



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 4 2003

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Christina M. Markus
King & Spalding
1700 Pennsylvania Avenue
Washington, DC 20006-4706

Docket No. 02P-0401/CP1

Dear Ms. Markus:

This letter responds to your citizen petition dated September 5, 2002 requesting that the Food and Drug Administration (FDA) stop distribution of unapproved ammonium lactate products and pursue enforcement action if product sponsors fail to comply.

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 yours,

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

02P-0401

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