U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

NOC Management Co. Inc. 12/15/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
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WARNING LETTER
CIN-11-140671-03

Via United Parcel Service

December 15, 2010

Mr. Dale Hartlage, President
NOC Management Co. Inc.
475 Victory Lane
Springboro, Ohio 45066-3047

Dear Mr. Hartlage:

We inspected your seafood processing facility, located at 475 Victory Lane, Springboro, Ohio 45066 on September 14-16, 2010. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123, and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR 123 & 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your fish and fishery products, including your vacuum packed fish and histamine forming fish, are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov[1].

Your significant violations were as follows:

1. You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and you must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm does not have a HACCP plan to control the hazard of *Clostridium botulinum* growth and toxin formation in your vacuum packed fish that your firm thaws under refrigeration in its intact packaging.

FDA recommends the use of equipment capable of monitoring and recording cooler temperatures on a 24 hour a day/7 day week basis, with a daily check of the temperatures and a daily check of the equipment when products are stored in coolers without ice or cooling media to control pathogen growth and potential toxin formation.

2. Because you chose to include a corrective action plan in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plans for your histamine forming fish are not appropriate. Your action plans do not ensure that no products enter commerce that are either injurious to health or otherwise adulterated as a result of deviations and do not correct the cause of the deviations. Specifically,

A. At the receiving critical control point, your actions listed as "re-ice, check internal temperature which must be ≤ 40°F, test 10 fish in entire lot or to verify transit temperature" are not appropriate, unless the re-icing occurs immediately after the product temperatures are taken and found to be within the temperature critical limits, because re-icing fish that have been temperature abused during transit to your facility will not mitigate or prevent distributio of potentially unsafe fish with elevated histamine levels due to the abusive conditions. In addition, your firm will no be capable of verifying transit temperatures because your firm is not monitoring transit temperatures as part of your control strategy at receiving. FDA does not recommend product testing as a corrective action when products have exceeded the listed critical limits, because random sampling will not reflect the condition of all of the fish in the lot following the excursions above the critical limits. Moreover, these actions do not address correcting the cause of the deviation.

B. At the storage critical control point your actions listed as "re-ice product, check temperature which must be ≤ 40°I or adjust cooler temperature" are not appropriate. Again, re-icing potentially temperature abused fish will not mitigate or prevent distribution of potentially unsafe fish with elevated histamine levels due to abusive conditions. I addition, a one time temperature check will not provide enough information about the cooler temperatures on which to base a corrective action. Moreover, these actions do not address correcting the cause of the deviation.

3. You must have a HACCP plan that, at a minimum lists a monitoring procedure and frequency at the storage critical contro point to comply with 21 CFR 123.6(c)(4). A critical control point is defined as 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for histamine producing fish lists a monitoring procedure and frequency at the "Refrigerated Storage" critical control point that is not adequate to control histamines. Your plan lists that you will "check for ice" and check the "Cooler" twice daily during plant operating hours. Unless your firm does not store product in the cooler outside of normal business hours such as Sundays and holidays, your firm needs to check the presence of adequate ice surrounding the fish twice daily including those days when your firm is not in full operation. Moreover, monitoring cooler temperatures twice daily when your firm is relying on cooler temperatures as the monitoring procedure at storage is not adequate because intermittent checks will not provide information about the temperatures of the cooler between those checks. FDA recommends the use of equipment capable of monitoring and recording cooler temperatures on a 24 hour a day/7 day week basis, with a daily check of the temperatures and a daily check of the equipment when products are stored in coolers without ice or cooling media.

4. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b) and (c)(7). However, your firm did not record monitoring observations at the receiving and storage critical control points to control histamines listed in your HACCP plan for histamine producing fish. Specifically, your firm does not record the presenc of ice at the receiving and storage critical control points as listed in your plan. In addition, your firm does not maintain original sanitation records or records required by your firms HACCP plan for histamine producing fish. Your firm transcribes from the original records into a computer database and the original record is destroyed.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in you response documentation such as HACCP and verifications records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation (21 CFR Part 123) and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Allison C. Hunter, Compliance Officer, 6751 Steger Dr, Cincinnati, Ohio 45237. If you have questions regarding any issues in this letter, please contact Ms. Hunter at 513-679-2700, Extension 134 or at allison.hunter@fda.hhs.gov.

Sincerely,

/S/

Teresa C. Thompson
District Director
Cincinnati District

Noc Management Co Inc - Closeout letter

- Noc Management Co Inc - Closeout letter[2]

Links on this page:

1. http://www.fda.gov
2. /ICECI/EnforcementActions/WarningLetters/ucm260292.htm