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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0468]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays;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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ``Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays.'' This draft guidance document

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describes a means by which herpes simplex virus types 1 and/or 2 (HSV 1 and/or 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 proposed rule to reclassify these devices from class III into class II (special controls).

DATES: Submit written or electronic comments on this draft guidance by April 10, 2006.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the draft guidance document entitled ``Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays'' to the Division of Small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., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to

301-443-8818. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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, 301-594-2096.

SUPPLEMENTARY INFORMATION:

I. Background

FDA developed this draft guidance document as a special control to support the classification of in vitro diagnostic devices for the laboratory diagnosis of herpes simplex virus (HSV) infection into class II (special controls). HSV (types 1 and/or 2) serological assays are intended for testing specimens from individuals who have signs and symptoms of infection consistent with HSV 1 and/or 2; determining if an individual has been previously infected with HSV 1 and/or 2; or providing epidemiological information about these infections. The detection of these antibodies aids in the clinical diagnosis of an infection by HSV 1 and/or 2 in conjunction with other clinical laboratory findings.

This draft guidance document identifies the classification regulation and product codes for HSV 1 and/or 2 serological assays. In addition, other sections of this guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these assays and lead to a timely premarket notification (510(k)) review and clearance. This document supplements other FDA documents regarding the specific content of a premarket notification submission.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on class II special controls for HSV 1 and/or 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

To receive ``Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays'' by fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1305) followed by the pound sign (). Follow the remaining voice prompts to complete your request.

To receive ``Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays,'' you may either send a fax request to 301-443-8818 to receive a hard copy of the document, or send an e-mail request to gwa@cdrh.fda.gov to receive a hard copy or an electronic copy. Please use the document number (1305) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. 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 draft 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 807.87 have been approved under OMB Control No. 0910-0120; the collections of information in 21 CFR 801.109 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 21, 2005.
Linda S. Kahan,
Deputy Director, Center for Devices and Radiological Health.
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