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: November 9, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–29842 Filed 11–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00D–1557 and 00D–1558]

Guidance Documents for Premarket Notification (510(k)) Submissions for Indwelling Blood Gas Analyzers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two guidance documents. These two guidance documents are intended to serve as special controls for three devices that FDA has proposed previously to reclassify from class III (premarket approval) to class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on the proposed reclassification of the three devices. FDA is now inviting comment on these two guidance documents because they were not available for comment at the time of the publication of the proposed reclassification.

DATES: Submit written comments on the agency guidances by February 20, 2001.

ADDRESSES: Submit written comments on the agency guidances 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 for the appropriate guidance document found in table 1. Submit written requests for single copies on a 3.5″ diskette of one or both of these guidance documents 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 15, 1999 (64 FR 12774), FDA published a proposed rule to reclassify 38

preamendments class III devices into class II and to establish special controls for these devices. FDA invited interested persons to comment on the proposed rule by June 14, 1999. FDA received one request to reopen the comment period for six devices. The request noted that FDA had not made the guidance documents that were proposed as special controls for these six devices available for comment through FDA's good guidance practices (GGP's) (65 FR 56468, September 19, 2000). The request further noted that it was impossible to comment on the proposed reclassification without the guidance documents being available. Therefore, the requester asked that FDA extend the comment period until at least 90 days after the guidance documents are publicly available. FDA agreed with the request. FDA also identified three additional devices for which the agency had not issued the guidance documents proposed as special controls in accordance with the GGP policy. These three devices are the Indwelling Blood Carbon Dioxide Partial Pressure (P_{co2}) Analyzer (21 CFR 868.1150), the Indwelling Blood Hydrogen Ion Concentration (pH) Analyzer (21 CFR 868.1170), and the Indwelling Blood Oxygen Partial Pressure (P_{02}) Analyzer (21 CFR 868.1200).

The agency is announcing the availability of the two guidance documents (with separate docket numbers) for these three additional devices; the guidance documents, with their docket numbers, and Facts-on-Demand (FOD) numbers are as follows:

TABLE 1.

Name of Guidance	Docket Number	Facts-on-Demand Number
Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions	00D–1557	1126
Guidance for Electrical Safety, Electromagnetic Compatibility and Mechanical Testing for Indwelling Blood Gas Analyzer Premarket Notification Submissions	00D–1558	1161

II. Significance of Guidance Documents

These guidance documents represent the agency's current thinking on premarket notifications for these devices. These guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. Under FDA's GGP policy, each of these guidance documents is a Level 2 guidance.

III. Electronic Access

In order to receive these guidance documents via your fax machine, call the CDRH FOD 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 listed above followed by the pound sign (#). Follow the remaining voice prompts to complete your request. Persons interested in obtaining a copy of these guidance documents may 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 access to the Internet. Updated on a regular basis, the CDRH home page includes these guidance documents, 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 submit to the Dockets Management Branch (address above) written comments regarding these guidance documents by February 20, 2001. 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 for the guidance document as listed in table 1. If you wish to comment on more than one guidance document, please submit your comments separately for each guidance document. The guidance documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 31, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–29840 Filed 11–21–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (60 FR 56605 as amended November 6, 1995, as last amended at 65 FR 48007, dated August 4, 2000).

This notice reflects the change in the organizational structure of the Maternal and Child Health Bureau (RM).

Establish the Office of Communications (RM8)

The Office of Communications plans, designs, executes and evaluates national and international communication and information dissemination programs which include the development of written and broadcast materials conveying complex information about the Maternal and Child Health Bureau, the maintenance of effective working relationships with high-level public and private sector policy makers and development of recommendations to improve MCHB program effectiveness. Specifically: (1) From various public and private sources, collects, translates, interprets and distributes for public use, information on maternal and child health care legislation, innovations, research and data trends; (2) develops and provides information materials to MCHB health program planners, providers, consumers and others to assist in decision making and maintaining effective, efficient operations; (3) develops and produces in-house communications to help ensure the understanding of current maternal and child health issues and Bureau program objectives; (4) fosters and maintains relationships with and provides a referral service to Federal agencies, State and local governmental units, private health and medical organizations, and other organizations with which the Bureau has mutual interests; (5) provides technical assistance to Bureau program managers and project officers in identifying maternal and child health information