

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Display Date	11 21 00
Publication Date	11 22 00
Certifier	<i>[Signature]</i>

Food and Drug Administration

[Docket No. 00D-1566]

Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications; 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 “Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications.” Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule classifying ASCA devices into class II. FDA is issuing this guidance to provide a means by which ASCA devices may comply with the requirements of class II special controls.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5” diskette of the guidance document entitled “Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications” to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading

of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Deborah M. Moore, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293.

SUPPLEMENTARY INFORMATION:

I. Background

ASCA is a test system intended to measure *S. cerevisiae* antibodies in human serum or plasma as an aid in the diagnosis of Crohn's disease. The guidance sets forth the risk associated with this generic type of device, and lists recommendations for submission of a premarket notification. Designation of this guidance as a special control means that manufacturers of ASCA devices who comply with either the recommendations of this guidance or some alternate means that provide equivalent assurance of safety and effectiveness will be able to market their device after they have submitted a premarket notification (510(k)) and received a finding of substantial equivalence for their device. The guidance focuses on the following issues: Labeling, design controls, and clinical information. FDA believes that this special control, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness for this type of device.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the submission of premarket notifications for ASCA test systems. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (65 FR

56468, September 19, 2000). This guidance document is issued as a Level 2 guidance consistent with GGP's.

III. Electronic Access

In order to receive "Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications" via your fax machine, call the CDRH Facts-on-Demand system at 800-899-0381 or 301-827-0111 from a touchtone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1183) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so 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 access to the Internet. Updated on a regular basis, the CDRH home page includes "Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for *Anti-Saccharomyces cerevisiae* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

IV. Comments

Interested persons may, at any time, submit written comments regarding the guidance to the Dockets Management Branch (address above). Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and

received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/9/00
November 9, 2000

Linda S. Kahan

Linda S. Kahan
Deputy Director for Regulations Policy
Center for Devices and Radiological Health

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

[Signature]

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F