DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
M2438n

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

March 5, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 19

Bradley V. Beckman
Chief Executive Officer
Custom Cuts Company
2842 South Fifth Court
Milwaukee, Wisconsin 53207

Dear Mr. Beckman:

The Food and Drug Administration (FDA) and the Minnesota Department of Agriculture conducted an inspection at your Custom Cuts of St. Paul Inc., St. Paul, MN, facility on January 28 - February 1 and 3, 1999, after receiving information from the Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) that two samples of cut salad product tested positive for *Listeria monocytogenes type 1 (L. mono)*. During the inspection four samples of salad products and a set of environmental swabs were collected and identified with FDA sample numbers: 32205--Environmental swabs; 32206--Shredded cabbage (in-line); 32207--Shredded carrots (in-line); 32208--Finished salad coded 652434228. 32209--Finished salad coded 652434227.

Microbiological analysis of these samples reveals that products identified with sample numbers 32208 and 32209 are confirmed positive for the presence of *L. mono*. The environmental swabs identified as sample 32205 also confirm positive for *L. mono*. The presence of *L. mono* causes these salads to be adulterated according to 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.... These sample analyses show you have an on-going problem with microbiological contamination of your salad products from at least January 4, 1999, when the first WDATCP sample was collected to at least January 28, 1999, when FDA samples were collected.

The above cited violation is not intended to be an all-inclusive list of deficiencies that may exist with your products and at your facilities. It is your responsibility to ensure that all of your operations are in compliance with applicable State and Federal requirements.

We strongly recommend you determine the cause(s) of this microbiological problem and take corrective action as soon as possible. Failure to implement lasting corrective action may result in regulatory action being initiated by FDA without further notice. This action may include product seizure and/or injunction against 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 should be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

TPN/ccl

xc: Marylou Beckman
President
Custom Cuts of St. Paul Inc.
415 Grove Street
St. Paul, MN 55101