HFA 305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 7 2003

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

Re: Docket No. 02P-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the Food and Drug Administration (FDA) determine whether Periostat (doxycycline hyclate) 20-milligram capsules were withdrawn from sale for safety or efficacy reasons.

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

02P-0367

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