

application for license as Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR 515).

Persons knowing of any reason why the following applicant should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Ocean Freight Forwarder—Ocean Transportation Intermediary Applicant: MTS Logistics, Inc., 390 Fifth Avenue, Suite 701, New York, NY 10018, Officers: Sedat Saka, President (Qualifying Individual), Timur Fidan, Secretary.

Dated: November 16, 2000.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 00–29820 Filed 11–21–00; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

TIME AND DATE: 11:00 a.m., Monday, November 27, 2000.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: November 17, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–29942 Filed 11–17–00; 4:12 pm]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0040]

Submission for OMB Review; Comment Request Entitled Application for Shipping Instructions and Notice of Availability

AGENCY: Federal Supply Service, GSA.

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance (3090–0040).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Office of Acquisition Policy has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Application for Shipping Instructions and Notice of Availability. **DATES:** Comment Due Date: January 22, 2001.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, should be submitted to: Marjorie Ashby, General Services Administration (MVP), 1800 F Street NW., Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Marcia Crockett, Acquisition Operations & Electronic Commerce Center, Supply Management Division, (703) 305–7551.

SUPPLEMENTARY INFORMATION:

A. Purpose

The GSA is requesting the Office of Management and Budget (OMB) to approve information collection, 3090–0400, concerning Application for Shipping Instructions and Notice of Availability. This information collection supports and justifies the markup of the six percent surcharge for the GSA export reimbursable program. It also is used to evaluate and obtain the best cube utilization of shipping vans and containers for export direct delivery shipments. The form contains data necessary to prepare Transportation Control and Movement Documents (TCMD) which are required when material enters the Defense Transportation System.

B. Annual Reporting Burden

Respondents: 360; *Annual responses:* 3,000; *average hours per response:* .20; *burden hours:* 1,000.

Copy of Proposal

A copy of this proposal may be obtained from the GSA Acquisition

Policy Division (MVP), Room 4011, GSA Building, 1800 F Street NW., Washington, DC 20405, or by telephoning (202) 501–3822, or by faxing your request to (202) 501–3341.

Dated: November 15, 2000.

David A. Drabkin,

Deputy Associate Administrator, Office of Acquisition Policy.

[FR Doc. 00–29850 Filed 11–21–00; 8:45 am]

BILLING CODE 6820–61–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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: 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