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Firm Name: **FEI Number:**

Inspection Date(s): **FCE Number:**

Investigators:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

FDA ACIDIFIED FOOD INSPECTION REPORT

This inspection report is available in PDF and M.S. Word on the forms site: *http://www.fda.gov/opacom/morechoices/fdaforms/ora.html* (only the M.S. Word version has expandable fields). Narrative responses to each item can be entered in the item's "comments" area or where otherwise prompted. Complete documentation of deficiencies including deviations from Part 114 should be narrated with reference to photos, exhibits, etc in the Turbo EIR under "Objectionable Conditions and Mangement's Response". When necessary, refer the reader to the appropriate section of the Turbo EIR for a full explanation of details.

This form should be downloaded from the forms site to a computer dirve prior to completion and copying. The finished report should be submitted as an attachment to the Turbo EIR.

PROCESS ESTABLISHMENT, FILING AND SCHEDULES

1. HAVE PROCESSES BEEN ESTABLISHED FOR ALL ACIDIFIED FOODS PROCESSED AT THIS FACILITY? – Part 114.83..... Yes ☐ No ☐

   COMMENTS:

2. HAS THE FIRM REGISTERED WITH FDA AND FILED A PROCESS FOR ALL ACIDIFIED FOODS PROCESSED AT THIS FACILITY? – 108.25(c)..... Yes ☐ No ☐

   COMMENTS:

3. DO CRITICAL FACTORS/LIMITS LISTED IN SOURCE DOCUMENTS MATCH CRITICAL FACTORS/LIMITS FOR SELECTED PRODUCTS AND PROCESSES FILED WITH FDA?

   Yes ☐ No ☐

   (NOTE – CRITICAL FACTORS MAY EXIST THAT THE FIRM CONTROLS BUT HAVE NOT BEEN IDENTIFIED IN THE PROCESS FILING. CRITICAL FACTORS MAY ALSO EXIST THAT HAVE OR HAVE NOT BEEN IDENTIFIED AND ARE NOT CONTROLLED. COMPARE MINIMUM EQUILIBRIUM PH AND OTHER CRITICAL FACTORS LISTED ON PROCESS FILING FORMS WITH SIMILAR INFORMATION LISTED IN PROCESS LETTERS OR OTHER PROCESS SOURCE DOCUMENTATION.)

   COMMENTS:

4. HAVE FILED, SCHEDULED PROCESSES BEEN CHANGED IN SUCH A WAY THAT COULD AFFECT THE ATTAINMENT OF COMMERCIAL STERILITY?..... Yes ☐ No ☐

   (THERE ARE MANY FACTORS, WHICH CAN AFFECT THE ATTAINMENT OF COMMERCIAL STERILITY FOR ACIDIFIED FOODS. FOR EXAMPLE, A CHANGE IN THE FORMULATION SUCH AS SIZE OF SOLID PIECES, THE SOLID TO LIQUID RATIO OR THE TYPE AND/OR QUANTITY OF ACID USED COULD AFFECT THE FINISHED EQUILIBRIUM PH.)

   COMMENTS:

PROCESS DELIVERY

5. ARE RAW PRODUCT MATERIALS PREPARED ACCORDING TO THE METHOD (GRADING, WASHING, HYDRATING, BLANCHING), ETC. AND/OR FORMULATION SPECIFIED IN THE RECOMMENDED SCHEDULED PROCESS?

   Yes ☐ No ☐

   COMMENTS:

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DESCRIBE THE FIRM'S PROCEDURES FOR HANDLING/PREPARING RAW MATERIALS AND PRODUCT PREPARATION:

6. THERE ARE SEVERAL METHODS USED TO ACIDIFY LOW-ACID FOODS INCLUDING: BLANCHING IN ACID SOLUTIONS, IMMERSION OF BLANCHED FOODS IN ACID SOLUTIONS, DIRECT BATCH ACIDIFICATION, ADDITION OF ACID DIRECTLY TO INDIVIDUAL CONTAINERS, AND ADDITION OF ACID FOODS TO LOW-ACID FOODS.

