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

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 4, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–8273 Filed 4–1–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94D–0017]

International Conference on Harmonisation; Draft Guideline on Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on the Limit Dose; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guideline entitled ''Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on the Limit Dose.'' The draft guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guideline is intended to define the conditions under which it would be considered acceptable to use a ''limit dose'' for the high dose selection of nongenotoxic pharmaceuticals in long-term carcinogenicity studies. The draft guideline is an addendum to an earlier ICH guideline on criteria for establishing uniformity among international regulatory agencies for dose selection for carcinogenicity studies of human pharmaceuticals.

DATES: Written comments by June 2, 1997.

ADDRESSES: Submit written comments on the draft guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the draft guideline are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5473.

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs FY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

At a meeting held on November 6, 1996, the ICH Steering Committee agreed that a draft guideline entitled ''Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on the Limit Dose'' should be made available for public comment. The draft guideline is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft guideline is an addendum to an ICH final guideline published in the **Federal Register** of March 1, 1995 (60 FR 11278), entitled ''Guideline on Dose Selection for Carcinogenicity Studies of Pharmaceuticals.'' The draft guideline is intended to define the conditions under which it would be considered acceptable to use a ''limit dose'' for the high dose selection of nongenotoxic pharmaceuticals in long-term carcinogenicity studies.

Although not required, FDA has in the past provided a 75- or 90-day comment period for draft ICH guidelines. However, the comment period for this draft guideline has been shortened to 60 days so that comments may be received by FDA in time to be reviewed and then discussed at a July 1997 ICH meeting involving this guideline.

This draft guideline represents the agency's current thinking on dose selection for carcinogenicity studies of