



DEPARTMENT OF HEALTH & HUMAN SERVICES

PURCHASED

Public Health Service

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December 11, 1996

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1998
Telephone: 612-334-4100

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Refer to MIN 97-16

Joseph M. Weller
President
Nestle, USA
800 North Brand Boulevard
Glendale, California 91203

cc: HFI-35/FOI Sta
DWA

Dear Mr. Weller:

FDA has conducted two recent inspections of your Eau Claire, WI, infant formula processing plant.

The first inspection, conducted on August 21-22, 1996, was in response to your firm's recall of Alsoy soy formula, 13 fl. oz. concentrated liquid, due to discrepancies between the lid and product labels.

The second FDA inspection was conducted on October 15-28, 1996, and included an investigation covering the circumstances surrounding your firm's recall of Follow-Up ready-to-feed (RTF) liquid infant formula.

Both inspections reveal serious deficiencies which cause both of the referenced formula products processed at your Eau Claire facility to be adulterated within the meaning of Section 402(a)(4) and 412(d)(1) of the Federal Food, Drug and Cosmetic Act (the Act) as follows:

Alsoy:

The manufacturing of the infant formula under conditions which permitted the use of the wrong lid caused the Alsoy concentrate infant formula to be adulterated under Section 402(a)(4) because it was prepared under insanitary conditions whereby it may have been rendered injurious to health. Concentrated formula fed as diluted read-to-feed formula may result in life-threatening dehydration and hypernatremia (water deficiency and increased blood sodium) Infants fed this concentrated formula without normal dilution will develop hypertonicity and may develop symptoms such as diarrhea, cramping and vomiting.

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Follow-Up: Holding the product for extended time periods at temperatures in excess of that specified in the operating procedures, without evaluating the effects of this deviation on the safety and suitability of the product and the quality and/or availability of its nutrients is a deviation from Title 21 of the Code of Federal Regulations (CFR), part 106.30(c) and Section 412(d)(1) of the Act.

The holding of this product for extended periods of time at _____ could also create a condition that would create a likelihood that staphylococcal enterotoxin could form and therefore the product may become injurious to health, [402(a)(4)].

The above cited deviations are not intended to be all-inclusive. We acknowledge receipt of written responses after both inspections addressing our investigators' observations. The letters will be made part of your company file and the promised corrections will be verified during our next inspection.

In addition, we recently received a letter from Greg Pincar, Vice President-Operations, requesting a meeting to further discuss the issues. We are currently in the process of arranging a mutually suitable meeting date.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made. We will include the minutes of the upcoming meeting along with your written reply as the official response to this letter.

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Your reply should be directed to Compliance Officer Walter L. Stauffacher at the address indicated on the letterhead.

Sincerely yours,



John Feldman
District Director
Minneapolis District

WLS/rfk

cc: Russell Hill, Ph.D. 
Plant Manager
Nestle Food Company
1200 Nestle Avenue, P.O. Box 168
Eau Claire, WI 54702