which uses him in any capacity on PHS supported research must concurrently submit a plan for supervision of his duties. The supervisory plan must be designed to ensure the scientific integrity of Mr. Portuese's research contribution. The institution must submit a copy of the supervisory plan to ORI.

No scientific publications were required to be corrected as part of this Agreement.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. 97–8347 Filed 4–1–97; 8:45 am]

BILLING CODE 4160–17–P

Food and Drug Administration

[Docket No. 94N–0011]

Barry D. Garfinkel; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) denies Dr. Barry D. Garfinkel's request for a hearing and issues a final order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Barry D. Garfinkel, 2854 Glenhurst Ave., St. Louis Park, MN 55416, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on its finding that Dr. Garfinkel was convicted of a felony under Federal law for conduct relating to the development or approval of a drug product and for conduct relating to the regulation of a drug product under the act.

EFFECTIVE DATE: April 2, 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: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On November 19, 1993, the United States District Court for the District of Minnesota entered judgment against Barry D. Garfinkel for, among other counts, 3 counts of making a false statement in a matter within the jurisdiction of FDA, a Federal felony offense under 18 U.S.C. 1001. The basis for this conviction was Dr. Garfinkel's falsification of reports to conceal his failure to comply with the protocols of a clinical study of the drug Anafranil. Dr. Garfinkel's conviction was affirmed by the Eighth Circuit Court of Appeals on July 13, 1994.

As a result of this conviction, FDA served Dr. Garfinkel by certified mail on February 7, 1995, a letter proposing to issue an order under section 306(a) of the act (21 U.S.C. 335a(a)) permanently debarring him from providing services in any capacity to a person that has an approved or pending drug product application and offering him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(A) and (a)(2)(B) of the act, that Dr. Garfinkel was convicted of a felony under Federal law for conduct relating to the development, approval, and regulation of a drug product. Dr. Garfinkel requested a hearing in a letter dated February 16, 1995. However, Dr. Garfinkel has not submitted any information or analyses to justify a hearing. Dr. Garfinkel's failure to raise any issues of fact constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment (21 CFR 12.22).

II. Findings and Order

Therefore, the Deputy Commissioner for Operations, under section 306(a) of the act and under authority delegated to him (21 CFR 5.20), finds that Barry D. Garfinkel has been convicted of a felony under Federal law for conduct relating to the development or approval of a drug product and for conduct relating to regulation of a drug product (21 U.S.C. 335a(a)(2)(B)).

As a result of the foregoing finding, Barry D. Garfinkel is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 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 April 2, 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 Dr. Garfinkel, in any capacity, during his period of debarment, will be subject to a civil money penalty (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Dr. Garfinkel, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to a civil money penalty (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications or abbreviated antibiotic drug applications submitted by or with the assistance of Dr. Garfinkel during his period of debarment.

Dr. Garfinkel may file an application to attempt to terminate his debarment under section 306(d)(4)(A) of the act. Any such application would be reviewed under the criteria and processes set forth in section 306(d)(4)(C) and (d)(4)(D) of the act. Such an application should be identified with Docket No. 94N–0011 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: March 24, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–8272 Filed 4–1–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97M–0123]

Richard Wolf Medical Instruments Corp.; Premarket Approval of the Hulka Clip® Tubal Occlusion Device and Applicator System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Richard Wolf Medical Instruments Corp., Vernon Hills, IL, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Hulka Clip® Tubal Occlusion Device and Applicator System. After reviewing the recommendation of the Obstetrics and Gynecology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 5, 1996, of the approval of the application.