I. Withdrawal of Approval of NDA 50–744

CollaGenex Pharmaceutical, Inc. (CollaGenex), is the holder of NDA 50–744 for PERIOSTAT (doxycycline hyclate) 20-mg capsules. In a letter dated September 24, 2001, CollaGenex informed FDA that this drug product is no longer marketed and said it ''is hereby withdrawing NDA 50–744.'' In a citizen petition dated July 10, 2002 (Docket No. 2002P–0312/CP1), CollaGenex requested that FDA withdraw approval of the application. The applicant has, by its request, waived its opportunity for a hearing. Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, approval of NDA 50–744 and all amendments and supplements thereto, is hereby withdrawn.

II. Determination That Doxycycline Hyclate 20-Mg Capsules Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a) (21 CFR 314.161(a)), the agency may make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness at any time if the drug has been voluntarily withdrawn from sale.

In its July 10, 2002, citizen petition, CollaGenex requested that FDA refuse to approve any ANDA for a generic version of doxycycline hyclate 20-mg capsules until FDA determines that PERIOSTAT (doxycycline hyclate) 20-mg capsules were not withdrawn for reasons of safety or effectiveness. CollaGenex also requested that PERIOSTAT (doxycycline hyclate) 20-mg capsules be moved to the ''Discontinued Drug Product List'' of the Orange Book and that FDA publish a notice in the **Federal Register** withdrawing approval of PERIOSTAT (doxycycline hyclate) 20-mg capsules. CollaGenex noted in its petition that it now has an approved NDA for a tablet version of PERIOSTAT. On July 10, 2002, CollaGenex also filed a petition for stay of action (Docket No. 2002P–0312/PSA1) requesting that FDA stay approval or receipt of any ANDA for a generic version of PERIOSTAT capsules pending final resolution of the issues in CollaGenex's citizen petition. In a citizen petition dated August 13, 2002 (Docket No. 2002P–0367/CP1), submitted under 21 CFR 10.25(a), 10.30, 314.122, and 314.161, West-ward Pharmaceutical Corp., requested that FDA determine whether PERIOSTAT (doxycycline hyclate) 20-mg capsules were withdrawn from sale for reasons of safety or effectiveness. This **Federal Register** notice resolves all such issues in the citizen petitions referenced in this document.

FDA has reviewed its records and, under § 314.161, has determined that PERIOSTAT (doxycycline hyclate) 20-mg capsules were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will list doxycycline hyclate 20-mg capsules in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs for doxycycline hyclate 20-mg capsules may be approved by the agency.

Dated: May 6, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9624 Filed 5–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of the Committee: Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 23, 2005, from 9 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Michael Bailey, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180 or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512524. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation on the FDA Critical Path Initiative. The committee will also discuss, make recommendations, and vote on a premarket approval application for a fetal heart monitoring device that, in addition to standard features, is used during labor and delivery to measure, display, and analyze the ST waveform of the fetal electrocardiogram. Background information, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 16, 2005. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. and between approximately 3:30 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before June 16, 2005, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240–276–0450, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.2).

Dated: May 9, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–9672 Filed 5–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for the opportunity for public comment on proposed data collection projects (section 3506 (c) (2) (A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Maternal and Child Health Bureau (MCHB) Common Grant Guidance for Discretionary Grants (OMB No. 0915–0272)—Revision

The Health Resources and Services Administration (HRSA) proposes to continue utilization of current reporting requirements for SPRANS projects, CISS projects, and other grant programs administered by the Maternal and Child Health Bureau (MCHB), that include national performance measures developed in accordance with requirements of the ''Government Performance and Results Act (GPRA) of 1993'' [Pub. L. 103–62]. The MCHB developed and had approved by OMB a set of performance measures for its discretionary funding programs in 2003. No major changes have been made to the performance measures, only minor editorial or format changes have been made for clarification. The burden estimate for this activity is based upon information provided by current and past MCHB discretionary funds supported projects, as well as experience in completing the current forms. The reporting burden is as follows:

Type of form	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Application/Annual Report	750	1	6	4,500

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 day of this notice.

Dated: May 10, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–9675 Filed 5–13–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for the opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995 (Pub. L. 104–13)), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed grant information collection activity or to obtain a copy of the data collection plan and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for proper performance of grantee functions including whether the information will have practical utility; (b) the accuracy of the burden estimate of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the information collection burden on respondents, including the use of automated collection methods or other types of information technology.

Proposed Project: Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Title II Grant Application Information Supplements: NEW

The CARE Act (codified under Title XXVI of the Public Health Service Act) was first enacted by Congress in 1990, and reauthorized in 1996 and 2000. It addresses the unmet health needs of persons living with HIV disease by funding primary health care and support services that enhance access to and retention in care. The CARE Act funded services reach over 571,000 individuals; after Medicaid and Medicare, it is the largest single source of Federal funding for HIV/AIDS care for low-income, uninsured, and underinsured Americans. The Title II Care Grant Program (CGP) provides formula grants to all 50 States; the District of Columbia; the Commonwealth of Puerto Rico; the Territories of the Virgin Islands, Guam, and American Samoa; the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the