actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product COMTAN (entacapone). COMTAN is indicated as an adjunct to levodopa/carbidopa to treat patients with idiopathic Parkinson's disease who experience the signs and symptoms of end-of-dose ''wearing-off.'' Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for COMTAN (U.S. Patent No. 5,446,194) from Orion Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 17, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of COMTAN represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for COMTAN is 2,937 days. Of this time, 2,281 days occurred during the testing phase of the regulatory review period, while 656 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: October 6, 1991. The applicant claims November 29, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 6, 1991, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: January 2, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for COMTAN (NDA 20–796) was initially submitted on January 2, 1998.

3. *The date the application was approved*: October 19, 1999. FDA has verified the applicant's claim that NDA 20–796 was approved on October 19, 1999.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 416 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 22, 2002. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 18, 2002. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (see **ADDRESSES**). Three copies of any information 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. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 22, 2002.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 02–12784 Filed 5–21–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 01M–0478, 01M–0460, 01M–0454, 01M–0453, 01M–0452, 01M–0456, 01M–0451, 01M–0455, 01M–0578, 01M–0507, 01M–0579, 01M–0535, 01M–0462, 01M–0461, 01M–0536, 01M–0520, 01M–0439, 01M–0509, 01M–0490, 01M–0498, 01M–0479, 01M–0480, 01M–0482, 01M–0508, 01M–0522, 01M–0537, 01M–0523, 01M–0530, 01M–0531, 01M–0534, 01M–0567, 01M–0581]

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 approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness 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 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

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

SUPPLEMENTARY INFORMATION:

I. Background

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 FDA's home page at http://www.fda.gov on the Internet, 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 PMAs 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)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), 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 PMAs for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from October 1, 2001, through December 31, 2001. 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 PMAS MADE AVAILABLE OCTOBER 1, 2001, THROUGH DECEMBER 31, 2001

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P990050/01M–0478	Spectrascience, Inc.	Optical Biopsy System	November 14, 2000
P000020/01M–0460	C.R. Bard, Inc.	Stinger Ablation Catheter Templink Extension Cable	November 29, 2000
P990043/01M–0454	Diasorin, Inc.	DIASORIN ETI–EBK PLUS Assay	February 8, 2001
P990042/01M–0453	Diasorin, Inc.	DIASORIN ETI–AB–AUK PLUS Assay	March 30, 2001
P990041/01M–0452	Diasorin, Inc.	DIASORIN ETI–AB–EBK PLUS Assay	March 30, 2001
P990045/01M–0456	Diasorin, Inc.	DIASORIN ETI–AB–COREK PLUS Assay	March 30, 2001
P990038/01M–0451	Diasorin, Inc.	DIASORIN ETI MAK–2 PLUS Assay	March 30, 2001
P990044/01M–0455	Diasorin, Inc.	DIASORIN ETI–CORE IGMK PLUS Assay	March 30, 2001
P000040/01M–0578	Bei Medical Systems Co., Inc.	HYDROTHERMABLATOR Endometrial Ablation System	April 20, 2001
P990012/01M–0507	Roche Diagnostics Corp.	Elecsys Hbsag Immunoassay, Elecsys Hbsag Confirmatory, and Precicontrol Hbsag	June 1, 2001
P000053/01M–0579	American Medical Systems, Inc.	AMS SPHINCTER 800 Urinary Control System	June 14, 2001
P930027(S004)/01M–0535	Diagnostic Products Corp.	Immulite PSA, Immulite Third Generation PSA, Immulite 2000	June 19, 2001
P880086(S083)/01M–0462	St. Jude Medical, Inc.	Integrity AFX DR Model 5346 Dual Chamber Pulse Generator and Programmer Software Model 3307, V2.2a	July 11, 2001
P830045(S076)/01M–0461	St. Jude Medical, Inc.	Integrity AFX DR Model 5346 Dual Chamber Pulse	July 11, 2001
P010021/01M–0536	Ortho-Clinical Diagnostics, Inc.	Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrator	August 30, 2001
P890057(S014)/01M–0520	Sensor Medics Corp.	Model 3100b High Frequency Oscillatory Ventilator (HFOV)	September 24, 2001
P000029/01M–0439	Q-Med Ab	Deflux Injectable Gel Ren	September 24, 2001
P010017/01M–0509	Fisher Imaging Corp.	SENOSCAN Full Field Digital Mammagraphy System	September 25, 2001
P980008(S005)/01M–0490	Lasersight Technologies, Inc.	Lasersight Laserscan Lsx Excimer Laser System For Laser-Assisted In Situ Keratomileusis (LASIK)	September 28, 2001
P000036/01M–0498	Advanced Tissue Sciences	Dermagraft	September 28, 2001
P010019/01M–0479	Ciba Vision Corp.	Focus Night And Day (Lotrafilcon A) Soft Contact Lenses	October 11, 2001
P000030/01M–0480	Ciba Vision Corp.	Focus Night & Day (Lotrafilcon A) Soft Contact Lenses	October 12, 2001
H010002/01M–0482	Stryker Biotech	OP–1 Implant	October 17, 2001
P000052/01M–0508	Guidant Corp.	Galileo Intravascular Radiotherapy System	November 2, 2001
P930016(S014)/01M–0522	VISX, Inc.	VISX STAR Excimer Laser System	November 6, 2001
P010007/01M–0537	Diagnostic Products Corp.	Immulite/Immulite 2000 Afp Assays	November 9, 2001
P990015/01M–0523	Lifecore Biomedical, Inc.	Intergel Adhesion Prevention Solution	November 16, 2001
P000057/01M–0530	Ascension Orthopedics, Inc.	Ascension Mcp	November 19, 2001
P980006(S004)/01M–0531	Bausch & Lomb, Inc.	Purevision (Balafilcon A) Visibility Tinted Contact Lenses	November 20, 2001
P010032/01M–0534	Advanced Neuromodulation System, Inc.	Genesis Neurostimulation (Ipg) System	November 21, 2001
P010003/01M–0567	Cryolife, Inc.	BIOGLUE Surgical Adhesive	December 3, 2001
P010020/01M–0581	American Medical Systems, Inc.	AMS Acticon Neosphincter	December 18, 2001

