Firm Name, City & State: **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 on the forms site: *http://www.fda.gov/opacom/morechoices/fdaforms/ora.html*. 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 Management'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 drive prior to completion and copying. Submit the finished report as an attachment to the 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 THAT 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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6. DESCRIBE THE FIRM'S PROCEDURES FOR HANDLING/PREPARING RAW MATERIALS AND PRODUCT PREPARATION:

   COMMENTS:

7. WHAT IS THE SOURCE OF WATER USED FOR PROCESSING AND CLEAN-UP IN THE PLANT? IF IT IS NON-MUNICIPAL, WHAT IS ITS SOURCE – I.E., WELL OR SURFACE WATER? IF PRE-TREATED, WHAT IS THE METHOD, E.G., THROUGH SAND THEN CARBON FILTERED? IS THE WATER DISINFECTED? IF SO, DETERMINE THE METHOD OF DISINFECTION AND HOW IT IS MONITORED. IF NON-MUNICIPAL, WHAT IS THE FREQUENCY OF ANALYSIS CONDUCTED? IS THE WATER REGULATED BY THE STATE OR A LOCAL HEALTH AGENCY?

   COMMENTS:

8. IS THE PLANT WATER ADEQUATELY TREATED WITH CHLORINE OR OTHER APPROVED CHEMICALS TO RENDER IT POTABLE? ..... Yes ☐ No ☐

   HOW AND AT WHAT FREQUENCY IS THIS TREATMENT MONITORED?

   COMMENTS:

9. WHEN THERE IS A CHANGE IN RAW MATERIALS, PRODUCT FORMULATION, ACIDIFYING AGENTS OR ANY OTHER CONDITIONS THAT COULD AFFECT THE ATTAINMENT OR CONTROL OF EQUILIBRIUM pH, IS THE PROCESS AUTHORITY ADVISED AND IS THERE WRITTEN DOCUMENTATION OF THIS CONTACT? ..... Yes ☐ No ☐

   HOW DOES THE FIRM DECIDE IF THE CHANGE IS SIGNIFICANT ENOUGH TO CONTACT THE PROCESS AUTHORITY?

   COMMENTS:

10. 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:

11. 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: POTENTIOMETRIC ☐ COLORIMETRIC ☐ OTHER METHODS ☐

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

p H 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 ITS 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:

12. DESCRIBE IN DETAIL THE PROCEDURES THAT ARE FOLLOWED TO TEST FOR pH, INCLUDING CALIBRATION OF THE pH METER, PREPARATION OF THE SAMPLE, ETC.; FOR EXAMPLE, IS THE SAMPLE PREPARED BY BLENDING TOGETHER THE SOLID AND LIQUID COMPONENTS OF A CONTAINER OR BY BLENDING ONLY THE SOLID COMPONENTS OF A CONTAINER? IS THE pH OF ACIDIFIED VEGETABLES DETERMINED BY TESTING A BLEND OF THE SOLID AND LIQUID COMPONENTS OF THE CONTAINER OR OF THE SOLID AND LIQUID COMPONENTS SEPARATELY?

COMMENTS:

13. 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:

14. OBSERVE THE PRODUCTION OF A BATCH OF ACIDIFIED FOOD PRODUCTS. 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 AND MIN. THERMAL PROCESS TIME AND TEMP.) ARE BEING ACHIEVED.

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

COMMENTS:

15. 114.80(a)(1) REQUIRES ACIDIFIED FOODS TO BE THERMALLY PROCESSED TO DESTROY THE VEGETATIVE CELLS OF MICROORGANISMS 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 WATER IMMERSION ..... Yes ☐ No ☐
CONTINUOUS CONTAINER PASTEURIZATION ..... Yes ☐ No ☐
HEAT EXCHANGER ..... Yes ☐ No ☐
ASEPTIC HEATING AND PACKAGING ..... Yes ☐ No ☐
OTHER (EXPLAIN) ..... Yes ☐ No ☐

DESCRIBE THE FIRM'S HEATING PROCEDURES:

OTHER COMMENTS:

16. ARE MINIMUM INITIAL TEMPERATURES AND PROCESS TEMPERATURES ACHIEVED AS RECOMMENDED BY THE PROCESS AUTHORITY AND FILED WITH FDA? ARE THERE PROCESSING ISSUES THAT COULD ADVERSELY AFFECT THE THE DELIVERY OF SUFFICIENT THERMAL ENERGY TO THE PRODUCT?

FOR EXAMPLE, IF ACIDIFIED FOOD PRODUCTS ARE CONVEYED THROUGH A HEAT TUNNEL (STEAM OR HOT WATER) AND THE SPEED OF THE CONVEYOR BELT IS NOT MONITORED TO DETERMINE PROCESS TIME, THE PRODUCT MAY NOT BE RECEIVING A CORRECT THERMAL PROCESS. IN THIS CASE, TIME THE CONVEYOR BELT WITH A STOPWATCH USING A MARKED CAN AND DETERMINE HOW LONG IT TAKES FOR THE CAN TO PASS THROUGH THE TUNNEL. COMPARE THIS TIME WITH THE MINIMUM PROCESS TIME RECOMMENDED BY THE PROCESS AUTHORITY AND FILED WITH FDA.

IF THERE ARE CONCERNS ABOUT TEMPERATURE DISTRIBUTION IN A COOKER, THE FIRM MAY NEED TO CONDUCT A TEMPERATURE DISTRIBUTION TEST TO ASSURE THAT TEMPERATURE IS EQUAL THROUGHOUT THE VESSEL DURING THERMAL PROCESSING. FOR EXAMPLE, IF TEMPERATURE MONITORING DEVICES ARE DEFICIENT IN THE COOKING SECTION OF A HEAT TUNNEL, OR IF MULTIPLE TEMPERATURE MONITORING DEVICES ARE PRESENT BUT DISPLAY DIFFERENT TEMPERATURES, THIS MAY INDICATE THAT TEMPERATURE DISTRIBUTION THROUGHOUT THE VESSEL MAY NOT BE ADEQUATE.

