Firm Name:	**FEI Number:**
City, State	**FCE Number:**
Inspection Date(s):	**Investigators:**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

ASEPTIC PROCESSING AND PACKAGING REPORT

INSTRUCTIONS

Complete the question blocks below. Narrative responses to each item can be entered in the item's "comments" area or where otherwise prompted.

If problems are found with the firm's processing system, refer the reader to the EIR for a narrative description of specific problems with supporting evidence, under "Objectionable Conditions and Management's Response." Submit the completed form as an EIR attachment.

PROCESS ESTABLISHMENT AND SCHEDULED PROCESSES - 21 CFR 108.35

1. Report the Product(s) and SID and Supplementary SID number(s) covered on this inspection.

Product(s)

SID(s)

SUP SID

2. Has the firm registered the facility with the FDA and filed a process for all LACF products manufactured? - *21 CFR 108.35 (c)* ☐ Yes ☐ No

3. Does the firm have a process letter or other process source documentation listing critical factors necessary to control in the attainment of commercial sterility? ☐ Yes ☐ No

Based on the processing authorities' evaluation critical factors are specific to an individual product or on occasion listed for a grouping of products.

4. Do critical factors or limits listed in source documents match critical factors or limits for selected products and processes filed with FDA? ☐ Yes ☐ No

Critical factors may exist that the firm controls but have not been identified in the process filing and or has failed to identify and does not control. Critical factor limits recommended by the process authority should be equal to or greater than critical limits filed with FDA.

5. Does the firm have on file supplemental information listing procedures for pre-sterilization and sterility maintenance of processing and packaging equipment and sterilization of packaging material? ☐ Yes ☐ No

Validation studies such as commissioning letters, microbial filler challenges or sterile tank temperature distribution and inoculation studies for the sterile tank or aseptic packaging can often be found in the process authority's supporting documentation that was performed when the aseptic process was established.

ASEPTIC SYSTEM DESCRIPTION

6. Aseptic Processor Manufacturer and Model

7. Aseptic Filler Manufacturer and Model:

8. Does the firm use an aseptic surge tank? ☐ Yes ☐ No

9. Does a computer control any of the aseptic processor or filler functions? ☐ Yes ☐ No

10. Does the firm have documentation on hand which indicates that the computer system has been validated? ☐ Yes ☐ No

HEAT AND TEMPERATURE DISTRIBUTION - 21 CFR 113.83

11. Have there been any changes to the aseptic surge tanks or thermal processing system since the last temperature distribution study that could affect temperature distribution? ☐ Yes ☐ No

PRODUCT PREPARATION - 21 CFR 113.81

12. Are products prepared according to the method *(hydrating etc.)* and / or, formulation specified in the recommended scheduled process? ☐ Yes ☐ No

Be aware of changes in starches and other minor ingredients. For example, excess starches or other thickeners may change the fluid viscosity from turbulent to laminar flow. In addition, verify that ingredients are properly added to the batching system using accurate scales.

13. If rehydration of ingredients is critical to the thermal process does the firm meet the filed process parameters? ☐ N/A ☐ Yes ☐ No

Rehydration of powders like cocoa may be of concern in aseptically processed products.

14. Is the formulation of the product and aseptic processing conducted in a timely manner to prevent incipient spoilage? ☐ N/A ☐ Yes ☐ No

PRODUCT STERILIZER EQUIPMENT - 113.40(g)(1)(i)

15. Is the product heating system:

☐ Steam Injection ☐ Steam Infusion ☐ Scraped Surface ☐ Heat Exchanger ☐ Tubular ☐ Microwave

☐ Ohmic ☐ Other

Flow Control - 113.40 (g)(1)(i)(f)

16. Is the flow controlling device located upstream from the hold tube? ☐ Yes ☐ No

17. Is there a means of preventing unauthorized speed changes to the flow controlling device? ☐ Yes ☐ No

18. Does the firm use a flow meter to record or regulate product flow? ☐ Yes ☐ No

19. Identify the sensor used to send a signal to the recording chart. ☐ N/A

20. Is the product flow rate monitored and documented by the processor as a routine part of the system operation? ☐ Yes ☐ No

Product to Product Regenerator - 113.40 (g)(1) (i) (d)

21. If a product-to-product regenerator is used is it equipped with a differential pressure recorder-controller to assure that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product in the regenerator? ☐ Yes ☐ No

Differential Pressure Recorder-Controller - 113.40 (g)(1) (i) (e)

22. Are the sensors on the differential pressure recorder-controller installed at the sterilized product regenerator outlet and at the unsterilized (raw) product regenerator inlet? ☐ N/A ☐ Yes ☐ No

23. Identify the sensor(s) used to send a signal to the differential pressure - recording chart. ☐ N/A

24. Is the differential pressure recorder-controller tested quarterly or more frequently if necessary for accuracy? ☐ N/A ☐ Yes ☐ No

Both the sensor and recorder shall be tested for accuracy against an accurate reference device upon installation and at least once every 3 months of operation or more frequently if necessary. The differential pressure recorder-controller shall be accurate to within 2 pounds per square inch (13.8 kilopascals).

