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Draft Guidance for Industry; Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief.''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

issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 1179 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 21, 2000.

Linda S. Kahan,

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

[FR Doc. 00–22619 Filed 9–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Center for Substance Abuse Prevention (CSAP) National Advisory Council in September 2000.

The agenda will include the review, discussion and evaluation of individual grant applications and detailed discussion of information about the Center's procurement plans. Therefore a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, Section 10(d).

The agenda of the open portion will include CSAP's Director's Report, an update of CSAP's budget, SAMHSA's Administrator's Report, a report on CSAP's Decision Support System, and discussions of administrative matters and announcement.

If anyone needs special accommodations for persons with disabilities, please notify the contact listed below.

A summary of this meeting and roster of committee members may be obtained from Yuth Nimit, Executive Secretary, Rockwall II Building, Suite 910, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–8455.

Substantive program information may be obtained from the contact listed below.

Committee Name: Center for Substance Abuse Prevention, National Advisory Council.

Meeting Dates: September 11–12, 2000.

Place: Holiday Inn Bethesda 8120 Wisconsin Avenue, Versaille III Room, Bethesda, Maryland 20814, (301) 652–2000.

Closed: September 11, 2000, 8:30 a.m. to 4:00 p.m.

Open: September 12, 2000, 8:30 a.m. to 2:00 p.m.

Contact: Yuth Nimit, 5515 Security Lane, Rockwall II Building, Suite 910, Rockville, Maryland 20852, Telephone: (301) 443–8455.

Dated: August 29, 2000.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 00–22776 Filed 9–5–00; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4601–N–03]

Notice of Extension of Application Period and Modification of Number of Positions for the U.S.-Israel Bi-National Commission on Housing and Community Development

AGENCY: Office of International Affairs under the Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice of extension and modification.

SUMMARY: On June 26, 2000, HUD published a notice that announced the opportunity for individuals to apply to serve on the U.S.-Israel Bi-National Commission on Housing and Community Development. The deadline for receipt of applications was subsequently extended until August 28, 2000. This notice extends the deadline to apply for this Bi-National Commission until September 22, 2000. This notice also amends the original notice to permit up to twenty people to serve on the U.S. side of this Bi-National Commission.

DATES: In order to receive full consideration, requests must be received by HUD no later than September 22, 2000.

ADDRESSES: Please send your requests for consideration to U.S.-Israel Bi-National Commission, U.S. Department of Housing and Urban Development, Office of International Affairs, Room 8118, 451 Seventh Street, SW, Washington, DC 20410. You may fax your request to (202) 708–5536 (this is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: John Geraghty, U.S. Department of Housing and Urban Development, Office of International Affairs, Room 8118, 451 Seventh Street, SW, Washington, DC 20410, (202) 708–0770 (telephone), (202) 708–5536 (fax) (these are not toll-free numbers). Persons with hearing or speech impairments may access that number via TTY by calling the Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: On June 26, 2000 (65 FR 39419), HUD published a notice that provided the opportunity for individuals to apply to serve on the U.S.-Israel Bi-National Commission on Housing and Community Development and announced the selection and eligibility requirements. The Commission will consist of U.S. and Israeli representatives from the housing, real estate, community development,