of paternity and collection of child support. The Division, in consultation with the Division of Consumer Services, develops informational materials.

C. Office of Automation and Special Projects is headed by an Associate Commissioner who reports to the Deputy Director/Commissioner and provides leadership and direction to the Division of Child Support Information Systems. In addition, the Office of Automation and Special Projects has responsibility for implementation of the International Child Support Program, Native American Child Support Program, Advocacy Relations, Data Center Coordination, Grants Preparation and other projects and task forces appointed by the Deputy Director/Commissioner from time to time.

1. Division of Child Support Information Systems reviews, analyzes, and approves/disapproves State requests for Federal financial participation for automated systems development activities which support the Child Support program. It provides assistance to States in developing or modifying automation plans to conform to Federal requirements. It monitors approved State systems development activities; certifies state-wide automated systems; conducts periodic reviews to assure State compliance with regulatory requirements applicable to automated systems supported by Federal financial participation. It provides guidance to States on functional requirements for these automated information systems. It promotes interstate transfer of existing automated systems and provides assistance and guidance to improve ACF's programs through the use of automated systems.

II. Amend Notice 63 FR 81, dated January 2, 1998, Roman numeral III, Chapter KL, replace the term ''Office of the Assistant Secretary for Policy and External Affairs'' with ''Office of the Deputy Assistant Secretary for Policy and External Affairs.''

Date: January 25, 1998.

**Olivia A. Golden,**

*Assistant Secretary for Children and Families.*

[FR Doc. 98–2238 Filed 1–28–98; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98M–0037]**

### Medtronic, Inc.; Premarket Approval of the Interstim® Sacral Nerve Stimulation (SNS)™ 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 Interstim® Sacral Nerve Stimulation (SNS)™ System. After reviewing the recommendation of the Gastroenterology and Urology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 29, 1997, of the approval of the application.

**DATES:** Petitions for administrative review by March 2, 1998.

**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:** Laura J. Byrd, Center for Devices and Radiological Health (HFZ–472), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

**SUPPLEMENTARY INFORMATION:** On January 30, 1997, Medtronic, Inc., Minneapolis, MN 55432–3576, submitted to CDRH an application for premarket approval of the Interstim® Sacral Nerve Stimulation (SNS)™ System. The device is an implantable sacral nerve electrical stimulation system and is indicated for the treatment of urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments.

On August 6, 1997, the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 29, 1997, CDRH approved the application by a letter to the applicant from the Deputy Director of Clinical and Review Policy, 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 the 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 March 2, 1998, 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: January 5, 1998.

**Joseph A. Levitt,**

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

[FR Doc. 98–2114 Filed 1–28–98; 8:45 am]

**BILLING CODE 4160–01–F**