



93710d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1989
Telephone: 612-334-4100

November 21, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 06

Greg Ostrander
President and CEO
Michael Foods Company, Inc.
5353 Wayzata Boulevard, Suite 324
Minneapolis, Minnesota 55416

Dear Mr. Ostrander:

An inspection of your Kohler Mix Specialties, 4041 Highway 61, White Bear Lake, Minnesota, facility was conducted on April 30, May 1, 2, 13, 16 and 17, 2002. This inspection was conducted to determine your firm's compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and implementing regulations contained in Title 21, Code of Federal Regulations, Parts 108.35 and 113 (21 CFR 108.35 and 21 CFR 113).

During this inspection our investigators obtained documentation regarding the production of several of your products. A review of these records and observations made by the investigators show your products to be adulterated within the meaning of Section 402(a)(1) of the Act. The specifics of each deviation follow:

1. Your firm failed to always make, and record on a written operator's form, observations of operating conditions including the sterilization media flow rates, temperatures, the container and closure rates through the sterilization system at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved [21 CFR 108.35(h), 21 CFR 113.40(g)(2)(ii)(c), 21 CFR 113.40(g)(4), and 21 CFR 113.100(a)(4)].

During our inspection of your plant, our investigators observed that your firm's aseptic filling and packaging system operators fail to record critical filling and packaging parameters (line speed, hot air manifold temperature, laboratory verification of the hydrogen peroxide concentration, cap/lid stock hydrogen peroxide flow rate, aseptic zone overpressure, and

Page Two

Greg Ostrander
November 21, 2002

other critical factors identified in the scheduled process for the *MM* aseptic filling and packaging system in the Supplemental Information.

2. Your firm failed to always make, and record on a written operator's form, observations of the temperature-indicating device in holding tube outlet; temperature recorder in holding tube outlet; temperature recorder controller in final heater outlet; differential pressure recorder-controller, product flow rate as established by the metering pump or as determined by filling and closing rates; and proper performance of seam seals or other similar devices at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process [21 CFR 108.35(h), 21 CFR 113.40(g)(1)(ii)(e), 21 CFR 113.40(g)(4), and 21 CFR 113.100(a)(4)].

During our inspection of your plant, our investigators observed that your firm failed to always record critical factors during product sterilization of shelf-stable dairy creamers on a written operator's form. On January 10, 2002, start-up occurred at 4:17 p.m. and no critical factors were recorded until 6:00 p.m. Again on March 10, 2001, no critical factors were recorded during processing operations between 8:00 a.m. and 11:00 a.m.

3. Whenever any process is less than the scheduled process or when critical factors are out of control for any low-acid food or container system as disclosed from records by processor check or otherwise, your firm did not always fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively set aside that portion of the product involved for further evaluation as to any potential public health significance. Your firm did not always have such evaluations made by a competent processing authority in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Your firm did not always make a record of the evaluation procedures used and the results, nor did your firm always record deviations making them the subject of a separate file (or log) detailing the deviations and the actions taken [21 CFR 108.35(c)(3)(i) and 21 CFR 113.89].

During our inspection, our investigators determined that product at the product sterilizer on January 10, 2002, was not fully processed (minimum process temperature was revealed to have dropped to *MM*° F, eight degrees below the minimum process temperature of *MM*° F). Our investigators reported that there was no investigation or documentation to verify that the product thermal processing system defaulted to divert flow mode. Our investigators also reported there was no documentation to determine if product was reprocessed or set aside for evaluation by a competent processing authority, nor was there any process deviation log or file pertaining to the deviation.

Page Three

Greg Ostrander
November 21, 2002

4. Your firm did not always have processing and production records reviewed, initialed and dated by a representative of plant management who is qualified by suitable training or experience for completeness and to ensure that the product received the scheduled process, not later than one working day after the actual process, and before shipment or release for distribution. Furthermore your firm did not always identify recording thermometer charts by date, and other data as necessary so they can be correlated with the record of lots processed [21 CFR 108.35(h) and 21 CFR 113.100(b)].

Review of records by our investigators revealed that products were released by your firm prior to completing record review. According to the circular chart for production on March 10, 2001, the chart was reviewed on March 14, 2001. However, according to the RELEASE VERIFICATION - CREAMER SYSTEM 6 record, dated March 10, 2001, product was released March 13, 2001, a full day before record review had been completed. This failure to complete record review before product release was repeated for product produced May 5, July 10, and November 11, 2001. On January 10, 2001, there is no documentation that the critical factor record was ever reviewed. Furthermore, review of records by our investigators revealed that temperature recording charts for November 6, 10, 20, and December 11, 2001, were not properly identified in as much as the date was always recorded as January 11, 2001.

5. Your firm did not always enter processing and production information including product name, code number or number of containers per coding interval on forms [21 CFR 108.35(h) and 21 CFR 113.100(a)].

Our investigators observed that production and packing records for January 10, September 10, November 10, 2001, and January 10, 2002, did not always provide information indicating what product was being produced, the lot code used, or the number of containers that were filled during each lot code interval.

We request that you notify this office in writing within 15 working days of receipt of this letter stating the actions you will take to correct the violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and a reasonable time within which the corrections will be completed.

Failure to make prompt corrections may result in enforcement action, including seizure and injunction, being initiated by the Food and Drug Administration (FDA).

This letter does not represent a comprehensive review of all of the products distributed by your firm, nor does it represent a complete review of all product labeling. As president, it is your responsibility to ensure that all products

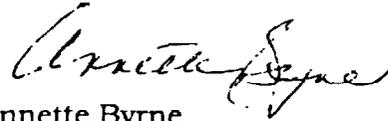
Page Four

Greg Ostrander
November 21, 2002

distributed by your firm are in compliance with the Act and its implementing regulations.

Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated in the letterhead. Ms. Wisecup may be reached at (612) 334-4100 ext. 124.

Sincerely,



Annette Byrne
Acting Director
Minneapolis District

TSW/ccl
TSW