



March 13, 2001

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-24-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Paul A. Buhl, President
Noon Hour Food Products, Inc.
215 N. Des Plaines Street
Chicago, IL 60661

Dear Mr. Buhl:

On November 15, 16 and 28, 2000, the Food and Drug Administration (FDA) conducted an inspection of your firm, as a follow-up to our inspections of March 26 and 27, 1998, and August 3, 1999. The purpose of these inspections was to determine compliance with both the FDA Hazard Analysis and Critical Control Point (HACCP) Regulations for seafood, implemented in December of 1997, and the Good Manufacturing Practice (GMP) Regulations for foods. Subsequent to the March 1998 inspection, we sent you a letter dated May 27, 1998, notifying you of serious HACCP deficiencies observed during that inspection. In that letter, we requested a response from you, but none was received. Following the November 2000 inspection, the investigator issued your Vice President, Mr. William L. Buhl, an FDA 483 (Inspectional Observations), listing observations that included new, as well as continued, HACCP deficiencies, several of which in particular can jeopardize the integrity of your HACCP system if left uncorrected. Several GMP defects were also noted. (A copy of the FDA 483 is enclosed.)

The deficiencies identified in these inspections include a significant deviation from FDA's seafood HACCP regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). This violation causes your products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP Regulations through links in FDA's home page at <http://www.fda.gov>.

Specifically, our investigator found the following repeated serious deviation, which we had earlier brought to your attention in our letter, dated May 27, 1998, pursuant to our previous inspection of March 1998:

In regard to your domestic seafood operation:

- Your firm has failed to implement a record-keeping system that indicates that you are recording the internal temperature of your herring products at receiving, which is a Critical Control Point for the hazard of histamines. [See 21 CFR 123.6(b).]

The above-cited violation is not intended to be all-inclusive. It is your responsibility to evaluate your program and ensure it is in compliance with the regulations. You should take prompt action to correct this violation. Although our investigator reported corrections for some other deficiencies noted during the inspection, we are concerned that this substantial violation was found to reoccur after the inspection in March 1998, and subsequent letter of May 27, 1998. Failure to promptly correct this violation may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

In addition to the deviation described above, the following observations were made during the November 2000 inspection:

In regard to your import seafood operation:

- Your firm has not developed a list of written product specifications that are designed to ensure that the products you import are safe, and are processed in accordance with seafood HACCP requirements. [See 21 CFR 123.12 (a)(2) (i).]
- Your firm has not developed written importer verification procedures, where no MOU exists for the products you import, as required by 21 CFR 123.12 (a)(2).
- For the Importer's Affirmative Step you have taken, relative to your foreign processor's listing as an approved Canadian exporter, your firm has not identified this step in your own written plan (verification procedure), as required by 21 CFR 123.12 (a)(2) and (a)(2)(ii).

- For the Importer's Affirmative Step you have taken, relative to your foreign processor's listing as an approved Canadian exporter, your firm has not maintained records that document your own evaluation of the performance and results of the Affirmative Step. These records are required as your verification of supplier acceptability for imported seafood products, in accord with 21 CFR 123.12 (a)(2)(ii) and (c).

In regard to your domestic seafood operation:

- Your firm lacks calibration records for your thermometers, which are process-control instruments used at Critical Control Points in your operation. These records are required by 21 CFR 123.8 (d). [This deviation was previously reported to you during our inspection of March 26 and 27, 1998, and in our subsequent letter, dated May 27, 1998.]
- Your firm has not conducted a HACCP records review for monitoring that occurs at receiving, processing and storage, as required by 21 CFR 123.8 (a)(3).

Additionally, our investigator reported that your firm was using unshielded light fixtures in the processing area, and was also storing insecticide in the general vicinity of your processing room.

Your reply to all of these concerns should be directed to James Karpus, Compliance Officer, at the Chicago District Office.

Sincerely

\s\
Raymond V. Mlecko
District Director

Enclosure: Form FDA 483

cc w/enclosure: Mr. William L. Buhl, Vice President
Noon Hour Food Products, Inc.
215 N. Des Plaines
Chicago, IL 60661