



d1776b

5/20/98

PURGED *REK*

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

May 12, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 25

Paul E. Scharfman
President
Specialty Cheese Company, Inc.
455 South River Street
Lowell, Wisconsin 53557

Dear Mr. Scharfman:

The Food and Drug Administration with the Wisconsin Department of Agriculture, Trade and Consumer Protection conducted an inspection at your Watertown and Lowell, WI, facilities on March 27, 1998, and March 30, 1998, respectively. During the Lowell inspection four samples of semi-soft Mexican style cheese were collected and identified with FDA sample numbers 37, 38, 39 and 40.

Microbiological analysis of these samples reveals that products identified with samples 37 and 38 are confirmed positive for the presence of *Listeria monocytogenes*. The presence of *L. monocytogenes* causes these cheeses to be adulterated according the Federal Food, Drug and Cosmetic Act (the Act) as follows:

Section 402(a)(1): A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health....

We acknowledge that you voluntarily destroyed the suspect molding equipment and are currently in the process of collecting and voluntarily destroying the

Page Two

Paul E. Scharfman
May 12, 1998

contaminated cheese. We also understand you have re-worked your standard sanitation operating procedure to be more rigorous and that you plan to adopt FDA's cheese vat sampling procedure as your future standard sampling operating procedure, and that you will not release for distribution any vat of cheese prior to the completion of the microbiological analysis in the future. It is also our understanding that you have contracted with a different cheese repacker and that you no longer produce the semi-soft Mexican style cheese.

We encourage you to continue your search for the causes of this microbiological problem and to take corrective actions as soon as possible. Failure to implement lasting corrective actions may result in regulatory action by FDA without further notice, such as product seizure and/or injunction for you and your company.

Please notify this office in writing within 15 working days of receipt of this letter of the current status of your corrective actions and the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent future recurrence of similar violations. Your response may be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead. Your continued cooperation is appreciated.

Sincerely,



James A. Rahto
Director
Minneapolis District

TPN/ccl