   ARE PRODUCTS ACIDIFIED ACCORDING TO THE METHOD AND/OR FORMULATION SPECIFIED IN THE RECOMMENDED SCHEDULED PROCESS? ..... Yes ☐ No ☐

   COMMENTS:

   DESCRIBE THE FIRM'S PROCEDURES FOR ACIDIFICATION:

7. DOES THE FIRM ADEQUATELY CONTROL pH TO ENSURE THAT THE EQUILIBRIUM pH OF FINISHED PRODUCTS DOES NOT EXCEED THE MAXIMUM VALUE SPECIFIED IN THE SCHEDULED PROCESS? ..... Yes ☐ No ☐

   pH IS MONITORED USING: Poteniometric ☐ Colorimetric ☐ Other methods ☐

   IF A pH METER IS USED, IT IS STANDARDIZED AND ACCURATE ..... Yes ☐ No ☐

   pH MONITORING RECORDS ARE PREPARED AND MAINTAINED ..... Yes ☐ No ☐

   (THE FIRM MUST FREQUENTLY MONITOR PH (114.80(A)(2)) AND PREPARE/MAINTAIN RECORDS 114.100(B); IF A PH METER IS USED, IT SHOULD BE ACCURATE, ADEQUATELY EQUIPPED AND STANDARDIZED TO ENSURE IT'S ACCURACY. PROPER PROCEDURES SHOULD BE FOLLOWED IN OPERATION OF THE PH METER AS PROVIDED BY THE INSTRUMENT MANUFACTURER AND SPECIFIED IN PART 114.90 (114.90(A),110.40(F)).)

   COMMENTS:

8. LIST ALL FACTORS CRITICAL TO THE ATTAINMENT OF COMMERCIAL STERILITY PER PROCESS AUTHORITY LETTER AND FILING FORM(S) FOR PRODUCTS COVERED DURING THIS INSPECTION (INCLUDE MAX EQUILIBRIUM pH, PROCESS TIME/TEMP AND ALL OTHER CRITICAL FACTORS:

   (LIST MINIMUM SCHEDULED PROCESS BELOW AS FILED WITH FDA.)

PRODUCT	***CONTAINER TYPE/SIZE***	***CRITICAL FACTORS***		
		Max. pH	*Min. Process Time*	*Min. Process Temp.*

   COMMENTS, INCLUDING OTHER CRITICAL FACTORS:

9. OBSERVE THE PRODUCTION OF A BATCH OF ACIDIFIED FOOD PRODUCT. DETERMINE IF ALL CRITICAL FACTORS LISTED ON FORM 2541a AND IN ANY PROCESS SOURCE DOCUMENT ARE BEING MONITORED AND THE RESULTS RECORDED. DETERMINE IF CRITICAL FACTORS (SUCH AS MAX EQUILIBRIUM pH, SOLID TO LIQUID RATIO, MIN THERMAL PROCESS TIME & TEMP) ARE BEING ACHIEVED.

   CRITICAL FACTORS UNDER CONTROL ..... Yes ☐ No ☐

   COMMENTS:

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10. 114.80 (A) (1) REQUIRES ACIDIFIED FOODS TO BE THERMALLY PROCESSED TO DESTROY THE VEGETATIVE CELLS OF MICROORGANISM OF PUBLIC HEALTH SIGNIFICANCE AND THOSE OF NON-HEALTH SIGNIFICANCE CAPABLE OF REPRODUCING IN THE FOOD UNDER NORMAL CONDITIONS OF STORAGE. ORGANISMS OF NON-HEALTH SIGNIFICANCE MAY BE CONTROLLED BY PRESERVATIVES. THERE ARE SEVERAL DIFFERENT METHODS AND EQUIPMENT THAT CAN BE USED TO THERMALLY PROCESS ACIDIFIED FOODS INCLUDING: HOT FILL AND HOLD, STILL WATER IMMERSION, CONTINUOUS CONTAINER PASTEURIZATION, HEAT EXCHANGERS, AND ASEPTIC HEATING AND PACKAGING.

