



DEPARTMENT OF HEALTH & HUMAN SERVICES

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**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: 313-226-6260

**WARNING LETTER**  
**2002-DT-28**

May 30, 2002

Ms. Mary Anna Daskas-Georgopoulos, President  
Chicago Beef Company  
1939 Adelaide Street  
Detroit, MI 48207

Dear Ms. Daskas-Georgopoulos:

On March 13-20, 2002, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 1939 Adelaide Street, Detroit, MI 48207. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 CFR 123).

The seafood processing regulations (21 CFR 123), which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. Prudent processors already take these kinds of measures. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating under HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection, the FDA investigator observed shortcomings in your system that are serious deviations from the principles of HACCP and the significant requirements of the program. These deviations, some of which were previously brought to your attention, cause your fresh tuna, mahi mahi, blue marlin, and aquaculture salmon to be in violation of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's homepage, <http://www.fda.gov>.

These deviations are as follows:

- (1) You must implement an affirmative action step which insures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for imported tuna, mahi mahi, and blue marlin manufactured by [REDACTED] and for imported salmon manufactured by [REDACTED].
- (2) You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have written product safety specifications for scombrototoxic species that you import from [REDACTED] such as fresh tuna, mahi mahi and blue marlin.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such sanctions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

In addition, the FDA investigator found shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. These deviations noted at your firm include:

- (1) You must have a written HACCP plan in place to control any food safety hazard that is reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan to control the hazard of pathogen growth in herring in wine sauce and creamed fillet of herring, which are warehoused under refrigeration and distributed by your firm, and to control the hazard of histamine formation in fresh blue marlin, fresh amberjack, and fresh wahoo that are distributed by your firm.
- (2) You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plans for scombrotoxin producing species, such as fresh tuna and mahi mahi, and for pasteurized crabmeat list a critical limit of 42° F at the Receiving CCP. These critical limits are not adequate to control histamine formation in scombrotoxin producing species or pathogen growth in pasteurized crabmeat. The Fish & Fishery

Products Hazards & Control Guide, third edition, recommends these fishery products be kept at a temperature of not more than 40° F throughout transit. In addition, the monitoring procedures in these plans for the Receiving CCP do not require continuous temperature monitoring throughout transit or observations of ice surrounding the product upon receipt.

- (3) You must adequately monitor sanitation conditions and practices, to comply with 21 CFR 123.11(b). However, during the investigation the following sanitation deficiencies were noted:
  - a. During the inspection, the [REDACTED] concentration in the employee hand dips was inaccurately documented on the sanitation monitoring record as being adequate; however, no iodine was observed being used.
  - b. Your sanitation monitoring record for March 13, 2002 had data pre-filled in at 8:30 AM to reflect that the 12:00 PM monitoring of "product residue removed from equipment before lunch" was accomplished.
  - c. Your sanitation monitoring record for March 13, 2002 includes monitoring documentation that is not concurrent with the work accomplished. On 3/13/02, it was observed that a sanitation monitoring procedure was accomplished at 3:00 PM; however, this work was not documented on the sanitation monitoring form by the end of the day. This work accomplishment was actually documented the following day.
- (4) You must verify that your HACCP plans are being effectively implemented, to comply with 21 CFR 123.8(a)(2)(ii). On-going verification activities include the calibration of process-monitoring instruments. During the inspection the thermometer in use to measure the temperature of pasteurized crabmeat at the Receiving CCP was checked and found likely to be providing erroneously low temperature readings. In addition, the thermometers used to monitor the Receiving CCP had not been calibrated bimonthly as required by the verification procedures listed in your HACCP plans for fresh tuna/mahi mahi and pasteurized crabmeat.
- (5) As part of the overall verification of your HACCP plans, you must perform a record review, including signing and dating, by an individual who has been trained in accordance with section 123.10, to comply with 21 CFR 123.8(a)(3). The current inspection found that 12 of 12 monitoring records for the Storage CCP, which is incorporated into the sanitation monitoring record, lacked documentation of the weekly review required by your HACCP plans for fresh tuna/mahi mahi and pasteurized crabmeat.

Ms. Mary Anna Daskas-Georgopoulos  
Chicago Beef Company

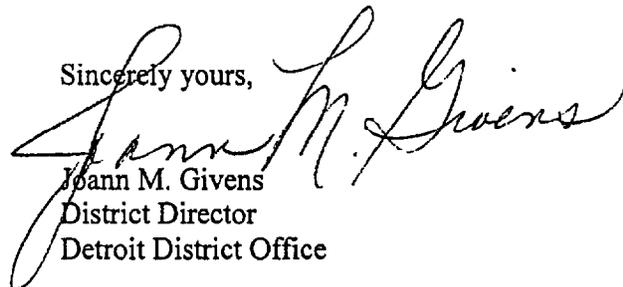
May 30, 2002  
Page 4

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal government.

Please notify this office in writing within fifteen (15) working days of receipt this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed with 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to Mr. David M. Kaszubski, Director Compliance Branch, U. S. Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207, telephone (313) 226-6260 ext 185.

Sincerely yours,



Joann M. Givens  
District Director  
Detroit District Office