NOTE – ALTHOUGH PART 114 DOES NOT SPECIFICALLY REQUIRE TEMPERATURE DISTRIBUTION STUDIES, EQUAL, UNIFORM TEMPERATURE THROUGHOUT A COOKING VESSEL IS IMPORTANT TO ENSURE THAT ALL FOOD CONTAINERS RECEIVE A PROPER HEAT TREATMENT DURING THERMAL PROCESSING.

COMMENTS:

17. 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:

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

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

114.89

COMMENTS:

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

(pH METERS MUST BE ACCURATE AND STANDARDIZED 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

20. DO PROCESSING AND PRODUCTION RECORDS INCLUDE FINISHED PRODUCT EQUILIBRIUM pH, MINIMUM PROCESS TEMPERATURE AND TIME PLUS ANY OTHER CRITICAL FACTORS AND 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:

21. IF AVAILABLE, REVIEW A SELECT NUMBER OF PROCESSING RECORDS (pH AND 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 P. 83 (ATTACHMENT 12) OF LACF 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 ACIFIED FOOD 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:

HANDLING PROCESS DEVIATIONS

22. ARE PROCESS DEVIATIONS (FOR EXAMPLE, FAILURE TO ACHIEVE THE MINIMUM PROCESS TIME AND/OR TEMPERATURE AND/OR MAXIMUM EQUILIBRIUM pH AS LISTED IN THE FILED SCHEDULED PROCESS) HANDLED IN ACCORDANCE WITH 114.89? ..... Yes ☐ No ☐

COMMENTS:

CONTAINER INTEGRITY

23. DO TESTING AND EXAMINATION OF CONTAINERS OCCUR OFTEN ENOUGH TO ENSURE THAT CONTAINERS SUITABLY PROTECT THE FOOD FROM LEAKAGE AND CONTAMINATION? – 114.80(a)(4) ..... Yes ☐ No ☐

(DESCRIBE ALL VISUAL AND DESTRUCTIVE TESTS PERFORMED, INCLUDING TESTING FREQUENCY AND ALL MEASURED PARAMETERS (SEE LACF 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 ITS CONTAINER INTEGRITY TESTING ACTIVITIES.

COMMENTS:

24. 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:

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

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

114.80(b)

*(THE PACKING PERIOD CODE **SHALL** BE CHANGED OFTEN ENOUGH TO ENABLE READY IDENTIFICATION OF LOTS DURING THEIR SALE AND 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:

26. IS THERE EVIDENCE OF ABNORMAL, SPOILED OR LEAKING CANS OF PRODUCT IN THE WAREHOUSE? ..... Yes ☐ No ☐

COMMENTS:

27. DETERMINE HOW THE FIRM HANDLES, INVESTIGATES AND DOCUMENTS ABNORMAL CONTAINERS. DOES THE FIRM EVALUATE SUCH CONTAINERS BY AGGRESSIVELY INCUBATING SAMPLES (E.G., AT 95 DEGREES F) AND TESTING FOR COMMERCIAL STERILITY? WHAT IS ITS PROCEDURE? BE AWARE THAT FIRMS MAY BE SORTING SUCH LOTS AND SHIPPING THE NORMAL-APPEARING CANS WITHOUT PROPER EVALUATION, BASING THEIR DECISION TO SHIP THE NORMAL CANS ON THEIR EVALUATION OF PROCESSING RECORDS THAT SHOW THE PRODUCTS RECEIVED A PROPER ACIDIFICATION AND THERMAL PROCESS. IF AVAILABLE, REVIEW SORT AND DESTRUCTION RECORDS TO DETERMINE THE PERCENTAGE OF DEFECTIVE PRODUCTS CULLED BY THE FIRM.

COMMENTS:

28. WHAT IS THE FIRM'S PROCEDURE IF ABNORMAL CONTAINERS OR SEAM DEFECTS ARE FOUND AFTER PROCESSING TO ASSURE THAT THE LOT IS SAFE FOR DISTRIBUTION? FOR EXAMPLE, IF A SUFFICIENT NUMBER OF ABNORMAL CONTAINERS AND/OR DEFECTS ARE FOUND FOLLOWING PROCESSING, IS A SPOILAGE DIAGNOSIS PERFORMED TO DETERMINE THE CAUSE OF THE ABNORMAL CONTAINERS OR SEAM DEFECTS? IS PROMPT CORRECTIVE ACTION TAKEN TO PREVENT REOCCURRENCE OF THE ABNORMAL AND/OR DEFECTIVE CONTAINERS AND IS THIS ACTION DOCUMENTED?

COMMENTS:

29. 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 GUIDE, PART 2. SAMPLE ABNORMAL LOTS FOLLOWING THIS SAMPLE SCHEDULE.

COMMENTS:

MISCELLANEOUS

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

COMMENTS:

31. DO THE FIRM'S RECORDS IDENTIFY INITIAL DISTRIBUTION OF PRODUCTION LOTS? – 114.100(d) ..... Yes ☐ No ☐

COMMENTS:

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

COMMENTS:

33. REVIEW CONSUMER COMPLAINT FILES FOR THE LAST 6 MONTHS. FOCUS THE REVIEW ON REPORTS OF SPOILAGE, SWOLLEN CANS, ETC. DETERMINE THE FREQUENCY OF SUCH REPORTS AND WHAT, IF ANY, ACTION THE FIRM TOOK IN RESPONSE TO THE REPORTS.

COMMENTS: