DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0070]

Hedviga Herman; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Ms. Hedviga Herman, 1326 42d St., Brooklyn, NY 11219, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Herman was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Ms. Herman has failed to request a hearing and, therefore, has waived her opportunity for a hearing concerning this action.

EFFECTIVE DATE: October 17, 1997.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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

SUPPLEMENTARY INFORMATION:

I. Background

On September 23, 1994, the United States District Court for the District of Maryland entered judgment against Ms. Hedviga Herman for, among other counts: (1) One count of introducing adulterated drugs into interstate commerce, a Federal felony offense under 21 U.S.C. 331(a) and 333(a)(2); (2) one count of introducing unapproved new drugs into interstate commerce, a Federal felony offense under 21 U.S.C. 331(d) and 333(a)(2); and (3) one count of obstruction of an agency proceeding, a Federal felony offense under 18 U.S.C. 1505.

As a result of these convictions, FDA served Ms. Herman by certified mail on February 20, 1996, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application, and offered her an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that she was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Ms. Herman was provided 30 days to file objections and request a hearing. Ms. Herman did not request a hearing. Her failure to request a hearing constitutes a waiver of her opportunity for a hearing and a waiver of any contentions concerning her debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Ms. Hedviga Herman has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Ms. Hedviga Herman is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective October 17, 1997 (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Ms. Herman, in any capacity, during her period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Ms. Herman, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Herman during her period of debarment.

Any application by Ms. Herman for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 95N–0070 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 1, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–27586 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0421]

Yoshitomi Fine Chemicals, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Yoshitomi Fine Chemicals, Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of Di-tert-butylcresyl phosphonite condensation product with biphenyl for use as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7B4557) has been filed by Yoshitomi Fine Chemicals, Ltd., 6–9 Hiranomachi 2-chome, Chuo-ku, Osaka 541, Japan. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of Di-tert-butylcresyl phosphonite condensation product with biphenyl,produced by the condensation of 2,4-di-tert-butylcresol with the Friedel-Crafts addition product of phosphorous trichloride and biphenyl,for use as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 23, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–27532 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on November 19 and 20, 1997, 8 a.m. to 5:30 p.m.; and November 21, 1997, 8 a.m. to 2 p.m.

Location: Holiday Inn, Versailles Ballrooms III and IV, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Ermona B. McGoodwin or Danyiel A. D'Antonio, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 19, 1997, the committee will discuss issues relating to the development of fluoroquinolones for use in pediatric patients. On the morning of November 20, 1997, the committee will discuss new drug application (NDA) 50–585/S046, ceftriaxone sodium (Rocephin® sterile vials, Roche Laboratories) for single dose intramuscular treatment of acute otitis media. On the afternoon of November 20, 1997, the committee will discuss NDA 20–799, ofloxacin otic (Floxin®, Daiichi Pharmaceuticals) for treatment of otitis externa, chronic suppurative otitis media with perforated tympanic membrane, and acute otitis media in pediatric patients with tympanostomy tubes. On November 21, 1997, the committee will discuss NDA 50–753, tobramycin solution for inhalation (TOBI®, PathoGenesis Corp.) for the management of cystic fibrosis patients.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 12, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 19 and 20, and between approximately 11 a.m. and 12 m. on November 21. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27530 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on regulatory issues.

Date and Time: The meeting will be held on November 18 and 19, 1997, 8:30 a.m. to 5 p.m.

Location: Quality Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Ermona McGoodwin or Danyiel D'Antonio, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 18, 1997, the Committee will discuss the evidence of safety and effectiveness in new drug application (NDA) 20–861, Prosynap (lubeluzole injection, Janssen Research Foundation) for the treatment of acute ischemic stroke in adults. On November 19, 1997, the Committee will discuss the evidence of safety and effectiveness in NDA 20–764, Lamictal CD Chewable Dispersible Tablets (lamotrigine, Glaxo Wellcome) for the treatment of the generalized seizures of Lennox-Gastaut syndrome in pediatric and adult patients.

Procedure: Interested persons may present data, information, or views, orally, or in writing, on issues pending before the Committee. Written submissions may be made to the contact person by November 12, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 18, 1997, and between 9 a.m. and 10 a.m. on November 19, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.2).

Dated: October 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27529 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.