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

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

Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMA's for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from April 1, 2000, through June 30, 2000. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMA'S MADE AVAILABLE APRIL 1, 2000, THROUGH JUNE 30, 2000

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970054/00M–1216	Hogan & Hartson	Biotrin Parvovirus B19 IGG EIA (V5191GUS).	August 6, 1999
P970055/00M–1215	Hogan & Hartson	Biotrin Parvovirus IGM EIA (V619IMUS).	August 6, 1999
P980008/00M–1231	Lasersight Technologies, Inc.	Laserscan LSX Excimer Laser System.	November 12, 1999
P990009/00M–1229	Fusion Medical Technologies, Inc.	Floseal Matrix/Floseal Matrix Hemostatic Sealant.	December 8, 1999
H990008/00M–1228	Interpore Cross International.	Telescopic Plate Spacer (TPS) Spinal System.	March 9, 2000
P990013/00M–1230	Starr Surgical Co.	Collamer Single-Piece (Plate-Haptic) Ultraviolet Absorbing Posterior Chamber Intraocular Lens.	April 2, 2000
P990048/00M–1300	Hogan & Hartson	Zeiss Visulas 690 and Visulink PD T/900 Laser System.	April 12, 2000
P990049/00M–1299	Coherent Medical Group	Coherent Opal Photoactivator Laser System.	April 12, 2000
P950020/00M–1298	Interventional Technologies.	(BSDB) PTCA Surgical Dilation Balloon.	April 18, 2000
H99012/00M–1354	Cardiovascular Diagnostics, Inc.	TAS Ecarin Clotting Time Test.	May 11, 2000

Dated: August 10, 2000.

Linda S. Kahan,

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

[FR Doc. 00–22700 Filed 9–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1455]

Draft Guidance for Industry; Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief.'' Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice of a panel recommendation to reclassify totally implanted spinal cord stimulators from class III (premarket approval) to class II (special controls). If this device is reclassified, this draft guidance document will serve as the special control for the reclassified device. This guidance is neither final nor in effect at this time.

DATES: Submit written comments on the draft guidance by October 6, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief'' to the Division of Small Manufacturers Assistance (DSMA) (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Russell P. Pagano, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief.'' Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice of a panel recommendation to reclassify totally implanted spinal cord stimulators from class III (premarket approval) to class II (special controls). If this device is reclassified, this draft guidance document will serve as the special control for the reclassified device.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on special controls for totally implanted spinal cord stimulators for pain relief. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is