used against sponsors and investigators who use unregistered IRBs? For example, should FDA amend the IND regulations to authorize the agency to place a study on clinical hold if a sponsor or investigator uses an unregistered IRB?
- Are additional changes to FDA regulations necessary? For example, would FDA have to revise or create requirements for sponsors and investigators? If so, which provisions would FDA have to revise? What new regulations would be needed?
- Are there other ways to ensure the use of registered IRBs?

B. Nonsubstantive, Technical Amendment to Part 56

The proposal would also make a nonsubstantive amendment to part 56. The proposal would revise the definition of ''An Application for an Investigational Device Exemption'' at § 56.102(b)(12) to eliminate the reference to part 813 (21 CFR part 813). This change is necessary because FDA removed the regulations at part 813 (which pertained to intraocular lenses) in 1997 (see 62 FR 4164, January 29, 1997).

III. Implementation

FDA intends to make any final rule based on this proposal effective within 60 days after the final rule is published in the **Federal Register**. Because the registration requirement would be new, the agency would then give all IRBs an additional 60 days to submit their initial registrations. For example, if FDA published the final rule in the **Federal Register** on January 1, 2005, the final rule would become effective on March 1, 2005 (60 days after the final rule's publication date), and IRBs would have another 60 days, to April 30, 2005, to submit their initial registration information. After this initial deadline, all subsequent registrations would adhere to the timeframes in proposed § 56.106(c).

FDA invites comment as to whether this tentative implementation schedule should be revised. Because IRB registration will eventually occur primarily through the Internet, the actual effective date of any final rule may change should any software or hardware problems arise that affect FDA's ability to obtain IRB registration information electronically.

IV. Legal Authority

In general, the act authorizes FDA to issue regulations pertaining to investigational uses of FDA-regulated products (see, e.g., section 409(j) of the act (21 U. S. C. 348(j)) (investigations involving food additives); section 505(i) of the act (investigations involving human drugs); section 520(g) of the act (investigations involving devices); and 721(f) of the act (21 U.S.C. 379e(f)) (investigations involving color additives)). Two provisions specifically refer to the use of IRBs as part of the investigational process (see sections 505(i) and 520(g) of the act (section

520(g) of the act refers to ''institutional review committees'' rather than IRBs, but the terms are synonymous)).

The act also requires the submission of a petition or application to FDA (see, e.g., sections 409(b) of the act (food additive petitions); section 505(b) of the act (new drug applications); section 505(j) of the act (abbreviated new drug applications); section 515(c) of the act (21 U.S.C. 360e(c)) (premarket approval applications for devices); and section 721(b) of the act (color additive petitions)) before marketing begins.

To implement these provisions of the act, section 701(a) of the act (21 U.S.C. 371(a)) gives FDA the authority to issue regulations for the efficient enforcement of the act. By requiring IRB registration, the proposed rule would, if finalized, aid in the efficient enforcement of the act's provisions regarding the investigational use of various FDA-regulated products (because then FDA would be able to conduct IRB inspections more efficiently). IRB registration would also help enforce those provisions regarding marketing applications (because marketing applications usually depend on clinical investigations involving human subjects, and IRBs are supposed to provide protections for the rights and welfare of such human subjects). Moreover, by requiring IRBs to register, the proposed rule would enable FDA to contact IRBs more quickly and efficiently on various issues, such as adverse reactions that may be attributed to a particular product, new regulatory requirements or policies, or problems associated with a particular protocol or clinical investigator. FDA's authority to regulate IRBs was discussed in more detail in the preambles to the initial proposed rule and the final rule establishing part 56 (43 FR 35186 at 35197, August 8, 1978 and 46 FR 8958 at 8959 and 8960, January 27, 1981). For the reasons discussed in the earlier preambles and previously on this document FDA concludes that it has sufficient legal authority to issue the proposed rule.

V. Economic Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any one year.''

The proposed rule is consistent with the principles set forth in Executive Order 12866 and these two statutes. As explained below, the proposed rule is not an economically significant regulatory action as defined in Executive Order 12866 and does not require a Regulatory Flexibility Analysis. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is approximately $110 million.

The proposed rule would require IRBs to register with FDA. The information sought through the registration process would be minimal, consisting largely of names and addresses for a contact person, the institution operating the IRB (if an institution exists), the senior officer of the institution who is responsible for overseeing the activities performed by the IRB, the IRB, and the IRB chairperson. The registration would also indicate whether the IRB reviews a ''small,'' ''medium,'' or ''large'' number of FDA-regulated protocols and the types of FDA-regulated products involved. IRBs would also indicate whether they are accredited and identify the accrediting body or organization. FDA estimates that initial IRB registration may require 1 hour to complete. If the average wage rate is $40 per hour, this means that each IRB would spend $40 for an initial registration ($40 per hour x 1 hour per initial registration).