WHAT TYPE OF THERMAL PROCESS DOES THE FIRM USE?

HOT FILL AND HOLD ..... Yes ☐ No ☐
STILL IMMERSION ..... Yes ☐ No ☐
CONTINUOUS CONTAINER ..... Yes ☐ No ☐
HEAT EXCHANGER ..... Yes ☐ No ☐
ASEPTIC HEATING & PACKAGING ..... Yes ☐ No ☐
OTHER (EXPLAIN) ..... Yes ☐ No ☐

DESCRIBE FIRMS HEATING PROCEDURES:

OTHER COMMENTS:

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11. DOES THE FIRM USE PRESERVATIVES TO PREVENT THE GROWTH OF MICROORGANISMS OF NON-HEALTH SIGNIFICANCE? ..... Yes ☐ No ☐

ARE THESE PRESERVATIVES USED IN ACCORDANCE WITH FDA FOOD ADDITIVE REGULATIONS?

Yes ☐ No ☐

LIST THE PRESERVATIVES AND LEVELS OF USE:

COMMENTS:

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12. WERE ANY PROCESS DEVIATIONS NOTED DURING THE INSPECTION? ..... Yes ☐ No ☐

IF SO, WERE THE DEVIATIONS PROPERLY HANDLED? ..... Yes ☐ No ☐

114.89

COMMENTS:

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13. ARE CRITICAL FACTORS MEASURED USING ACCURATE INSTRUMENTS? ..... Yes ☐ No ☐

(pH METERS MUST BE ACCURATE AND STANDARIZED AS PER 114.90 OR THE MANUFACTURER'S DIRECTIONS. EQUIPMENT USED TO MEASURE OTHER TEMPERATURES, WEIGHTS AND CRITICAL FACTORS MUST BE ACCURATE AS PER PART 110.40(f).)

COMMENTS:

DOCUMENTATION OF PROCESS DELIVERY

14. DO PROCESSING AND PRODUCTION RECORDS INCLUDE FINISHED PRODUCT EQUILIBRIUM pH, ANY OTHER CRITICAL FACTORS PLUS SUFFICIENT ADDITIONAL INFORMATION (PRODUCT, PRODUCT CODE, DATE, CONTAINER SIZE, ETC.) TO PERMIT A HEALTH HAZARD EVALUATION OF PROCESSES APPLIED TO EACH LOT? – [114.100(b)] ..... Yes ☐ No ☐

COMMENTS:

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15. IF AVAILABLE, REVIEW A SELECT NUMBER OF PROCESSING RECORDS (pH & RECORDS OF OTHER CRITICAL FACTOR MONITORING RECORDS), REPRESENTATIVE OF UP TO 7 PRODUCTION DAYS DURING A 3 MONTH PERIOD IMMEDIATELY PRIOR TO THIS INSPECTION. FOLLOW THE PROCEDURES FOR SELECTING RECORDS OUTLINED ON PAGE 83 (ATTACHMENT 12) OF LACF INSPECTION GUIDE-PART 2.

    DID THE REVIEW OF THESE RECORDS DISCLOSE ANY DEVIATIONS FROM PART 114 OR ANY DEFICIENCIES OR INFORMATION INDICATING THAT ANY LOT OF AF PRODUCED AT THIS ESTABLISHMENT MAY HAVE PROCESS DEVIATIONS? ..... Yes ☐ No ☐

    IF YES, EXPLAIN IN “COMMENTS” BELOW. REPORT THE TYPE AND DATES OF RECORDS REVIEWED.

