DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN - 9 2003

Christopher V. Powala
Senior Director, Drug Development
and Regulatory Affairs
CollaGenex Pharmaceuticals, Inc.
41 University Drive
Newtown, Pennsylvania 18940

Re: Docket No. 02P-0312/CP1

Dear Mr. Powala:

This letter responds to your citizen petition dated July 10, 2002, requesting that the Food and Drug Administration (FDA) (1) refuse to approve any abbreviated new drug application (ANDA) for a generic version of Periostat (doxycycline hyclate) 20 milligram capsules (the capsules) until FDA determines that they were not withdrawn for reasons of safety or effectiveness; (2) refuse to receive or approve any ANDA for a generic version of the capsules not accompanied by a petition seeking a determination about whether the capsules were withdrawn for safety or effectiveness reasons; (3) immediately move the capsules to the *Discontinued Drug Product List* in the *Approved Drug Products with Therapeutic Equivalence*; and (4) publish a Federal Register notice announcing the withdrawal of the NDA for the capsules.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

cc:
Nancy L. Buc
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Washington, D.C. 20006

02P-0312

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