



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

WARNING LETTER NYK 2002-04

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

October 23, 2001

Mr. Gerritt Vreeman, President  
Purac America, Inc.  
111 Barclay Blvd., # 280  
Lincolnshire, IL 60069-3610

Dear Mr. Vreeman:

The Food and Drug Administration (FDA) has information which shows your firm violated the Federal Food, Drug, and Cosmetic Act.

On June 6, 2001 your firm imported [REDACTED] drums of Lactic Acid into the United States from Spain under Entry Number 231-9298385-8. An investigation conducted by this office revealed the entry was not held intact for FDA sampling, and has been distributed. We have requested U.S. Customs to order redelivery of the entry.

This action taken by your firm is in violation of 21 CFR 1.90, which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from the FDA. A "Release" by the U.S. Customs Service is a conditional release, which merely permits you to take possession of the shipment. When other Federal Agencies, such as the FDA, also exercise jurisdiction over a product offered for importation, their release must be obtained before a product may be legally distributed.

It is your responsibility, as the owner/importer, to ensure imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder. Failure to promptly correct these violations and prevent future violations may result in regulatory action without future notice.

Mr. Gerritt Vreeman, President  
Purac America, Inc.  
Lincolnshire, IL

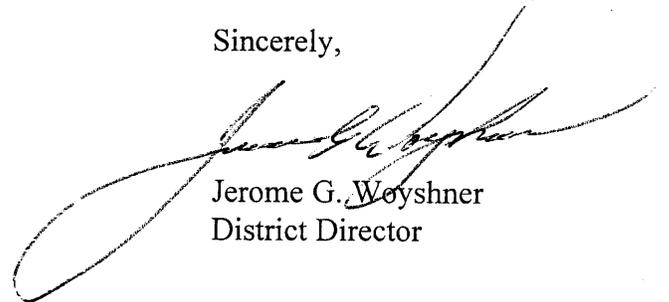
October 23, 2001

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Within fifteen (15) working days of the receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent a recurrence of the violation. Your response should be directed to Michael Wirth, Compliance Officer.

If you require further information, you may contact Michael Wirth at (716) 551-4461, Extension 3144.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", is written over the typed name and title.

Jerome G. Woyshner  
District Director

cc: Ms. Ann Marie Paul, Field National Import Specialist  
United States Customs Service  
111 West Huron Street  
Buffalo, New York 14202

Jacqueline M. Klahn  
Port Director  
U. S. Department of Agriculture  
783 Busti Ave., 1<sup>st</sup> Floor  
Buffalo, New York 14213