II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html.

Dated: May 10, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–12728 Filed 5–21–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Community-Based Dental Partnership Program Grant Announcement

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds; correction.

SUMMARY: In notice document FR Doc. 02–9617, Vol. 67, No. 76, Friday, April 19, 2002, make the following correction:

On page 19440 in the second column under OBTAINING APPLICATION GUIDANCE AND KIT, correct the website address to be: *www.hab.hrsa.gov/grant.htm.*

Dated: May 16, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–12786 Filed 5–21–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Title III Early Intervention Services Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds; correction.

SUMMARY: In notice document FR Doc. 02–9814, Vol. 67, No. 78, Tuesday, April 23, 2002, make the following correction:

On page 19761 in the second column under OBTAINING APPLICATION GUIDANCE AND KIT, correct the website address to be: *www.hab.hrsa.gov/grant.htm.*

Dated: May 16, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–12785 Filed 5–21–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, NIH.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, NIH.

Date: June 6, 2002.

Time: 8:30 AM to 4:30 PM.

Agenda: Topics proposed for discussion include but are not limited to: Science Education and Career Development; Bioterrorism and Emerging Infections; and an Update on Implementation of an Awards Using Human Embryonic Stem Cell Lines.

Place: 31 Center Drive, Building 31, Room 4C32 (NIAMS Conference Room), Bethesda, MD 20892.

Contact Person: Janice C. Ramsden, Committee Mgmt. Officer, Office of the Director, NIH, Building 1, Room 333, Bethesda, MD 20892, 301–496–0959.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: *http://www.nih.gov/about/director/acd.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 14, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–12763 Filed 5–21–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Cancer Disparities Research Partnerships Plan.

Date: June 19, 2002.

Time: 8:30 AM to 2:00 PM.

Agenda: To review and evaluate grant applications.

Place: Executive Plaza North, Conference Room F, 6130 Executive Boulevard, Rockville, MD 20852.

Contact Person: Gerald G. Lovinger, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8101, Rockville, MD 20892–7405, 301/496–7987.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 15, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–12756 Filed 5–21–02; 8:45 am]

BILLING CODE 4140–01–M