

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-D-0035]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to the Center for Veterinary Medicine**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 1, 2010.

**ADDRESSES:** 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: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All

comments should be identified with the OMB control number 0910-0450. Also include the FDA docket number found in brackets in the heading of this document

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Guidance for Industry on How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to The Center for Veterinary Medicine—(OMB Control Number 0910-0450)—Extension**

Section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act), gives FDA the authority to set conditions under which animals treated with investigational new animal drugs may be marketed for food use. Under this authority, FDA's Center for Veterinary Medicine (CVM) issues to a new animal drug sponsor (sponsor) a slaughter authorization letter that sets the terms under which animals treated with investigational new animal drugs may be slaughtered. The U.S. Department of

Agriculture (USDA), also monitors the slaughter of animals treated with investigational new animal drugs under the authority of the Meat Inspection Act (21 U.S.C. 601-95). Sponsors must submit slaughter notices each time animals treated with investigational new animal drugs are presented for slaughter, unless this requirement is waived by an authorization letter (21 CFR 511.1(b)(5) and 9 CFR 309.17). These notifications assist CVM and USDA in monitoring the safety of the food supply. Slaughter notices were previously submitted to CVM and USDA in paper format. CVM's guidance on "How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to the Center for Veterinary Medicine" provides sponsors with the option of submitting a slaughter notice to CVM and USDA via the Internet as an e-mail attachment. The electronic submission of slaughter notices is part of CVM's ongoing initiative to provide a method for paperless submission. The likely respondents are new animal drug sponsors.

In the **Federal Register** of February 5, 2010 (75 FR 6034), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Section of the act/ FDA Form Number	Number of Respondents	Annual Frequency of Responses	Total Annual Responses <sup>2</sup>	Hours per Response	Total Hours
512j/3488	40	0.4	16	.08	1.3

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Electronic submissions received between January 1, 2008, and December 31, 2008.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (40). The number of total annual responses are based on a review of the actual number of submissions made between January 1, 2008, and December 31, 2008. Sixteen total annual responses times .08 hours per response = 1.3 total hours.

Submitting a slaughter notice electronically represents an alternative to submitting a notice on paper of intent to slaughter. The reporting burden for compilation and submission on paper of this information is included in OMB clearance of the information collection provisions of 21 CFR 511.1 (OMB number 0910-0450). The estimates in table 1 of this document reflect the burden associated with putting the same

information on FDA Form 3488, and resulted from previous discussions with sponsors about the time necessary to complete this form.

Dated: April 27, 2010.  
**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*  
 [FR Doc. 2010-10084 Filed 4-29-10; 8:45 am]  
**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-D-0600]

**Guidance for Industry on Tobacco Health Document Submission; Availability; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 20, 2010 (75 FR 20606). The notice announced the availability of a guidance entitled "Tobacco Health Document

Submission.” The notice published with an inadvertent error in the **ADDRESSES** section. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:**

Joyce A. Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20957, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2010-9134, appearing on page 20606, in the **Federal Register** of Tuesday, April 20, 2010, the following correction is made:

1. On page 20606, in the second column, in the **ADDRESSES** section, the second sentence is corrected to read: “Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent.”

Dated: April 27, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-10160 Filed 4-29-10; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-D-0263]

**Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc); Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc),” dated May 2010. The guidance document provides recommendations to establishments that collect Whole Blood or blood components intended for transfusion, with recommendations for a requalification method or process for reentering deferred donors into the donor pool based on a determination that previous tests that were repeatedly reactive for antibodies to hepatitis B core antigen (anti-HBc) were falsely positive and that there is no evidence of infection with hepatitis B virus (HBV). These recommendations are based on the recent availability of FDA-licensed

hepatitis B virus nucleic acid tests (HBV NAT) that are particularly sensitive when single samples are tested. These tests provide an additional, powerful method of determining whether a donor who has been deferred because of anti-HBc reactivity is truly infected by HBV. The guidance announced in this notice finalizes the draft guidance of the same title dated May 2008.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a document entitled “Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc),” dated May 2010. The guidance document provides recommendations to establishments that collect Whole Blood or blood components for a requalification method or process for the reentry of deferred donors into the donor pool based on a determination that previous tests that were repeatedly reactive for anti-HBc were falsely positive and that there is no evidence of infection with HBV. Currently, donors who are repeatedly reactive on more than one occasion for anti-HBc (samples from more than one collection from the donor are repeatedly reactive for anti-HBc) must be indefinitely deferred in

accordance with current regulations. Situations have occurred with some frequency in which two anti-HBc tests are false positives because of the relative non-specificity of these tests. The result is that many otherwise suitable donors are indefinitely deferred because of their anti-HBc test results even though medical follow-up of such donors indicates that they are not infected with HBV. FDA-licensed HBV NAT assays, which are particularly sensitive when single samples are tested, are now available and provide an additional, powerful method of determining whether a donor who has been deferred because of anti-HBc reactivity is truly infected by HBV. Due to the availability of FDA-licensed HBV NAT assays and the improved specificity of anti-HBc assays, FDA is recommending in the guidance a reentry algorithm for donors deferred due to falsely positive repeatedly reactive tests for anti-HBc.

In the **Federal Register** of May 21, 2008 (73 FR 29519), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated May 2008.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910-0338.

**III. Comments**

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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