FDA estimates that reregistration would require less time, especially if the IRB verifies existing information. If reregistration requires 30 minutes, then the cost of reregistration to each IRB would be approximately $20 ($40 per hour x 0.5 hours per reregistration).

Revising an IRB's registration information would probably involve costs similar to reregistration costs. If the revision requires 30 minutes, then the cost of revising an IRB's registration information would be approximately $20 per IRB.

Given the minimal registration information that would be required and the low costs associated with registration, this proposed rule is not a significant regulatory action, and FDA certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. Therefore, the proposal is not a significant regulatory action under Executive Order 12866 and does not require a Regulatory Flexibility Act analysis.

Additionally, assuming that an estimated 5,000 IRBs would register, the proposed rule, if finalized, would result in a 1-year expenditure of $200,000 (5,000 IRBs x $40 registration wage costs per IRB). Because the total expenditure under the rule will not result in a 1-year expenditure of $100 million or more, FDA is not required to perform a cost-benefit analysis under the Unfunded Mandates Reform Act.

VI. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the

methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Institutional Review Boards: Registration Requirements.

Description: The proposed rule would require IRBs to register with FDA.

Description of Respondents: Businesses and individuals.

The estimated burden associated with the information collection requirements of this proposed rule is 8,750 hours.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
56.106(c) (initial registration)	5,000	1	5,000	1	5,000
56.106(c) (reregistration)	2,500	1	2,500	0.5	1,250
56.106(e)	5,000	1	5,000	0.5	2,500
Total					8,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimates are based on the following considerations. According to a 1998 OIG report, there are 3,000 to 5,000 IRBs in the United States, and most are associated with hospitals and academic centers (Ref. 1, p. 3). While not all IRBs are involved in clinical investigations regulated by FDA, the agency, for purposes of the PRA, will use 5,000 as the maximum number of IRBs subject to the proposed rule. Additionally, because the proposed rule would require basic information about an IRB (such as names and addresses) and because registration would, in most cases, be done electronically, FDA will assume that registration will take only 1 hour per IRB. Thus, the total burden hours would be 5,000 hours (5,000 IRBs x 1 hour per IRB).

Reregistration and revisions to existing registration information should require less time than initial registration. FDA will assume that reregistration and revisions will take only 30 minutes per IRB. FDA will also assume, based on OHRP's experience with its IRB registration program, that 50 percent of IRBs (2,500) will reregister and that all (5,000) will revise their registration information. Therefore, the total burden hours for reregistration will be 1,250 hours (2,500 IRBs x 0.5 hours per IRB), and the total burden hours for revisions will be 2,500 hours (5,000 IRBs x 0.5 hours per IRB).

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to send comments regarding information collection by August 5, 2004, to the Office of Information and Regulatory Affairs, OMB. Submit written comments on the information collection provisions by August 5, 2004. See section III of this document for the effective date of any final rule based on this document.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

IX. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposal. Submit written comments to OMB (see the **ADDRESSES** in section VII of this document) on the information collection provisions. Two paper copies of any comments are to be submitted, 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.

X. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. OIG, HHS, ''Institutional Review Boards: A Time for Reform,'' June 1998.

List of Subjects in 21 CFR Part 56

Human research subjects, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 56 be amended as follows:

PART 56—INSTITUTIONAL REVIEW BOARDS

1. The authority citation for 21 CFR part 56 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

§ 56.102 [Amended]

2. Section 56.102 is amended in paragraph (b)(12) by removing the phrase ''parts 812 and 813'' and by adding in its place the phrase ''part 812.''

3. Section 56.106 is added to subpart A to read as follows:

§ 56.106 Registration.

(a) *Who must register*? Each IRB in the United States that reviews clinical investigations regulated by FDA under section 505(i) or 520(g) of the act and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products must register at a site maintained by the Department of Health and Human Services (HHS). (A research permit under section 505(i) of the act is usually known as an investigational new drug application (IND), while a research permit under section 520(g) of the act is usually known as an investigational device exemption (IDE).) An individual authorized to act on the IRB's behalf must submit the registration information.

(b) *What information must an IRB register*? Each IRB must provide the following information:

(1) The name and mailing address of the institution operating the IRB and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB;

(2) The IRB's name, the names of each IRB chair person and each contact person (if one exists) for the IRB, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address;

(3) The number of active protocols (small, medium, or large) involving FDA-regulated products reviewed (both initial reviews and continuing reviews). For purposes of this regulation, an ''active protocol'' is any protocol for which an IRB conducted an initial or continuing review during the preceding calendar year. A ''small'' number of protocols is 1 to 25 protocols; ''medium'' is 26 to 499 protocols, and ''large'' is 500 protocols or more;

(4) A description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews; and

(5) An indication whether the IRB is accredited and, if so, the date of the last accreditation and the name of the accrediting body or organization.

