	OMB control Nos.
491.3, 491.8	0938–0792
491.9	0938–0334
493.1–493.2001	0938–0151, 0544, 0581, 0599, 0612, 0650, & 0653
493.551–493.557	0938–0686
493.1269—493.1285	0938–0170
493.1840	0938–0655
498.40–498.95	0938–0486, & 0567
1003.100, 1003.101, 1003.103	0938–0700
1004.40, 1004.50, 1004.60, 1004.70	0938–0444
45 CFR:	
5b	0938–0734
146	0938–0702
146.121	0938–0819
146.141	0938–0827
148	0938–0703 & 0797

Dated: January 15, 2002.

John P. Burke III,

CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 02–1686 Filed 1–23–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0851]

Determination of Regulatory Review Period for Purposes of Patent Extension; T-Scan 2000

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for T-Scan 2000 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device T-Scan 2000. T-Scan 2000 is intended for use as an adjunct to mammography in patients who have equivocal mammographic findings within ACR–BI–RADS categories 3 and 4. In particular, it is not intended for use in cases with clear mammographic or non-mammographic indications for biopsy. This device provides the radiologist with additional information to guide a biopsy recommendation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for T-Scan 2000 (U.S. Patent No. 4,291,708) from Transcan Research and Development Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 13, 2000, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of T-Scan 2000 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 T-Scan 2000 is 1,595 days. Of this time, 964 days occurred during the testing phase of the regulatory review period, while 631 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: December 5, 1994. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective December 5, 1994.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: July 25, 1997. FDA has verified the applicant's claim that the premarket approval application (PMA) for T-Scan 2000 (PMA P970033) was initially submitted July 25, 1997.

3. *The date the application was approved*: April 16, 1999. FDA has

verified the applicant's claim that PMA P970033 was approved on April 16, 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 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by March 25, 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 July 23, 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. 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: September 28, 2001.

Jane A. Axelrad,

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

[FR Doc. 02–1723 Filed 1–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of 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 meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, 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.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(6), 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 Advisory Board.

Dates: February 20–21, 2002.

Open: February 20, 2002, 8:45 AM to 4 PM.

Agenda: Program reports and presentations: Business of the Board.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Name of Committee: National Cancer Advisory Board, Subcommittee on Planning and Budget.

Open: February 20, 2002, 11:55 AM to 12:55 PM.

Agenda: To discuss activities related to the Subcommittee on Planning and Budget.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Ms. Cherie Nichols, Executive Secretary, Subcommittee on Planning and Budget, National Cancer Institute, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 11A03, Bethesda, MD 20892, (301) 496–5515.

Name of Committee: National Cancer Advisory Board, Subcommittee on Clinical Investigations.

Open: February 20, 2002, 12:55 PM to 1:55 PM.

Agenda: To discuss activities related to the Subcommittee on Clinical Investigations.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Ellen Feigal, Executive Secretary, Subcommittee on Clinical Investigations, National Cancer Institute, National Institutes of Health, 9000 Rockville Pike, Building 31, 3A44, Bethesda, MD 20892, (301) 496–6711.

Name of Committee: National Cancer Advisory Board.

Closed: February 20, 2002, 4:15 PM to Recess.

Agenda: Review of grant applications; Discussion of confidential personnel issues.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Name of Committee: National Cancer Advisory Board.

Open: February 21, 2002, 8:45 AM to Adjournment.

Agenda: Program reports and presentations; Business of the Board.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's homepage: *deainfo.nci.nih.gov/advisory/ncab.htm,* where an agenda and any additional information for the meeting will be posted when available.

(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: January 17, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–1794 Filed 1–23–02; 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 a meeting of the President's Cancer Panel.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended, because the premature disclosure of other and the discussions