NCIMS HACCP SYSTEM PILOT AUDIT REPORT (12/99 R1) **DATE:**

TYPE OF AUDIT:	**( ) STATE REGULATORY**	**( ) STATE LISTING**	**( ) FDA AUDIT OF LISTING**
FIRM NAME:	**LICENSE/PERMIT #:**		**IMS PLANT #:**
ADDRESS:	**CITY:**	**STATE:**	**ZIP CODE:**

IMS LISTED PRODUCT (S) MANUFACTURED & REVIEWED: **(Detailed Product Description(s) & Flow Diagram(s) MUST be attached).**

ITEMS MARKED INDICATE DEVIATIONS/DEFICIENCIES/NON-CONFORMITIES THAT DID NOT MEET THE NCIMS HACCP PILOT PROGRAM CRITERIA DESCRIBED BELOW (See attached Audit Discussion sheet [s] for details).

Section 1
OTHER NCIMS REQUIREMENTS

- ☐ Raw milk supply from NCIMS listed source(s).
- ☐ Labeling compliance as required.
- ☐ Prevention of adulteration of milk products.
- ☐ Drug residue control program implemented.
- ☐ Drug residue control program records complete.
- ☐ Other items as noted.

Section 2
HACCP SYSTEM PREREQUISITE PROGRAMS

- ☐ Written prerequisite program prepared by firm as required or justified by the hazard analysis.
- ☐ Prerequisite program adequately implemented by firm.
- ☐ Prerequisite program audited/validated by firm.
- ☐ Prerequisite program maintained by firm.
- ☐ Written prerequisite program signed and dated as required.
- ☐ Firm's prerequisite program(s) issue date(s) _____.

Section 3
HACCP SYSTEM SANITATION STANDARD OPERATING PROCEDURES (SSOPs)

- ☐ Written Sanitation Standard Operating Program (SSOPs) as required.
- ☐ Sanitation conditions and practices monitored as required including;
  - ☐ Safety of water used for food or food contact surfaces (including steam and ice).
  - ☐ Food contact surface cleanliness (including gloves, outer garments, utensils, etc.).
  - ☐ Cross contamination of products, packaging and contact surfaces by insanitary objects and or practices (e.g. pasteurizer pressure differential).
  - ☐ Protection from contamination of food, packaging and contact surfaces from adulteration, including: lubricant, fuel, pesticides, cleaners, sanitizers, condensate and other foreign material.
  - ☐ Control of employee health conditions that could result in the microbiological contamination of food, packaging or contact surfaces.
  - ☐ Pest exclusion from plant.
- ☐ Sanitation control records for the above elements of sanitation available.
- ☐ Sanitation monitoring records adequately reflect sanitation conditions observed.
- ☐ Sanitation monitoring performed at a frequency to ensure conformance with the written SSOPs.
- ☐ Corrective action performed in a timely manner when sanitation monitoring records reflect sanitation deficiencies.
- ☐ Employees trained in sanitation operations.

Section 4
HAZARD ANALYSIS

- ☐ Hazard analyses conducted and written for each kind or group of milk or milk product processed.
- ☐ Written hazard analysis identifies all potential food safety hazards and further determines those that are reasonably likely to occur (including hazards within and outside the processing plant environment).
- ☐ Hazard analysis reassessed after changes in raw materials, formulations, processing methods/systems, distribution, intended use or consumers.
- ☐ Personnel adequately trained to administer the firm's hazard analysis.
- ☐ Written hazard analysis signed and dated as required.
- ☐ Firm's hazard analysis issue date _____.

Section 5
HACCP PLAN

- ☐ Written HACCP plan prepared for each kind or group of milk or milk products.
- ☐ Written HACCP plan implemented.
- ☐ Written HACCP plan identifies all food safety hazards that are reasonably likely to occur.
- ☐ Personnel adequately trained to administer the firm's HACCP Plan.
- ☐ HACCP plan signed and dated as required.
- ☐ Firm's HACCP plan issue date _____.

Section 6
CRITICAL CONTROL POINTS (CCP)

- ☐ HACCP plan lists Critical Control Point(s) for each food safety hazard identified as reasonably likely to occur.
- ☐ Critical Control Point(s) identified in the HACCP plan are adequate control measures for the food safety hazard(s) identified.
- ☐ Control measures associated with critical control point(s) listed in the HACCP plan are appropriate at the processing step identified.

Section 7
CRITICAL LIMITS (CL)

- ☐ HACCP plan lists critical limits for each critical control point(s).
- ☐ Critical limits defined in the HACCP plan are adequate to control the hazard identified.
- ☐ Critical limits defined in the HACCP plan are achievable with existing monitoring instruments or procedures.
- ☐ Critical limits are met.

