is an appropriate special control to provide reasonable assurance of the safety and effectiveness of the device.

FDA notes that it has considered a comment from a manufacturer of a totally implanted SCS for pain relief and a comment from the petitioner after the September 16 and 17, 1999, Panel meeting in its formulation of these tentative findings. These comments have been placed in the docket referenced in the heading of this document.

### X. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Advanced Neuromodulation Systems, Inc., Plano, TX, Classification Proposal and Summary of Safety and Effectiveness Information for the Totally Implanted Spinal Cord Stimulator, received June 16, 1999.

2. Transcript of the September 16 and 17, 1999, Neurological Devices Panel Meeting, September 17, 1999, volume, pp. 153–284.

### XI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### XII. Analysis of Impacts

FDA has examined the impacts of the notice under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this potential reclassification action is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this potential reclassification action is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the reclassification action, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation.

### XIII. Paperwork Reduction Act of 1995

FDA concludes that this reclassification action contains no new collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### XIV. Federalism

FDA has analyzed this reclassification action in accordance with the principles set forth in Executive Order 13132. FDA has determined that the reclassification action does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the action does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

### XV. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this document by October 6, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 22, 2000.

**Linda S. Kahan,**

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

[FR Doc. 00–22618 Filed 9–5–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 00N–1485]**

### Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors; Notice of Availability; Public Meeting by Satellite

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability and announcement of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the report entitled ''Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors'' and a public meeting via an interactive satellite teleconference. The purpose of the meeting is to present: The methodology used for developing a baseline on the occurrence of the Centers for Disease Control and Prevention (CDC)-identified foodborne illness risk factors in retail-level institutional food establishments, restaurants, and retail food stores and the data from the baseline inspections that were conducted by FDA Regional Food Specialists in 1998 to 1999.

*Date and Time:* The meeting will be held on October 27, 2000, 1 p.m. to 4 p.m. Satellite coordinates for the broadcast will be posted on the FDA Internet at www.fda.gov beginning October 13, 2000. The report will be available beginning September 11, 2000, on the FDA Internet at www.fda.gov and hard copies will be available after October 1, 2000, from the contact persons listed below.

*Location:* The satellite meeting will be broadcast nationwide from the FDA broadcast studio at the Center for Devices and Radiological Health, 16071–B Industrial Dr., Gaithersburg, MD 20877.

*Contact:* Denise M. Buckmon or LaKesha P. Abbey, Office of Field

Programs (HFS–625), Center for Food Safety and Applied Nutrition, Food and Drug Administration, Switzer Bldg., rm. 1042, 200 C St. SW., Washington, DC 20204, 202–205–8140, FAX 202–205–5560, e-mail: ''dbuckmon@cfsan.fda.gov'' or ''LAbbey@cfsan.fda.gov''.

*Registration:* Stakeholders interested in being a member of the studio audience should indicate their interest by October 13, 2000, by providing name, title, firm name, address, telephone number, and fax number to the contact persons listed below. Seating is limited to 45 persons.

If you are interested in attending as a member of the studio audience and need any reasonable accommodations due to a disability, including a sign language interpreter, please contact Denise M. Buckmon or LaKesha P. Abbey at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA advises Federal agencies, State, local, and tribal governments on food safety standards for institutional food service establishments, restaurants, and other retail food stores. In this advisory role, FDA works closely with other Federal agencies to provide guidance and assistance to enhance the regulatory programs of State, local, and tribal jurisdictions.

In January 1996, the National Partnership for Reinventing Government (NPR), formerly the National Performance Review, issued a report entitled ''Reinventing Food Regulations.'' In this report, NPR concluded that ''foodborne illness caused by harmful bacteria and other pathogenic microorganisms in meat, poultry, seafood, dairy products, and a host of other foods is a significant public health problem in the United States.'' For years, regulatory and industry food safety programs have been designed to minimize the occurrence of foodborne illness. In 1997, the President called for the creation of a Food Safety Initiative (FSI). FSI established steps for Federal agencies with the primary responsibility of food safety to take in order to reduce foodborne illness. Key necessary actions included: Enhancing surveillance and building an early-warning system; improving responses to foodborne outbreaks; improving risk assessment; developing new research methods; improving inspections and compliance; and furthering food safety education.

To improve responses to foodborne illness outbreaks and risk assessment capabilities, the level of risky practices and behaviors need to be identified. There is, however, a lack of a national baseline on the occurrence of foodborne illness risk factors.

This report and meeting are designed to establish a national baseline on the occurrence of foodborne illness risk factors within the retail segment of the food industry. The CDC-identified foodborne illness risk factors being tracked are: Food from unsafe sources, inadequate cooking, improper holding temperature, contaminated equipment, and poor personal hygiene.

The purpose of the meeting is to present the methodology used for developing a baseline on the occurrence of CDC-identified foodborne illness risk factors in retail-level institutional food establishments, restaurants, and retail food stores. In addition, FDA will present data from the baseline inspections conducted by the FDA Regional Food Specialists in 1998 and 1999.

FDA intends to use the baseline to measure industry and regulatory efforts to change behaviors and practices directly related to foodborne illness. In addition, the data from this report and meeting along with future studies planned for 2003 and 2008 are expected to provide input into the Healthy People 2010's Food Safety Objective 10.6. Objective 10.6 is designed to improve food preparation practices and food employee behaviors at institutional food service establishments, restaurants, and retail food stores. Healthy People 2010 is a national health promotion and disease prevention initiative with the objective to improve the health of all Americans.

Dated: August 31, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 00–22851 Filed 9–1–00; 2:29 pm]

**BILLING CODE 4160–01–F**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. 00M–1215, 00M–1216, 00M–1228, 00M–1229, 00M–1230, 00M–1231, 00M–1298, 00M–1299, 00M–1300, 00M–1354]**

### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket applications (PMA) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMA's through the Internet and the agency's Dockets Management Branch.

**ADDRESSES:** Summaries of safety and effectiveness are available on the Internet at http://www.fda.gov/cdrh/pmapage.html. Copies of summaries of safety and effectiveness are also available by submitting a written request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 in the **SUPPLEMENTARY INFORMATION** section of this document when submitting a written request.

**FOR FURTHER INFORMATION CONTACT:** Thinh X. Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on the Internet on FDA's home page at http://www.fda.gov; by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch; and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMA's and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the