

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.

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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]

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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