

relationship between use of antimicrobial agents and the incidence of antimicrobial resistance at 40 U.S. hospitals. The proposed Phase 3 study of Project ICARE will be very similar to Phase 2 ICARE with minor revisions. We hope to enroll 40 hospitals and address many confounding factors of antimicrobial resistance. In addition, these hospitals will serve as a sentinel surveillance system for different antimicrobial resistant pathogens, such as vancomycin resistant staphylococci. About half of the hospitals have participated in Phase 2 of Project

ICARE. Participating hospitals will all be active participants of the CDC's National Nosocomial Infections Surveillance (NNIS) system. Phase 3 of Project ICARE is a refinement of the Phase 2 study and will allow interhospital comparison of data (i.e., sending interim reports back to study hospitals) facilitated by incorporating differences in culturing frequency, case-mix by ICU type and speciality wards (i.e., internal organization), barrier precautions, and prescribing practice policies. Phase 3 will also allow for valid comparison of attempts at

reducing antimicrobial resistance in study hospitals (i.e., publish results of interventions to reduce antimicrobials resistance at study hospitals). Also, key parameters of antimicrobial use could be correlated with antimicrobial resistance levels and tracked through the hospital's quality improvement indicator process, pharmacy and therapeutics committee, or medical staff. Unnecessary use of antimicrobials may be reduced by these efforts if the information can be provided to hospitals. Average cost to respondents is \$17.18.

Form name	Number of respondents	Number responses/respondent	Average burden/response (in hours)	Total burden (in hours)
Primary contact	40	12	1	480
Pharmacy	40	48 (median)	2.0	3,840
Microbiology	40	60 (median)	0.5	1,200
Isolates	40	80 (maximum)	0.20	640
Total	6,160

Dated: January 23, 1998.
Charles Gollmar,
Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).
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 BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Child Support Enforcement; Statement of Organization, Functions, and Delegations of Authority

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (DHHS), Administration for Children and Families (ACF) as follows: Chapter KF, The Office of Child Support Enforcement (OCSE) (62 FR 14152), as last amended, March 25, 1997. This reorganization will establish two new offices within the OCSE, Office of Central Office Operations and Office of Automation and Special Projects.

I. Amend Chapter KF as follows:
 a. KF.00 Mission. Delete in its entirety and replace with the following:
 KF.00 Mission. The Office of Child Support Enforcement (OCSE) advises the Secretary, through the Assistant Secretary for Children and Families, on matters relating to child support enforcement. The Office, in conjunction with Regional Offices, provides

direction, guidance and oversight to State Child Support Enforcement (CSE) program offices and for activities authorized and directed by title IV-D of the Social Security Act and other pertinent legislation. The general purpose of the CSE legislation is to permit States to develop programs for establishing and enforcing support obligations by locating absent parents, establishing paternity when necessary, obtaining child support orders, and enforcing those orders. The specific responsibilities of this Office are to: Develop, recommend and issue policies, procedures and interpretations for State programs for locating non-custodial parents, establishing paternity, and obtaining child support; develop procedures for review and approval or disapproval of State plan material; conduct audits of child support programs; assist States in establishing adequate reporting procedures and maintaining records for the operation of the CSE programs and of amounts collected and disbursed under the CSE program and the costs incurred in collecting such amounts; provide technical assistance and training to the States to help them develop effective procedures and systems for establishing paternity, establishing support orders and collecting child support; certify applications from States for permission to utilize the courts of the United States to enforce court orders for support against absent parents; operate the Federal Parent Locator Service; certify to the Secretary of the Treasury amounts of child support obligations that require

collection in appropriate instances; submit an annual report to Congress on all activities undertaken relative to the CSE program; approve advanced data processing planning documents; and review, assess and inspect planning, design and operation of state management information systems.
 b. KF.10 Organization. Delete in its entirety and replace with the following:
 KF.10 Organization. The Office of Child Support Enforcement is headed by a Director and consists of:
 Office of the Director (KFA)
 Office of Central Office Operations (KFB)
 Division of Audit (KFB1)
 Division of Program Operations (KFB2)
 Division of Policy and Planning (KFB3)
 Division of Consumer Services (KFB4)
 Division of State and Local Assistance (KFB5)
 Office of Automation and Special Projects (KFC)
 Division of Child Support Information Systems (KFC1)
 c. KF.20 Functions. Delete in its entirety and replace with the following:
 KF.20 Functions. A. Office of the Director. The Director is also the Assistant Secretary for Children and Families and is directly responsible to the Secretary for carrying out OCSE's mission. The Deputy Director/Commissioner has day-to-day operational responsibility for Child Support Enforcement programs. The Deputy Director/Commissioner assists the Director in carrying out responsibilities of the Office and provides direction and leadership to the

Office of Central Office Operations and Office of Automation and Special Projects.

