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 regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2007, through March 31, 2007. 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 FROM JANUARY 1, 2007, THROUGH MARCH 31, 2007

| PMA No./Docket No. | Applicant | Trade Name | Approval Date |
|---|---|---|---|
| P040051/2007M–0109 | Stelkast Co. | STELKAST SURPASS ACETABULAR SYSTEM | May 12, 2006 |
| P050037/2007M–0006 | Bioform Medical, Inc. | RADIESSE 1.3 CC AND 0.3 CC | December 22, 2006 |
| P050052/2007M–0007 | Bioform Medical, Inc. | RADIESSE 1.3 CC AND 0.3 CC | December 22, 2006 |
| P050018/2007M–0032 | Angioscore, Inc. | ANGIOSCULPT SCORING BALLOON CATHETER | January 8, 2007 |
| P060001/2007M–0049 | EV3, Inc. | PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS | January 24, 2007 |
| H060004/2007M–0038 | Fujirebio Diagnostics, Inc. | FUJIREBIO MESOMARK ASSAY | January 24, 2007 |
| P050007(S1)/2007M–0058 | Abbott Vascular Devices | STARCLOSE VASCULAR CLOSURE SYSTEM | February 2, 2007 |
| P050013/2007M–0086 | Tissue Seal, LLC. | HISTOACRYL & HISTOACRYL BLUE TOPICAL SKIN ADHESIVE | February 16, 2007 |
| P980022(S15)/2007M–0107 | Medtronic Minimed | GUARDIAN RT & PARADIGM REAL–TIME CONTIUOUS GLUCOSE MONITORING SYSTEMS | March 8, 2007 |
| P050053/2007M–0084 | Medtronic Sofamor Danek USA, Inc. | INFUSE BONE GRAFT | March 9, 2007 |
| P060019/2007M–0108 | Irvine Biomedical, Inc. | IBI THERAPY COOL PATH ABLATION CATHETER & IBI–1500T9 RF ABLATION GENERATOR | March 16, 2007 |

## II. Electronic Access

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

Dated: May 24, 2007.

**Linda S. Kahan,**

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

[FR Doc. E7–11002 Filed 6–6–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2007N–0208]**

### Science Board to the Food and Drug Administration; Amendment of Notice

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

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Science Board to the Food and Drug Administration (Science Board). This meeting was originally announced in the **Federal Register** of May 21, 2007 (72 FR 28499). The amendment is being made to reflect a change in the *Agenda* and *Procedure* portions of the document. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF–33), 5600 Fishers Lane, Rockville, Maryland, 20857, 301–827–6687, *carlos.peña@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 21, 2007, FDA announced that a meeting of the Science Board would be held on June 14, 2007. On page 28499, in the second and third columns, the *Agenda* and *Procedure* portions of document are amended to read as follows:

*Agenda*: The Science Board will hear about and discuss the agency's bioinformatics initiative and fellowship program. The Science Board will hear about and review the scientific validity of the agency's ''Interim Melamine and Analogues Safety/Risk Assessment'' (*http://www.cfsan.fda.gov/~lrd/fr070530.html*, Docket No. 2007N–0208). The Science Board will then continue its discussion of the review of both the agency's science programs and the National Antimicrobial Resistance Monitoring System (NARMS) Program, from the March 31, 2006, Science Board meeting. Discussions will first include a

subcommittee update to the Science Board on the progress of the review of the agency's science programs. The Science Board will then hear about and discuss the subcommittee review of the NARMS Program including the public meeting regarding the NARMS Program on April 10, 2007, and subsequent deliberations.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. We are extending the written submission deadline based upon the amended **Federal Register** notice. Written submissions may be made to the contact person on or before June 9, 2007. Two oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 p.m., and 3:15 p.m. and 4:15 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 9, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing sessions. The contact person will notify interested persons regarding their request to speak by June 9, 2007.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.2) and 21 CFR part 14, relating to the advisory committees.

Dated: June 1, 2007.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 07–2829 Filed 6–4–07; 11:10 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2007E–0010]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; CHANTIX

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for CHANTIX 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, 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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director 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 CHANTIX (varenicline tartrate). CHANTIX is indicated as an aid to smoking cessation treatment. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CHANTIX (U.S. Patent No. 6,410,550) from Pfizer, Inc., 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 26, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CHANTIX 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 CHANTIX is 2,401 days. Of this time, 2,219 days occurred during the testing phase of the regulatory review period, while 182 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 15, 1999. The applicant claims September 15, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 15, 1999, 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*: November 10, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for CHANTIX (NDA 21–928) was initially submitted on November 10, 2005.

3. *The date the application was approved*: May 10, 2006. FDA has verified the applicant's claim that NDA 21–928 was approved on May 10, 2006.

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 545 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 6, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence