ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Theodore R. Stevens, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION: On December 24, 1996, Avanta Orthopaedics Corp., San Diego, CA 92121, submitted to CDRH an application for premarket approval of the Braun-Cutter Trapezo-metacarpal Prosthesis. The device is a finger joint metal/polymer cemented prosthesis and is indicated for total joint replacement in skeletally mature patients with pain or instability of the trapezo-metacarpal joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

On June 9, 1997, the Orthopedics and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 19, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details. Petitioners may, at any time on or before October 23, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 26, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–25127 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0392]

Mallinckrodt, Inc.; Premarket Approval of Albunex®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the supplemental application by Mallinckrodt, Inc., St. Louis, MO, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Albunex® . After reviewing the recommendation of the Radiological Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 17, 1997, of the approval of the supplemental application.

DATES: Petitions for administrative review by October 23, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212.

SUPPLEMENTARY INFORMATION: On September 3, 1995, Mallinckrodt, Inc., St. Louis, MO 63134, submitted to CDRH a supplemental application for premarket approval of Albunex . The device is an ultrasound contrast agent and is indicated for use with transvaginal ultrasound to assess fallopian tube patency.

On February 24, 1997, the Radiological Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the supplemental application. On June 17, 1997, CDRH approved the supplemental application by a letter to the applicant from the Deputy Director of Clinical and Review Policy of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for

resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before October 23, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 26, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–25180 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0318]

Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products; Guidance Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products,'' dated December 11, 1996. The guidance document is intended to provide recommendations to the blood industry and may include information useful to other interested persons.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled ''Revised Precautionary Measures to Reduce the Possible Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products,'' dated December 11, 1996, and sent to all registered blood and plasma establishments and all establishments engaged in manufacturing plasma derivatives.

The guidance document updates and supersedes the FDA guidance documents of August 8, 1995, entitled ''Disposition of Products Derived from Donors Diagnosed with, or at Known High Risk for, Creutzfeldt-Jakob Disease'' and ''Precautionary Measures to Further Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease by Blood and Blood Products,'' and the November 25, 1987, guidance document entitled ''Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone.''

The guidance document presents recommendations for donor deferral, product disposition, recipient notification, and labeling. The recommendations were developed after considering donor and product risk factors and the impact such recommendations could have on the availability of blood and blood products. Topics addressed in the guidance document include: (1) Recommended questions that will help identify donors at an increased risk for CJD; (2) recommended actions to take when a donor is identified to be at an increased risk for developing CJD; (3) recommended actions to take when a donor is subsequently diagnosed with CJD; (4) recommendations for recipient notification and counseling; (5) recommendations for disposition of implicated products; and (6) recommendations for the labeling of implicated products intended for research or further manufacture into non-injectable products. The guidance document also includes FDA's recommendations regarding ''lookback'' notification of persons possibly exposed to CJD contaminated blood or blood products.

As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. It is intended to provide recommendations and does not set forth requirements. In response to public comment, development of suitable alternatives or other new information, FDA may revise the guidance document at anytime to improve its usefulness. Any revisions to this guidance document will be announced in the **Federal Register**. The recommendations in the guidance document represent the agency's current thinking on precautionary measures to use to reduce the possible transmission of CJD by blood and blood products. 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, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance document. 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. Any comments previously submitted to the Division of Blood Applications (HFM–370), CBER, FDA, do not have to be resubmitted. Comments previously submitted will be filed with the Dockets Management Branch (address above) under the docket number in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determining whether further revision is warranted.

Persons with access to the Internet may obtain the guidance document