Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements contained in this AD and has assigned OMB Control Number 2120–0056.

(1) If the inspection was done on or before the effective date of this AD: Send the report within 30 days after the effective date of this AD.

(2) If the inspection was done after the effective date of this AD: Send the report within 30 days after the inspection is done.

**Alternative Methods of Compliance (AMOCs)**

(m)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Ivan Li, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle ACO, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6437; fax (425) 917–6590; Or, e-mail information to *9–ANM–Seattle–ACO–AMOC–Requests@faa.gov.*

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Issued in Renton, Washington, on August 7, 2009.

**Stephen P. Boyd,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. E9–20382 Filed 8–24–09; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 803

**[Docket No. FDA–2008–N–0393]**

**RIN 0910–AF86**

## Medical Device Reporting: Electronic Submission Requirements

*Correction*

In proposed rule document E9–19683 beginning on page 42203 in the issue of Friday, August 21, 2009 make the following correction:

On page 42204, in the first column, under the **DATES** section, in the first line, ''November 19, 2009'' should read ''Submit written or electronic comments on the proposed rule by November 19, 2009''.

[FR Doc. Z9–19683 Filed 8–24–09; 8:45 am]

**BILLING CODE 1505–01–D**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 866

**[Docket No. FDA–2009–N–0344]**

## Microbiology Devices; Reclassification of Herpes Simplex Virus Types 1 and 2 Serological Assays

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its device classification regulations by correcting the regulation classifying herpes simplex virus (HSV) serological assays by removing the reference to HSV serological assays other than type 1 and type 2. When reclassifying this device, FDA mistakenly distinguished between HSV serological assays type 1 and type 2 and all other HSV serological assays. At that time, and today, the only preamendments HSV serological assays FDA was aware of were type 1 and type 2, and therefore, the classification of HSV assays other than type 1 and type 2 was incorrect. FDA is correcting the classification of this device to eliminate possible confusion resulting from this error. Elsewhere in this issue of the **Federal Register**, we are publishing a companion direct final rule. This proposed rule will provide a procedural framework to finalize the rule in the event we receive significant adverse comment and withdraw the direct final rule.

**DATES:** Submit written or electronic comments by November 9, 2009.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA–2009–N–0344, 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:

- *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.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions*: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. 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 ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket*: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), 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:** Scott McFarland, Center for Devices and Radiological Health WO/66, rm. 5543, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6217.

**SUPPLEMENTARY INFORMATION:**

### I. Why Is This Companion Proposed Rule Being Issued?

This proposed rule is a companion to the direct final rule correcting § 866.3305 (21 CFR 866.3305) by removing HSV serological assays other than type 1 and type 2 from the regulation. The direct final rule and this companion proposed rule are substantively identical. This companion proposed rule provides the procedural framework to finalize the rule in the event that the direct final rule receives any significant adverse comment and is withdrawn. We are publishing the direct final rule because we believe the rule is noncontroversial, and we do not anticipate receiving any significant adverse comments. If no significant

adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a confirmation document within 30 days after the comment period ends confirming when the direct final rule will go into effect.

If we receive any significant adverse comment regarding the direct final rule, we will withdraw the direct final rule within 30 days after the comment period ends and proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment rulemaking procedures under the Administrative Procedure Act (APA) (5 U.S.C. 552a *et seq.*). The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule and vice versa. We will not provide additional opportunity for comment. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the APA (5 U.S.C. 553).

Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule, and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

In the **Federal Register** of November 21, 1997 (62 FR 62466), you can find additional information about FDA's direct final rulemaking procedures in the guidance document entitled ''Guidance for FDA and Industry: Direct Final Rule Procedures.'' This guidance document may be accessed at *http://www.fda.gov/regulatoryinformation/guidances.htm.*

## II. What Is the Background of the Rule?

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), the Food and Drug Modernization Act of 1997 (FDAMA) (Public Law 105–115), and the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), are commonly referred to as ''preamendments devices.'' Under section 513 of the act, FDA classifies preamendments devices according to the following steps: (1) FDA receives a recommendation from a device classification panel (an FDA advisory committee); (2) FDA publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) FDA publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, are commonly referred to as ''postamendments devices.'' These devices are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f)) into class III and require premarket approval, unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act; or (3) FDA issues an order under section 513(i) of the act (21 U.S.C. 360c(i)) finding the device to be substantially equivalent to a predicate device that does not require premarket approval.

