FEE SCHEDULE JANUARY 1, 1998—SEPTEMBER 30, 1998

Vessel size (GRT[1])	Inspection[2]	Consultation
Extra Small (< 3,001)	$ 1,075	$ 3,225
Small (3,001–15,000)	$ 2,150	$ 6,450
Medium (15,001–30,000)	$ 4,300	$12,900
Large (30,001–60,000)	$ 6,450	$19,350
Extra Large (60,001–90,000	$ 8,600	$25,800
Mega (>90,000)	$10,750	$32,250

[1] GRT-Gross Register Tonnage in cubic feet, as shown in Lloyd's Register of Shipping.
[2] Inspections and reinspections involve the same procedure, require the same amount of time, and will, therefore, be charged at the same rate.

Appendix B

Sample

Fax to: Henry Falk, M.D., Director, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., (F28), Atlanta, GA 30341–3724 Facsimile (770) 488–4127

Fax copy to: Program Manager, Vessel Sanitation Program, Special Programs Group, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., (F16), Atlanta, GA 30341–3724, Facsimile (770) 488–4127

We request the presence of a DHHS representative for consultation on cruise liner (NAME). We tentatively expect to take delivery of the cruise liner on (DATE). We would like to schedule the consultation for (DATE). We expect the consultation to take approximately (NUMBER OF DAYS).

We will pay CDC in accordance with the consultation fee published in the **Federal Register**, and for all expenses in connection with the shipyard inspection. We will make all necessary arrangements for lodging and transportation, which includes airfare and ground transportation in (CITY, STATE, COUNTRY). We will provide in-kind for lodging and transportation expenses. All remaining expenses, such as en route per diem and meals and miscellaneous expenses, including ground transportation to and from the airport nearest the representatives work site or residence, should be sent to the following address:

Company
Attention:
Street Address
City, State, Country
Zip Code
Office Telephone Number
Facsimile Number

If you have questions regarding this confirmation, please contact:

Signed:

[FR Doc. 97–30056 Filed 11–14–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 97N–0263 and 87N–0262]

European Research Associates, Ltd. et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new drug applications (NDA's). The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports on these NDA's.

EFFECTIVE DATE: November 17, 1997.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs or antibiotics for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of July 10, 1997 (62 FR 37063), FDA offered an opportunity for a hearing on a proposal to withdraw approval of four NDA's because the firms had failed to submit the required annual reports for these NDA's.

The agency received one request for a hearing from Global Pharmaceutical Corp., Castor and Kensington Aves., Philadelphia, PA 19124–5694. Global has filed an annual report for NDA 9–273, Rauwolfia Serpentina Tablets, 50 and 100 milligram (mg). Therefore, approval of this NDA is not being withdrawn.

The holders of the other three applications did not respond to the notice of opportunity for hearing. Failure to file a written notice of participation and request for a hearing as required by 21 CFR 314.200 constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the NDA's listed in the table in this document.

Application No.	Drug	Applicant
NDA 11–623	Mucilose Super Powder	European Research Associates, Ltd., Pailinakis Bldg., Elisabeth Ave., P.O. Box N3334, Nassau, N.P., Bahamas.
NDA 12–748	Duotrate (pentaerythritol tetranitrate) Capsules, 45 mg	Jones Medical Industries, Inc., 1945 Craig Rd., St. Louis, MO 63146.
NDA 16–470	Duotrate (pentaerythritol tetranitrate) Capsules, 30 mg	Do.

The last two products listed, NDA's 12–748 and 16–470, were named in a notice of opportunity for hearing published in the **Federal Register** of October 14, 1984 (49 FR 40213), proposing to withdraw the applications, along with other applicants' products, because they lack substantial evidence of effectiveness. In response to that notice, hearings were requested and a hearing was granted (52 FR 32170; August 26, 1987); Jones Medical, the

successor in interest to NDA's 12–748 and 16–470, filed a Notice of Participation; on May 10, 1989, the Administrative Law Judge issued his Initial Decision, ordering that NDA's 12–748 and 16–470, and others, be withdrawn; Jones Medical, as well as two other parties, appealed that decision to the Commissioner. On the basis of the present withdrawal of approval of NDA's 12–748 and 16–470 for failing to file required annual reports, the appeal by Jones Medical in Docket No. 87N–0262 is regarded as withdrawn.

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority of 21 CFR 5.82, finds that the holders of the applications listed above have repeatedly failed to submit reports required by § 314.81. Therefore, under this finding, approval of the NDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective November 17, 1997.

Dated: November 6, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–30148 Filed 11–14–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0459]

Osteonics Corp.; Premarket Approval of the Osteonics Constrained Acetabular Insert

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Osteonics Corp., Allendale, NJ, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Osteonics Constrained Acetabular Insert. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 13, 1997, of the approval of the application.

DATES: Petitions for administrative review by December 17, 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: Erin I. Keith, 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 16, 1996, Osteonics Corp., Allendale, NJ 07401–1677, submitted to CDRH an application for premarket approval of the Osteonics Constrained Acetabular Insert. The device is a constrained hip and is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

On June 10, 1997, the Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 13, 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 (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 December 17, 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: October 16, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–30149 Filed 11–14–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting of Board of Scientific Counselors

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Eye Institute, December 8 and 9, 1997 in Building 10, Room 10B16, National Institutes of Health, Bethesda, Maryland.

This meeting will be open to the public on December 8 from 9 a.m. until approximately 10 a.m. for general remarks by the Director, Intramural Research Program, National Eye Institute (NEI), on matters concerning the intramural program of the NEI. Attendance by the public will be limited to space available.

In accordance with provisions set forth in section 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, the meting will be closed to the public on December 8 from approximately 10 a.m. until recess and