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.

DATES: Petitions for administrative review by May 2, 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: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION: On December 30, 1987, Richard Wolf Medical Instruments Corp., Vernon Hills, IL 60061, submitted to CDRH an application for premarket approval of the Hulka Clip® Tubal Occlusion Device and Applicator System. The device is a contraceptive tubal occlusion device and is indicated for female sterilization (permanent contraception) by occluding the fallopian tubes.

On May 25, 1988, the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application subject to the submission of the data from the long-term animal carcinogenic studies demonstrating the safety of the device materials. On September 5, 1996, 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 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 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 May 2, 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: March 7, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–8274 Filed 4–1–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97M–0121]

Medtronic, Inc.; Premarket Approval of the Legend Plus® Pacing System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Medtronic, Inc., Minneapolis, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Legend Plus® Pacing System. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of February 7, 1997, of the approval of the application.

DATES: Petitions for administrative review by May 2, 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: Mitchell J. Shein, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

SUPPLEMENTARY INFORMATION: On July 21, 1993, Medtronic, Inc., Minneapolis, MN 55432, submitted to CDRH an application for premarket approval of the Legend Plus® Pacing System. The device consists of the following components: The Legend Plus® Pulse Generator Models 8446 and 8448; the Model 9790 and 9790C Programmers with the Model 9891 Baseline Software and the Model 9807 Software. The device system includes implantable pulse generators and associated programming hardware and software and is indicated for permanent ventricular or atrial pacing applications. Their use is indicated in the treatment of patients who may benefit from a pacing rate that changes in response to activity.

Ventricular indications include: (1) Chronic atrial flutter or fibrillation with slow ventricular response; (2) sinus node dysfunction or sick sinus syndrome (e.g., sinus bradycardia, sinus arrest and/or exit block, bradycardia-tachycardia syndrome, chronotropic insufficiency, etc.,); and (3) AV block.

Atrial indications include: Sinus node dysfunction or sick sinus syndrome (e.g., sinus bradycardia, sinus arrest and/or exit block, bradycardia-tachycardia syndrome, etc.,) with intact AV conduction.

On May 9, 1995, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On February 7, 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 act (21 U.S.C. 360e(d)(3)) authorizes any interested