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Food and Drug Administration  
Department of Health and Human Services  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

PETITION FOR STAY OF ACTION

A. Decision Involved

CollaGenex Pharmaceuticals, Inc. ("CollaGenex") submits this petition under 21 C.F.R. § 10.35 to request that the Commissioner of Food and Drugs stay action on any abbreviated new drug application (ANDA) for a generic version of Periostat (doxycycline hyclate) 20 mg capsules ("the capsules") until the agency has responded to CollaGenex's Citizen Petition.

In its Citizen Petition, CollaGenex requests that because the capsules were voluntarily withdrawn from sale in the United States in 2001, the Commissioner of Food and Drugs: 1) refuse to approve any ANDA for a generic version of the capsules until FDA determines that they were not withdrawn for reasons of safety or effectiveness; 2) refuse to receive or approve any ANDA for a generic version of the capsules that is not accompanied by a petition seeking a determination about whether they were withdrawn for reasons of safety or effectiveness; 3) rescind any previous receipt of any ANDA that refers to the capsules as the listed drug; and 4) immediately move the capsules to the "Discontinued Product List" in the Orange Book and publish a Federal Register notice announcing the withdrawal of the NDA for the capsules, both of which should be retroactive to the date of the capsules' withdrawal from sale.

B. Action Requested

CollaGenex believes that at least one ANDA has been submitted for a generic version of the capsules. Specifically, it has learned that West-Ward Pharmaceutical Corporation has asked to add its version of the capsules to the New Jersey Drug Utilization Council's ("the Council's") list of approved generic substitutes, List of Interchangeable Drug Products, August 2002 Proposed Amendments, available at [www.state.nj.us/health/mgmt/rulepro0802a.htm](http://www.state.nj.us/health/mgmt/rulepro0802a.htm), a step generic drug companies usually take only after submission of an ANDA. CollaGenex asks that FDA stay approval or receipt of this and any other ANDA for a generic version of the capsules pending final resolution of the issues in CollaGenex's Citizen Petition.

The need for dispatch in this case is particularly acute because the Council will hold a public hearing about West-Ward's request on July 15, 2002, and is expected to act on the

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request by August 23, 2002. Drug Utilization Review Council Meeting and Submission Dates, 2002-2003, available at [www.state.nj.us/health/mgmt/durcmtsub.htm](http://www.state.nj.us/health/mgmt/durcmtsub.htm). Consequently, CollaGenex asks that FDA respond to this Petition for Stay of Action within 30 days.

### C. Statement of Grounds

#### Mandatory Stay

Under 21 C.F.R. § 10.35(e), FDA must grant a stay of action if all of the following apply:

- (1) the petitioner will otherwise suffer irreparable injury;
- (2) the petitioner's case is not frivolous and is being pursued in good faith;
- (3) the petitioner has demonstrated sound public policy grounds supporting the stay; and
- (4) the delay resulting from the stay is not outweighed by public health or other public interests.

As demonstrated below, all of these criteria are met here.

Without a stay, CollaGenex will suffer irreparable injury. Periostat is CollaGenex's only approved product.<sup>1</sup> Approval of a generic version of the capsules would deprive it of significant revenue. There is no mechanism by which sales and market share lost to generic products can be recovered. Like the loss to plaintiffs in Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 29 (D.D.C. 1997) (citation omitted), the loss to CollaGenex in the absence of a stay, "[w]hile... 'admittedly economic,'" would be without "adequate compensatory or other corrective relief" that can be provided at a later date, tipping the balance in favor of [the]...relief."

CollaGenex's case is not frivolous and is being pursued in good faith. As its Citizen Petition demonstrates, CollaGenex's case is not only not frivolous, it is compelling. CollaGenex voluntarily withdrew the capsules from sale and submitted all the required paperwork to FDA. Consequently, FDA cannot lawfully receive any ANDA that refers to the capsules as the listed drug that is not accompanied by a petition seeking a determination that the capsules were not withdrawn for reasons of safety and effectiveness, and it cannot approve such an ANDA until it makes that determination. 21 C.F.R. §§ 314.122 and 314.127(a)(11). Furthermore, CollaGenex's case is being pursued in good faith. It began attempting to address this situation as soon as it realized that an ANDA for a generic version of the capsules might have been submitted.

Sound public policy grounds support the stay. The NDA and ANDA processes are intended to simultaneously encourage the costly research and development efforts that lead to the discovery of therapeutically important new drugs and expedite the availability of safe, effective, and less expensive versions of approved drugs. FDA approval or receipt of an

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1. CollaGenex currently markets Periostat in tablet form.

ANDA for a generic version of the capsules that is not accompanied by a petition seeking a determination that their withdrawal was not for reasons of safety or effectiveness would be contrary to those processes, and therefore would upset the delicate balance between those often competing aims.

The delay will not harm the public interest. There is a “strong public interest in requiring an agency to act lawfully...and to treat all similarly situated and regulated parties equally.” Bracco Diagnostics, 963 F. Supp at 30. FDA approval or receipt of an ANDA for a generic version of the capsules that is unaccompanied by a petition seeking a determination that the capsules were not withdrawn for reasons of safety and effectiveness would treat this ANDA differently from the way it treats all other ANDAs for generic versions of products that were withdrawn from sale. Moreover, “[t]he public’s interest in ‘the faithful application of the laws’ outweigh[s] its interest in immediate access to [a competing] product.” Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998).

#### Discretionary Stay

FDA regulations also authorize the agency to grant a stay if it “is in the public interest and in the interest of justice.” 21 C.F.R. § 10.35(e). Both the public interest and the interest of justice demand that FDA adhere to its own rules. If FDA will not grant a mandatory stay, it should grant a discretionary stay.

#### D. Conclusion

CollaGenex’s Citizen Petition asks only that FDA follow its own rules regarding the receipt and approval of ANDAs. This stay should be granted so that FDA can make sure that it does so.

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