(c) *When must an IRB register*? Each IRB must submit an initial registration within 30 days before the date when the IRB intends to review clinical investigations regulated by FDA. Each IRB must renew its registration every 3 years. IRB registration becomes effective when HHS posts that information on its Web site.

(d) *Where can an IRB register*? Each IRB may register electronically through [Web site address to be added in the final rule]. If an IRB lacks the ability to register electronically, it must send its registration information, in writing, to [mailing address to be added in the final rule].

(e) *How does an IRB revise its registration information*? If an IRB's contact or chair person information changes, the IRB must revise its registration information by submitting any changes in that information within 90 days of the change. An IRB's decision to disband or to discontinue reviewing clinical investigations regulated by FDA is a change that must be reported within 30 days of the change. All other information changes may be reported when the IRB renews its registration. The revised information must be sent either electronically or in writing in accordance with paragraph (d) of this section.

Dated: June 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15131 Filed 7–2–04; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

RIN 1024–AD14

Delaware Water Gap National Recreation Area, Pennsylvania and New Jersey; U.S. Route 209 Commercial Vehicle Fees

AGENCY: National Park Service, Interior.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Park Service (NPS) proposes to change the fee schedule for those commercial vehicles permitted to travel U.S. Route 209 through Delaware Water Gap National Recreation Area. This paragraph sets a fee schedule by number of axles. It also lists the exceptions to commercial fee requirements. Congress authorized collection of the fees to establish a sustainable program to manage commercial traffic. In recent years, the cost of fee collection has been significantly greater than annual revenue. The intent of the proposed rule is to increase fees to a level that will allow the program to be completely supported by commercial entities using the route.

DATES: Comments must be submitted on or before August 5, 2004.

ADDRESSES: Address all comments concerning this proposed rule to the Chief Ranger's Office, Delaware Water Gap National Recreation Area, River Road, Bushkill, PA 18324.

You may submit comments by sending electronic mail (E-mail) to: *DEWA_Public_Comment@nps.gov*.

FOR FURTHER INFORMATION CONTACT: Chief Ranger Philip Selleck, at 570–588–2414.

SUPPLEMENTARY INFORMATION:

Commercial Use Background

On March 14, 1983, the Commonwealth of Pennsylvania transferred ownership of approximately 21 miles of U.S. Route 209 within the boundaries of Delaware Water Gap National Recreation Area to the National Park Service. This portion of road was a heavily traveled commercial vehicle route between Interstates 80 and 84, primarily because it is shorter and flatter and more direct than the alternate routes, and therefore was preferred by the commercial vehicle operators. Since § 5.6 of Title 36 Code of Federal Regulations (36 CFR 5.6), prohibits the use of roads within National park areas by commercial through traffic, the National Park Service announced that U.S. Route 209 would be closed to commercial vehicles on April 25, 1983. Due to negative comments from the trucking industry concerning the announced closure, the NPS Director, on April 23, 1983, announced a 180-day delay in the implementation of the closure.

On July 30, 1983, Congress enacted Public Law 98–63, closing U.S. Route 209 to commercial vehicle use, with certain exceptions, and directed the National Park Service to establish a commercial operation fee for certain commercial vehicles excepted from the closure. In order to implement the statute, Delaware Water Gap National Recreation Area began operation of two commercial vehicle check stations, one each near the North and South entrances to the recreation area on U.S. Route 209. The check stations were operated 24 hours a day.

Public Law 98–63, as amended by Public Law 98–151 and Public Law 99–88, closed U.S. Route 209 to all commercial vehicles except:

(1) Those vehicles operated by businesses based within the recreation area;

(2) Those vehicles operated by businesses which as of July 30, 1983, operated a commercial vehicular facility in Monroe, Pike, or Northampton Counties, PA, and the vehicle operation originates or terminates at such facility;

(3) Those vehicles operated in order to provide services to businesses and persons located in or contiguous to the boundaries of the recreation area, that area determined to be composed of Lehman, Delaware, Milford, Dingman, Stroud, Westfall, Smithfield, Middle Smithfield and Upper Mount Bethel townships in Pennsylvania;

(4) Up to 125 northbound, and 125 southbound, commercial vehicles serving businesses and persons in Orange, Ulster, Rockland and Sullivan Counties, New York.

The exceptions to the closure of U.S. Route 209 were to remain in effect unless further action was taken by Congress.

Under the Omnibus Parks and Public Lands Management Act of 1996, Public