In the **Federal Register** of November 9, 1983 (47 FR 50823), FDA classified the preamendments devices, herpes simplex virus serological reagents, into class III (21 CFR 866.3305). At the time FDA classified the device, the only preamendments HSV serological assays FDA was aware of were type 1 and type 2 HSV serological assays. Since that time, FDA has not become aware of any other preamendments HSV serological assays, nor has it received a premarket notification for a HSV serological assay other than a type 1 or type 2 HSV serological assay.

In the **Federal Register** of April 3, 2007 (72 FR 15828), FDA published a final rule reclassifying the preamendments device HSV serological assays from class III to class II. In that rulemaking FDA identified the device being reclassified as type 1 and type 2 HSV serological assays and identified other HSV serological assays as class III devices. However, as stated previously, the only preamendments HSV serological assays which FDA is aware of are type 1 and type 2 HSV serological assays. To avoid any possible confusion, FDA is correcting the regulation to accurately describe this generic type of device. This proposed final rule corrects the classification regulation by removing the reference to HSV serological assays other than type 1 and type 2.

## III. What Does This Companion Proposed Rule Do?

In this proposed rule, FDA is correcting § 866.3305 by removing the reference to HSV serological assays other than type 1 and type 2 from the regulation.

## IV. What is the Legal Authority for This Proposed Rule?

FDA is issuing this proposed rule under the device and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 360i, 371, and 374).

## V. What is the Environmental Impact of This Proposed Rule?

FDA has determined under 21 CFR 25.30(i) and 21 CFR 25.34(b) 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.

## VI. What is the Economic Impact of This Proposed Rule?

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). The agency believes that this proposed rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we do not believe any companies are currently selling or producing these devices, the agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of 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 the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

### VII. How Does the Paperwork Reduction Act of 1995 Apply to This Proposed Rule?

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

### VIII. What Are the Federalism Impacts of This Proposed Rule?

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 Executive order and, consequently, a federalism summary impact statement is not required.

### IX. How Do You Submit Comments on This Proposed Rule?

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.

### List of Subjects in 21 CFR Part 866

Biologics, Laboratories, and Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed to amend 21 CFR part 866 as follows:

## PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

1. The authority citation for 21 CFR part 866 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 866.3305 is amended by removing paragraph (c) and by revising paragraph (b) to read as follows:

### § 866.3305 Herpes simplex virus serological assays.

* * * * *

(b) *Classification.* Class II (special controls). The device is classified as class II (special controls). The special control for the device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays.'' For availability of the guidance document, see § 866.1(e).

Dated: August 17, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9–20415 Filed 8–24–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE TREASURY

## Alcohol and Tobacco Tax and Trade Bureau

## 27 CFR Parts 40, 41, 44, and 45

**[Docket No. TTB–2009–0002; Notice No. 98; Re: Notice No. 95, T.D. TTB–78 and T.D. TTB–80]**

**RIN 1513–AB72**

## Implementation of Statutory Amendments Requiring the Qualification of Manufacturers and Importers of Processed Tobacco and Other Amendments Related To Permit Requirements, and the Expanded Definition of Roll-Your-Own Tobacco; Extension of Comment Period

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau, Treasury.

**ACTION:** Notice of proposed rulemaking; reopening of comment period.

**SUMMARY:** In response to a request filed on behalf of several industry members, the Alcohol and Tobacco Tax and Trade Bureau is reopening the comment period for Notice No. 95, a notice of proposed rulemaking published in the **Federal Register** on June 22, 2009. The proposed rule seeks comments on a concurrently published temporary rule implementing permit requirements for manufacturers and importers of processed tobacco and an expansion of the definition of roll-your-own tobacco adopted in the Children's Health Insurance Program Reauthorization Act of 2009. The text of the regulations contained in the temporary rule serves as the text of the proposed regulations.

**DATES:** The comment period for the proposed rule (Notice No. 95) published June 22, 2009, at 74 FR 29433 is reopened. Written comments on Notice No. 95 must now be received on or before October 20, 2009.

**ADDRESSES:** You may send comments on Notice No. 95 to one of the following addresses:

- *http://www.regulations.gov* (via the online comment form for Notice No. 95 as posted within Docket No. TTB–2009–0002 at ''Regulations.gov,'' the Federal e-rulemaking portal);
- Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044–4412; or
- *Hand Delivery/Courier in Lieu of Mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200–E, Washington, DC 20005.

See the Public Participation section of Notice No. 95 for specific instructions and requirements for submitting