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

during the regulatory review period by December 4, 2007. 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 Division of Dockets Management. Three copies of any mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 2, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–10915 Filed 6–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–1232] (formerly 98D–1232)

Guidance for Industry and Food and Drug Administration Staff; Assayed and Unassayed Quality Control Material; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry and FDA staff entitled ''Assayed and Unassayed Quality Control Material.'' The guidance describes FDA's current practices concerning assayed an unassayed quality control material, including information to include in a 510(k) for assayed quality control material, as well as labeling recommendations.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Assayed and Unassayed Quality Control Material'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0396.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides recommendations to manufacturers regarding preparation of premarket notifications and labeling for quality control (QC) material. These materials are intended to monitor reliability of a test system and help minimize reporting of incorrect test results. They are often the best source of ongoing feedback that a laboratory has to monitor whether results reported to physicians are sufficiently reliable. QC materials may be marketed together with a specific test system, or alternatively, for more general use.

Both assayed and unassayed QC materials are discussed in the guidance document. Both types of QC materials are subject to FDA's Quality System Regulation (part 820 (21 CFR part 820)) and labeling regulation (§ 809.10 (21 CFR 809.10)). However, most types of unassayed QC materials are exempt from premarket notification. (See ''Classification and Identification of QC Material'' of the guidance document for exceptions.) Although premarket notifications are number required for unassayed QC materials, some aspects of this guidance document concerning labeling, stability, and matrix effects are still relevant for these materials.

The draft version of this guidance was issued February 3, 1999. FDA received one set of comments on the draft guidance document during the comment period. The document reflects FDA's consideration of the comments and has also been updated to provide clarification as needed.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on assayed and unassayed quality control material. 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 requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Assayed and Unassayed Quality Control Material; Availability,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (2231) to identify the guidance you are requesting.

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 Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 610 have been approved under OMB control number 0910–0206; the collections of information in 21 CFR part 807 have been approved under OMB control number 0910–0120; the collections of information in § 809.10