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Food and Drug Administration
Rockville MD 20857

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Elizabeth A. Marro
Senior Director, Regulatory Affairs
and Quality Assurance
West-ward Pharmaceutical Corporation
465 Industrial Way West
Eatontown, NJ 07724

Re: Docket No. 2002P-0367/CP1

Dear Ms. Marro:

This letter responds to your citizen petition dated August 13, 2002, requesting that the Food and Drug Administration (FDA) determine whether Periostat (doxycycline hyclate) 20-milligram (mg) capsules were withdrawn from sale for safety or efficacy reasons.

The FDA has reviewed its records and determined that Periostat (doxycycline hyclate) 20-mg capsules were not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain Periostat (doxycycline hyclate) 20-mg capsules in the *Discontinued Drug Product List* section of *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 594-2041.

Sincerely,

Mary Catchings
Division of Regulatory Policy
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

cc:

Eugene M. Pfeifer
Elizabeth S. Crockett
King & Spaulding
1730 Pennsylvania Avenue, NW
Washington, DC 20006

2002P-0367

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegations of Authority

Notice is hereby given that under the authority vested in the Assistant Secretary for Children and Families by the memorandum dated October 1, 2003 from the Assistant Secretary for Administration and Management, I hereby redelegate to the Deputy Assistant Secretary for Administration, the following authority:

Authority Delegated

The authority to issue formal grievance decisions on matters under the line of supervision where the Assistant Secretary has the authority to decide the matter being grieved, except in cases where the Deputy Assistant Secretary for Administration has issued a prior decision.

Conditions and Limitations

This delegation excludes those authorities specifically reserved to or by the Secretary in the memorandum dated October 11, 2001.

This authority is to be exercised in accordance with the policies of the Department and the Administration for Children and Families.

Effective Date

This redelegation is effective on the date of signature. I hereby ratify any actions the Deputy Assistant Secretary for Administration may have taken pursuant to this authority prior to the effective date of this delegation.

Effect on Existing Delegations

This redelegation supersedes the redelegation to the Deputy Assistant Secretary for Administration dated February 10, 2005, relating to grievances.

Dated: May 6, 2005.

Wade F. Horn,

Assistant Secretary for Children and Families.

[FR Doc. 05-9697 Filed 5-13-05; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System 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 Committee: Circulatory System 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 22, 2005, from 8 a.m. to 4:30 p.m., and on June 23, 2005, from 8 a.m. to 4:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8320, ext. 143, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 22, 2005, the committee will discuss, make recommendations, and vote on a premarket approval application for a cardiac device intended to treat patients with heart failure. On June 23, 2005, the committee will discuss, make recommendations, and vote on a humanitarian device exemption for an artificial heart. Background information for the topics, 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 8, 2005. On both days, oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 8, 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 Shirley Meeks, Conference Management Staff, at 240-276-0450, ext. 105, 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 Walcott,

Associate Commissioner for External Relations.

[FR Doc. 05-9673 Filed 5-13-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2002P-0312 and 2002P-0367 (formerly Docket Nos. 02P-0312 and 02P-0367)]

CollaGenex Pharmaceuticals, Inc.; Withdrawal of Approval of a New Drug Application; Determination That Doxycycline Hyclate 20-Milligram Capsules Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of one new drug application (NDA). CollaGenex Pharmaceuticals, Inc., notified the agency in writing that PERIOSTAT (doxycycline hyclate) 20-milligram (mg) capsules were no longer marketed and requested that approval of NDA 50-774 be withdrawn. FDA has determined that PERIOSTAT (doxycycline hyclate) 20-mg capsules were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for doxycycline hyclate 20-mg capsules.

DATES: The withdrawal of approval of NDA 50-744 is effective June 15, 2005.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

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.