

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Docket No. 2005D-0468

**Guidance for Industry and Food and Drug Administration Staff; Class II
Special Controls Guidance Document: Herpes Simplex Virus Types 1 and
2 Serological Assays; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays." This guidance document describes a means by which herpes simplex virus type 1 and 2 (HSV 1 and 2) serological assays may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying these devices from class III (premarket approval) into class II (special controls).

DATES: Submit written or electronic comments on agency guidances at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr.,

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Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0496.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 9, 2006 (71 FR 1399), FDA published a proposed rule to reclassify herpes simplex virus types 1 and 2 serological assays from class III (premarket approval) into class II (special controls). In addition, FDA issued a draft class II special controls guidance document entitled “Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays” to support the proposed reclassification. Herpes simplex virus types 1 and 2 serological assays are in vitro diagnostic devices that test for specific antibodies. In conjunction with other clinical laboratory findings, the detection of these HSV type 1 and/or 2 -specific antibodies aids in the clinical laboratory diagnosis of an acute or past infection by HSV type 1 and/or 2. FDA did not receive any comments on the proposed reclassification. FDA is now identifying the guidance document entitled “Class

II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays” as the guidance document that will serve as the special control for these devices.

The guidance document provides a means by which herpes simplex virus types 1 and 2 serological assays may comply with the requirement of special controls for class II devices. Following the effective date of the final reclassification rule, any firm submitting a premarket notification (510(k)) for herpes simplex virus type 1 and 2 serological assays will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on herpes simplex virus types 1 and 2 serological assays. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive “Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays” you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1305 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. 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 part 807 subpart E have been approved under OMB Control No. 0910–0120; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB Control No. 0910–0485.

V. Comments

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. The guidance and received comments may be seen in the

Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 3/23/07
March 23, 2007



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Center for Devices and Radiological Health.

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