



West-ward
PHARMACEUTICAL CORP.

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August 28, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: Docket 02P-0312: CollaGenex Pharmaceuticals Citizen Petition and
Petition for Stay of Action re: Periostat® Capsules**

Dear Sir or Madam:

We are writing in opposition to certain actions requested by CollaGenex Pharmaceuticals, Inc. ("CollaGenex") in a citizen petition and petition for stay of action dated July 10, 2002, Docket 02P-0312, namely that the Commissioner refuse to approve abbreviated new drug applications ("ANDAs") for generic Periostat® (doxycycline hyclate) capsules: (a) until FDA determines that the drug product was not withdrawn for reasons of safety and effectiveness; and (b) unless the abbreviated applications are accompanied by a petition seeking such a determination, as provided under 21 C.F.R. § 314.122. CollaGenex claims that it withdrew its NDA for Periostat® (doxycycline hyclate) 20 mg capsules in September 2001 in accordance with 21 C.F.R. § 314.150(c).¹

FDA should deny these actions CollaGenex requests with respect to West-ward Pharmaceutical Corporation's ("West-ward") ANDA for doxycycline hyclate 20 mg capsules. West-ward submitted ANDA 65-103 for doxycycline hyclate capsules, 20 mg, on August 30, 2001, *well before* CollaGenex notified FDA of its intent to withdraw the application for Periostat® capsules. Periostat® capsules never were withdrawn for sale, albeit CollaGenex chose to stop distribution when it depleted its capsule inventory. FDA accepted West-ward's ANDA for filing as of August 31, 2001, also *before* CollaGenex sought to withdraw its Periostat® application. Thus, West-ward's ANDA need not be accompanied by a petition under 21 C.F.R. § 314.122, and FDA need not determine that the Periostat® capsules application was withdrawn for reasons of safety and effectiveness in order to approve West-ward's ANDA.

¹ In its citizen petition, CollaGenex also requests that FDA move Periostat® capsules to the "Discontinued Drug Product List" in the Orange Book and announce the withdrawal of approval of the NDA in the Federal Register as provided by 21 C.F.R. § 314.152. West-ward does not object to these requests. However, whether or when FDA grants these requests have no bearing on the agency's ability to approve West-ward's ANDA for doxycycline hyclate 20 mg capsules.

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If, however, FDA determines that a petition under 21 C.F.R. § 314.122 is required, FDA should immediately make a determination that Periostat® capsules were not withdrawn from the market for safety and effectiveness reasons. In the interest of preventing any delay in the approval of its ANDA, West-ward has submitted a citizen petition requesting that FDA make a determination that Periostat® capsules were withdrawn for reasons other than safety and effectiveness. As discussed in the attached petition (which has been filed with Dockets under separate cover), CollaGenex elected to stop marketing Periostat® capsules for reasons not related to the safety and effectiveness of the product. CollaGenex did not disclose those reasons in its petitions, because such disclosures would provide a basis for denial of the actions it seeks in the petitions.²

CollaGenex also filed a petition for stay of action to request that the Commissioner stay action on any ANDA for a generic version of Periostat® capsules until the agency has responded to its citizen petition. FDA should deny this petition. Its sole purpose is to unnecessarily delay approval of West-ward's ANDA. FDA's regulations do not require it to respond to the CollaGenex petition before it may approve an ANDA that refers to a listed drug that has been voluntarily withdrawn. Moreover, the CollaGenex contention that the criteria for a mandatory stay have been met is without merit. Petitioner's failure to disclose the reason it no longer markets Periostat® capsules show, contrary to its claim, that the petition is frivolous and is not being pursued in good faith

The CollaGenex petitions seek to erect procedural hoops through which FDA and West-ward must jump in order to delay approval of West-ward's ANDA and thereby prevent generic competition. Such unnecessary delay would be harmful to the public interest. Accordingly, FDA should dismiss CollaGenex's petitions or promptly make a determination that CollaGenex withdrew Periostat® capsules from sale for reasons other than safety or effectiveness.

Sincerely,



Elizabeth A. Marro
Senior Director
Regulatory Affairs and Quality Assurance
West-ward Pharmaceutical Corporation

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² In failing to disclose the reasons, CollaGenex has provided an erroneous certification in violation of 21 C.F.R. § 10.30(b).