The Office is responsible for developing regulations, guidance and standards for States to observe in locating absent parents; establishing paternity and support obligations and enforcing support obligations; maintaining relationships with Department officials, other federal departments, State and local officials, and private organizations and individuals interested in the CSE program; coordinating and planning child support enforcement activities to maximize program effectiveness; and approving all instructions, policies and publications issued by OCSE staff.

B. Office of Central Office Operations is headed by an Associate Commissioner who reports to the Deputy Director/Commissioner and provides leadership and direction to the divisions of Audit, Program Operations, Policy and Planning, Consumer Services, and State and Local Assistance.

Within the Office of Central Office Operations, an administrative staff assists the Associate Commissioner in managing the formulation and execution of program and salaries and expense budgets and in providing administrative, personnel and data processing support services to OCSE staff.

1. Division of Audit, as required by section 452(a)(4) of the Social Security Act (the Act), develops, plans, schedules and conducts periodic audits of State CSE programs in accordance with audit standards promulgated by the Comptroller General of the United States.

The Division will audit, at least once every three years (or more frequently in the case of a State which fails to meet the performance standards and the tests of the reliability of program data), the reliability of the State's financial and statistical data reporting systems used in calculating the paternity establishment percentage and the performance indicators used as the basis for the payments of performance based financial incentives to the States. These audits will examine the computer systems general and application controls and include in depth testing of the data produced by the system to ensure that it is valid, complete and reliable. The Division will also conduct financial audits to determine whether federal and other funds made available to carry out the State programs are being appropriately expended, and properly and fully accounted for. These audits will also examine collections and

disbursements of support payments for proper processing and accounting treatment.

The Division will also provide technical assistance to States in developing their self-assessment capabilities and implementing the annual reporting requirements contained in the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996.

In addition, the Division will also conduct other audits and examinations of program operations as may be necessary or requested by program officials for the purpose of improving the efficiency, effectiveness and economy of State and local child support activities; develops consolidated reports for the Director and Deputy Director/Commissioner, OCSE based on findings; provides specifications for the development of audit regulations and requirements for audits of State CSE programs; and coordinates and maintains effective liaison with the HHS Inspector General's Office and with the General Accounting Office.

2. Division of Program Operations is responsible for the day-to-day operation of the Federal Parent Locator Service (FPLS), the Federal Tax Refund Offset Program and Project 1099, the IRS Full Collection Project, and the SSN Enumeration Verification System. The Division is also responsible for the design, development, implementation and operation of the Federal Case Registry and the National Directory of New Hires within the expanded FPLS. It is responsible for monitoring contracts with vendors who provide automated systems support and quality assurance to these programs; working with vendors to define scope of work to be performed and by whom; negotiating interagency agreements; and providing contract oversight. The Division, in consultation with the Division of State and Local Assistance, also provides technical assistance to State and local child support enforcement agencies and other State agencies involved in these program areas. The Division provides guidance and expertise to States concerning other State, interstate and national locate networks and sources. In addition, the Division works with the U.S. Department of State on passport revocation.

3. Division of Policy and Planning proposes and implements national policy on the CSE program and provides policy guidance and interpretations to States in developing and operating their programs according to federal law. It develops legislative proposals and regulations to implement new

legislation, court decisions or directives from higher authority. The Division develops procedures for review and approval of State plans by the OCSE regional offices. It develops and monitors research, interstate, and other demonstration and evaluation studies and publishes program statistics. The Division is also responsible for strategic planning and performance measurements and standards development. It prepares legislative cost estimates and is responsible for national child support budget formulation.

4. Division of Consumer Services provides direction and leadership for a variety of consumer affairs activities in support of the nationwide child support enforcement program. Provides advice on strategies and approaches to be used to improve public understanding of and access to OCSE programs and policies. Develops and publishes informational materials and disseminates through the National Reference Center. Promotes "best" child support practices to the public through monthly publication of the Child Support Report. Advises the Deputy Director/Commissioner through the Associate Commissioner of the impact of child support enforcement policy and program upon consumers and provides a focal point for intergovernmental and consumer relations and consultation. The Division is also responsible for national electronic communications activities including disseminating information and operation of the OCSE Homepage on the internet and insuring that the information is placed thereon in a timely and accurate manner.

5. Division of State and Local Assistance, in concert with regional offices, provides information and assistance on State Child Support Enforcement operations. It provides national direction and leadership for training and technical assistance activities to increase Child Support Enforcement (CSE) program effectiveness both at Federal and State levels; develops guides and resource materials and serves as a clearinghouse for specialized program techniques for use by ACF regional offices and States; and ensures transfer of best practices among State and local CSE enforcement agencies. The Division operates a national CSE training center; provides logistical support for both training events and meetings; and monitors contracts with organizations affiliated with child support enforcement programs in the areas of training and technical assistance. The Division provides outreach and liaison services to a variety of special interest populations concerning establishment

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)TM 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)TM 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)TM 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]

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