



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 17, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-88

Bernie I. Souphanavong, Owner
Northland Soy Products, Inc.
2905 Tanglewood Drive
Anchorage, Alaska 99517

WARNING LETTER

Dear Mr. Souphanavong:

We inspected your firm located at 2905 Tanglewood Drive, Anchorage, Alaska, on June 14, 17, and 20, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. You are also in violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and 21 CFR 101, Food Labeling. A FDA 483 form (copy enclosed) listing the deviation was presented to Arthur L. Powell, Production Supervisor, at the conclusion of the inspection on June 20, 2000. This deviation causes your sprouts to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act, and food labeling information, through links in FDA's homepage at www.fda.gov.

Your firm's sprouts are adulterated within the meaning of section 402(a)(4) of the Act because they are being produced under insanitary conditions that may render the sprouts injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your firm.

Labeling

In addition to the above deficiency, the labeling for your Fresh Alaskan Soft Tofu and Fresh Alaskan Firm Tofu are in violation of Section 403 of the Act and 21 CFR Part 101 - Food Labeling. The ingredient statement for these products must include all the ingredients by common or usual name in descending order of predominance by weight (21 CFR 101.4(a)(1)). The tofu labels do not declare "Delta Glucono Lactone" as an ingredient. Failure to declare this ingredient has also been brought to your attention during FDA inspections of your firm on January 27 and 29, 1993, and June 23 and 24, 1999.

Bernie I. Souphanavong, Owner
Northland Soy Products, Inc., Anchorage, Alaska
Re: Warning Letter SEA 00-88
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This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa Althar, Compliance Officer at (425) 483-4940 or via e-mail at lalthar@ora.fda.gov.

Sincerely,



Charles M. Breen
District Director

Enclosures:

Form FDA 483 –June 14, 17, and 20, 2000

21 CFR PART 110

Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: ADEC with disclosure statement