    COMMENTS:

CONTAINER INTEGRITY

16. DOES TESTING AND EXAMINATION OF CONTAINERS OCCUR OFTEN ENOUGH TO ENSURE THAT CONTAINERS SUITABLY PROTECT THE FOOD FROM LEAKAGE AND CONTAMINAITON? 114.80(a)(4) ..... Yes ☐ No ☐

    (DESCRIBE ALL VISUAL AND DESTRUCTIVE TESTS PERFORMED INCLUDING TESTING FREQUENCY AND ALL MEASURED PARAMETERS (SEE LACF FIELD GUIDE-PART 3 FOR A DESCRIPTION OF METAL, GLASS AND FLEXIBLE PACKAGE CLOSURES, SEALING PARAMETERS, CONTAINER DEFECTS AND INTEGRITY TESTS.)

    NOTE – PART 114 DOES NOT REQUIRE THAT THE FIRM PREPARE AND MAINTAIN CONTAINER INTEGRITY MONITORING RECORDS. ENCOURAGE THE FIRM TO DOCUMENT THEIR CONTAINER INTEGRITY TESTING ACTIVITIES.

    COMMENTS:

17. ARE CONTAINER HANDLING PROCEDURES AND CONVEYANCE EQUIPMENT ADEQUATE TO PROTECT THE CONTAINER BODY AND SEALS FROM DAMAGE THAT COULD RESULT IN LEAKAGE AND POST PROCESS CONTAMINATION? – 110.40(a); 110.80 ..... Yes ☐ No ☐

    (LIDS AND EMPTY AND FILLED/SEALED CONTAINERS SHOULD BE HANDLED WITH CARE; CONVEYANCE TRACKS SHOULD BE CLEAN, SANITARY AND DRY.)

    COMMENTS:

18. IS EACH CONTAINER IDENTIFIED WITH A VISIBLE CODE THAT SPECIFIES THE PACKER, THE PRODUCT AND THE YEAR, DAY AND PERIOD OF PACK? ..... Yes ☐ No ☐

    IS THE PACKING PERIOD CODE CHANGED OFTEN ENOUGH TO ASSURE READY IDENTIFICATION OF LOTS DURING THEIR SALE & DISTRIBUTION? ..... Yes ☐ No ☐

    114.80(b)

    (THE PACKING PERIOD CODE SHALL BE CHANGED OFTEN ENOUGH TO ENABLE READY IDENTIFICATION OF LOTS DUIRNG THEIR SALE & DISTRIBUTION. CODES MAY BE CHANGED PERIODICALLY AS FOLLOWS – AFTER INTERVALS OF 4-5 HOURS; AFTER PERSONNEL SHIFT CHANGES; OR AFTER EACH BATCH AS LONG AS ONE BATCH DOES NOT REPRESENT MORE THAN ONE PERSONNEL SHIFT.)

    COMMENTS:

19. FIELD EXAMINE INDIVIDUAL CONTAINERS OF ANY SUSPECT PRODUCT CODES IDENTIFIED THROUGH INSPECTION OR RECORD REVIEW FOLLOWING THE PROCEDURES OUTLINED IN THE SAMPLE SCHEDULE ON P.85 OF THE LACF INSPECTION GUIDE, PART 2. SAMPLE ABNORMAL LOTS FOLLOWING THIS SAMPLE SCHEDULE.

    COMMENTS:

20. DOES THE FIRM HAVE A RECALL PLAN ON FILE? – 108.25(e) ..... Yes ☐ No ☐

    COMMENTS:

Firm Name: **FEI Number:**

21. DOES THE FIRMS RECORDS IDENTITY INITIAL DISTRIBUTION OF LOTS OF PRODUCT – 114.100 (d)

Yes ☐ No ☐

COMMENTS:

22. HAVE APPROPRIATE PLANT PERSONNEL ATTENDED AND COMPLETED A SCHOOL APPROVED BY FDA? – 108.25(f) ..... Yes ☐ No ☐

COMMENTS: