



DEPARTMENT OF HEALTH & HUMAN SERVICES

M 3373n  
New York District

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

WARNING LETTER NYK 2000-26

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

January 25, 2000

Mr. Denis Wellington  
Chief Executive Officer/General Manager  
Puratos Corporation  
U.S. Corporate Headquarters  
1941 Old Cuthbert Road  
Cherry Hill, New Jersey 08034

Dear Mr. Wellington:

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

On December 3, 1999, your firm imported caramel milk chocolate into the United States under Entry No. 551-8927346-3. An investigation conducted by this office revealed the entry was not held intact, and six of the [REDACTED] boxes of chocolate had been repackaged, and sent to Piedmont Provisions in Winston-Salem, North Carolina.

This shipment has been detained, refused admission, and 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.

Failure to promptly correct these violations and prevent future violations may result in regulatory action without future notice, such as seizure or automatic detention, to ensure that imported products are held intact until released by FDA. 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.

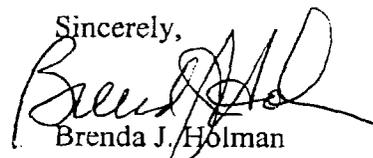
Within fifteen (15) working days of the receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violation(s), including an explanation of each step being taken to prevent a recurrence of the violation(s). Your response should be directed to Mark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

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal, or commercial information purged.

I have also enclosed a memo regarding the President's Initiative To Ensure The Safety of Imported Foods, and two public meetings to be held by FDA in February 2000, for your information.

If you require further information, you may contact Mark P. Prusak at (716) 551-4461, Extension 3153.

Sincerely,



Brenda J. Holman  
District Director

Enclosure

cc:

Mr. Stephen A. Dagrosa, Manager QC/QA  
Puratos Corporation  
U.S. Corporate Headquarters  
1941 Old Cuthbert Road  
Cherry Hill, New Jersey 08034

Mr. Michael Dahm, Branch Manager  
A.N. Deringer, Inc.  
1010 Niagara Street  
Buffalo, New York 14213