

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 debaring 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.

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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.