See attached "Audit Discussion Sheet" for explanation of deviations/deficiencies/non-conformities.

NCIMS HACCP PILOT PROGRAM CRITERIA (continued)
ITEMS MARKED INDICATE DEVIATIONS/DEFICIENCIES/NON-CONFORMITIES THAT DID NOT MEET THE NCIMS HACCP PILOT PROGRAM CRITERIA DESCRIBED BELOW (See attached Audit Discussion sheet [s] for details).

Section 8
MONITORING

☐ HACCP plan defines monitoring procedures for each critical control point.

☐ HACCP plan defines **what** will be monitored at each critical control point.

☐ HACCP plan defines **how** monitoring procedures will be performed at each critical control point.

☐ HACCP plan defines the **frequency** at which monitoring will be performed at each critical control point.

☐ HACCP plan defines by **whom** the monitoring will be performed at each critical control point.

☐ Monitoring procedures as defined in the HACCP plan followed.

☐ Monitoring procedures as defined in the HACCP plan adequately measure critical limits at each critical control point.

☐ Monitoring record data consistent with the actual value (s) observed during the audit.

☐ Employees trained in monitoring operations.

Section 9
CORRECTIVE ACTION

☐ Predetermined corrective actions defined in the HACCP plan ensure product which may be injurious to health or otherwise adulterated as a result of a deviation do not enter commerce.

☐ Predetermined corrective actions defined in the HACCP plan ensure the cause of the deviation is corrected.

☐ Appropriate corrective action taken for products produced during a deviation from critical limits defined in the HACCP plan.

☐ Corrective actions defined in the HACCP plan were observed followed when deviations occurred.

☐ Affected product produced during the deviation segregated and held, **AND**

- ☐ A review to determine product acceptability performed, **AND**
- ☐ Corrective action taken to ensure that no adulterated and/or product that is injurious to health enters commerce.

☐ Cause of deviation was corrected.

☐ Reassessment of HACCP Plan performed and modified accordingly.

☐ Corrective actions documented.

Section 10
VERIFICATION & VALIDATION

☐ HACCP plan defines verification procedures.

☐ HACCP plan defines the frequency of verification.

☐ Reassessment of HACCP plan conducted annually, **OR**

- ☐ After changes that could affect the hazard analysis, **OR**
- ☐ After significant changes in the operation including raw materials and/or source, product formulation, processing methods/systems, distribution intended use or intended consumer.

☐ HACCP plan reassessment performed by trained individual as required.

☐ Program in place to review consumer complaints.

☐ Verification records reviewed as required – including date and signature.

Section 10
VERIFICATION & VALIDATION (CONTINUED)

☐ Verification records review performed by trained individual.

☐ Calibration of process monitoring instruments performed as required.

☐ Calibration of process monitoring instruments performed at the frequency defined in the HACCP plan.

☐ Critical control point monitoring records reviewed to verify and document that values are within critical limits.

☐ Monitoring record review performed as required.

☐ Corrective action record reviewed as required.

☐ Records of calibration of process control instruments and end product or in-process testing results listed as verification activities in the HACCP plan reviewed.

☐ Verification records or documents are present that validate the effectiveness of the control measure and established critical limit in controlling the identified hazard.

Section 11
RECORDS

☐ Required information included in the record - e.g. name/location of processor and/or date/time of activity and/or signature/initials of person performing operation and/or identity of product/product code.

☐ Processing/other information entered on record at time observed.

☐ Records retained as required - e.g. one year for refrigerated products/ two years for preserved, shelf-stable or frozen products.

☐ Records relating to adequacy of equipment or processes retained for 2 years.

☐ HACCP records available for official review and/or copying.

☐ Personnel adequately trained to administer the firm's HACCP System.

Section 12
AUDIT FOLLOW-UP ACTION

☐ Previous audit findings corrected.

☐ Previous audit findings remain corrected at time of this audit.

☐ State Enforcement Audit Reports issued and follow- up conducted as required (HACCP Listing Audits & FDA Audits only).

☐ Other items as noted.

NAME OF AUDITOR (S) (Please Print)

_____

_____

SIGNATURE(S):

_____

_____

DATE: _____

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET

FIRM NAME: _____ DATE of AUDIT: _____

EXPLANATION OF DEVIATIONS/DEFICIENCIES/NON-CONFORMITIES THAT DID NOT MEET THE NCIMS HACCP PILOT PROGRAM CRITERIA.

(Use additional sheets as necessary.)

NOTE:
When State Regulatory Audits are conducted;
Corrective action timelines for all identified deviations, deficiencies and non-conformities must be established.

_____

Auditor Name(s) and Signature(s):

Date: _____

NCIMS HACCP SYSTEM AUDIT REPORT DISCUSSION SHEET (continued)

Auditor Name(s) and Signature(s):

Date: _____