implementation of this project. For example, a doctoral degree in economics or behavioral science with experience in the design and implementation of large-scale data collection processes and valuation of nonmarketed goods and services.

b. Evidence of organizational capacity for large-scale data collection.

c. Evidence of ability to cooperate in interorganizational and interdisciplinary settings.

4. Strategic Plan (25 Percent)

a. The objectives of the project are appropriate, feasible, and time-appropriate for the project.

b. The extent to which the multiple objectives of the project can be accomplished within the first year and how further objectives can be met in subsequent years.

5. Program Evaluation (10 Percent)

a. The extent to which the applicant proposes a strategy of ongoing evaluation and feedback for this project.

b. The adequacy of the applicant's plan to evaluate the overall effectiveness and success of the project.

6. Women and Racial and Ethnic Minorities in Research (5 Percent)

The extent to which the applicant addresses that they have met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (b) The proposed justification when representation is limited or absent; (c) A statement as to whether the design of the study is adequate to measure differences when warranted; (d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

7. Budget (not Scored)

The extent to which the applicant describes the total amount of funds requested in each of the object class categories and clearly links the budget items to objectives and activities proposed for the budget period.

8. Human Subjects (not Scored)

The extent to which the applicant has addressed necessary human subjects protections.

H. Other Requirements

Technical Reporting Requirements: Provide CDC with the original plus two copies of

1. Semi-annual progress reports including the following for each goal or activity involved in the study: (a) Comparison of actual accomplishments to the objectives established for the period; (b) the reasons for slippage if objectives were not met; (c) other pertinent information including, when appropriate, analysis and explanation of unexpectedly high costs for performance.

2. Financial Status Report is required within 90 days of each budget period.

3. Final financial status report and performance report are required within 90 days after the end of the project period.

Send all reports to: David Elswick, Grants Management Specialist Grants Management Branch, Procurement and Grants Office Centers for Disease Control and Prevention, (CDC) Room 300, 255 East Paces Ferry Road, NE., Mailstop E–13 Atlanta, GA 30305–2209.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1, included in the application kit.

AR98–1 Human Subjects Requirements
AR98–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR98–9 Paperwork Reduction Act Requirements
AR98–10 Smoke-Free Workplace Requirements
AR98–11 Healthy People 2000
AR98–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act, section 317(k)(2) 42USC247247(b)(k)(2). The Catalog of Federal Domestic Assistance number assigned to this project is 93.283.

J. Where To Obtain Additional Information

To receive additional written information call 1–888–GRANTS4. You will be asked to leave your name, address, and phone number and will need to refer to Announcement **98103**. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. **PLEASE REFER TO ANNOUNCEMENT NUMBER 98103 WHEN REQUESTING INFORMATION AND SUBMITTING AN APPLICATION**.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained by contacting:

David Elswick, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement **98103**
Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE., M/S E–13, Atlanta, GA 30305–2209, telephone (404) 842–6521

See also the CDC home page on the Internet: *http://www.cdc.gov*.

Programmatic technical assistance may be obtained from Mark L. Messonnier, Economist, Prevention Effectiveness Branch, Division of Prevention Research and Analytic Methods, Epidemiology Program Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop D–01, Atlanta, Georgia 30333, telephone (404) 639–4474.

Dated: July 13, 1998.

John L. Williams,

Director, Procurement and Grants Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–19074 Filed 7–16–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0291]

Determination of Regulatory Review Period for Purposes of Patent Extension; QUADRAMET®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for QUADRAMET® 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 human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 drug 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 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 QUADRAMET® (samarium sm 153 EDTMP). QUADRAMET® is indicated for relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance radionuclide bone scan. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for QUADRAMET® (U.S. Patent No. 4,898,724) from The Dow Chemical Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 7, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of QUADRAMET® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for QUADRAMET® is 2,844 days. Of this time, 2,189 days occurred during the testing phase of the regulatory review period, 655 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) became effective (21 U.S.C. 355)*: June 16, 1989.

The applicant claims January 28, 1986, as the date the investigational new drug application (IND) for QUADRAMET® (IND 33,240) became effective for purposes of regulatory review period determination. Applicant also states the notice of clinical investigation exemption was submitted on May 16, 1989. However, FDA records indicate that the IND effective date was June 16, 1989, which was 30 days after FDA receipt of IND 33,240.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: June 13, 1995.

FDA has verified the applicant's claim that the new drug application (NDA) for QUADRAMET® (NDA 20,570) was initially submitted on June 13, 1995.

3. *The date the application was approved: March 28, 1997*. FDA has verified the applicant's claim that NDA 20,570 was approved on March 28, 1997.

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 1,412 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 15, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 13, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 (address above) in three copies (except that individuals may submit single copies) and 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: June 23, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–19027 Filed 7–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription Drugs Advisory Committee: Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Nonprescription Drugs Advisory Committee. This meeting was announced in the **Federal Register** of June 26, 1998 (63 FR 34902). The amendment is being made to cancel the entire session on July 28, 1998. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Rhonda W. Stover or Angie Whitacre, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12541.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 1998 (63 FR 34902), FDA announced that a meeting of the Nonprescription Drugs Advisory Committee would be held on July 28 and 29, 1998.

1. On page 34902, in the third column, the ''*Date and Time*'' portion is amended to read as follows:

Date and Time: The meeting will be held on July 29, 1998, 8:30 a.m. to 5 p.m.

2. On page 34902, beginning in the third column, the ''*Agenda*'' portion is amended by removing the first paragraph.