

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Withdrawal of Approval of a New Drug Application; Determination That Doxycycline Hyclate 20-Milligram Capsules Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(doxycycline hyclate) 20-milligram (mg) capsules were no longer marketed and requested that approval of NDA 50–774 be withdrawn. FDA has determined that PERIOSTAT (doxycycline hyclate) 20-mg capsules were not withdrawn from sale for reasons of safety or effectiveness.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 [*insert date 30 days after date of publication in the Federal Register*].

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Center for Drug Evaluation and Research, approval of NDA 50–744 and all amendments and supplements thereto, is hereby withdrawn.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 Determination That Doxycycline Hyclate 20-Mg Capsules Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S