DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



Food and Drug Administration Rockville MD 20857

NOV 20 2006

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

Re: Docket No. 2006P-0218/CP1

Dear Ms. Marro:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on May 24, 2006. Your petition requests that the Agency determine whether Triamcinolone Diacetate Suspension, 40 mg/mL (NDA 12-802) has been voluntarily withdrawn from distribution and sale for safety or efficacy reasons.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 possible given the numerous demands on the Agency's resources.

Sincerely,

Maney E. Booker Jane A. Axelrad

Associate Director for Policy

Center for Drug Evaluation and Research