Temperature Controller – 113.40(g)(1)(i)(c)

25. Is the temperature controller sensor installed in the product flow at the exit of the final heater? ☐ Yes ☐ No

26. Identify the sensor used as the temperature controller.

Product Holding Tube – 113.40(g)(1)(i)(g)

27. Do the holding tube diameter and length conform to those listed in the filed scheduled process? ☐ Yes ☐ No

28. Is the holding tube sloped upward at least 0.25 inches / foot (2.1 cm / meter) ☐ Yes ☐ No

29. Is the holding tube designed so that no portion of the tube can be heated between product inlet and outlet? ☐ Yes ☐ No

Temperature Indicating Device (TID) – 113.40(g)(1)(i)(a)

30. Is the aseptic processor equipped with at least one temperature-indicating device (TID) that accurately indicates the temperature during processing? ☐ Yes ☐ No

31. Identify the sensor that serves as the TID.

32. Is the TID installed where it can be accurately and easily read? ☐ Yes ☐ No

33. Is the TID used as the reference instrument during processing? ☐ Yes ☐ No

34. Are calibration records for the TID established and maintained? ☐ Yes ☐ No

35. Is the TID accurate to 1 °F (0.5 °C)? ☐ Yes ☐ No

Temperature Recording Device – 113.40(g)(1)(i)(b)

36. Is the sensor for the temperature recording device installed at the hold tube outlet between the holding tube and the inlet to the cooler? ☐ Yes ☐ No

37. Identify the sensor used to send a signal to the Temperature Recording Device.

38. Are additional temperature recording device sensors installed on the system where temperature is specified as a critical factor in the scheduled process? ☐ Yes ☐ No

For example, are temperature sensors at the end of the processor line or at the end of the tank loop used to indicate the system has met sterility requirements as defined in the SUP-SID.

39. Identify the sensor(s) used to indicate that the aseptic processor was brought to a state of commercial sterility.

This is normally referred to as the processor end of line or return temperature.

40. Is the appropriate chart paper used with the temperature recording device? ☐ Yes ☐ No

Chart paper must have both the appropriate range (2 °F (1 °C) within a range of 10 °F (5 °C) of the process temperature) and working scale (< 55 °F per inch (12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature).

41. If the temperature-recording device creates multipoint plottings of temperature readings does it record the temperature at intervals that will assure that the parameters of the process time and process temperature were met? ☐ Yes ☐ No

42. If the temperature-recording device creates a digital record of temperature readings does it record the temperature at intervals that will assure that the parameters of the process time and process temperature were met? ☐ Yes ☐ No

Flow Diversion Device – 113.40(g)(1)(i)(h)

43. Is the aseptic processing system equipped with a flow diversion valve? ☐ Yes ☐ No

If the firm elects to install a flow diversion system, it should be installed in the product piping between the final product cooler and the product filler or aseptic surge tank.

44. Is the flow diversion system designed to automatically divert flow away from the filler or aseptic surge tank? ☐ Yes ☐ No

Flow diversions systems should be designed and operated in accordance with recommendations of an aseptic processing and packaging authority.

Equipment Downstream from the Holding Tube – 113.40(g)(1)(i)(i)

45. Does the firm have aseptic surge tank(s) installed for the processing system being covered during this inspection? ☐ Yes ☐ No

46. Are critical factors filed in the SUP-SID specifying both the sterilization procedure and conditions for maintenance of sterility for the aseptic surge tank(s)? ☐ N/A ☐ Yes ☐ No

47. Identify the sensor(s) used to indicate that the aseptic tank and line between the aseptic tank and the aseptic filler was brought to a state of commercial sterility. ☐ N/A

For example, are temperature sensors installed at the end of the tank loop used to indicate the system has met sterility requirements as defined in the SUP-SID.

48. Did the firm follow the filed aseptic tank sterilization procedures including adequately venting or purging air prior to sterilization? ☐ N/A ☐ Yes ☐ No

49. Is sterile air over-pressure maintained on aseptic surge tanks? ☐ N/A ☐ Yes ☐ No

50. Identify the sensor(s) used to indicate the aseptic tank overpressure is maintained according to the SUP-SID. ☐ N/A

51. Does the firm document sterile air or gas over-pressure and the maintenance of commercial sterility for the aseptic surge tank(s)? ☐ N/A ☐ Yes ☐ No

52. What type of filter system is used to sterilize the air?

For example, the box filter is generally sterilized with a chemical or dry heat — steam or hot water potentially will affect its integrity and should be avoided. Cartridge filters are designed to be used either for liquids or air and can be sterilized many different ways but moist heat and steam are preferred.

☐ HEPA ☐ Cartridge ☐ Sterilizing (capable of being sterilized) ☐ Non-sterilizing ☐ Other ☐ N/A

53. Identify the sensor(s) used to indicate the aseptic tank filters met the sterilization requirements defined in the SUP-SID. ☐ N/A

54. Are sterile air tank filters changed according to the manufacturer or process authority recommendations? ☐ N/A ☐ Yes ☐ No

55. Are rotating or reciprocating shafts and valve stems equipped with steam seals or other effective barriers at potential access points? ☐ N/A ☐ Yes ☐ No

These access points SHOULD be equipped with effective barriers. If they are installed, then records of their proper functioning MUST be maintained in accordance with 113.100(a)(4).

Some common locations for these steam seals include on sterile homogenizers or on agitating shafts on aseptic hold tanks. Depending on the installation steam barriers may also be present at valve clusters.

ASEPTIC FILLER – CONTAINER STERILIZATION, FILLING AND CLOSING OPERATION – 21 CFR 113.40(g)(2)(i)

56. What type of aseptic packaging system is being used by the firm?

☐ Metal Containers and Lids ☐ Paperboard Form/ Fill / Seal ☐ Paperboard Erect / Fill / Seal
☐ Plastic Containers and Lids ☐ Pre-sterilized Containers ☐ Thermoform / Fill / Seal ☐ Other

57. What media is used for the container and closure sterilization?

Select all that apply.

☐ Electron Beam ☐ Hydrogen Peroxide ☐ Irradiated (Pre-sterilized) ☐ Peracetic Acid
☐ Steam ☐ Ultraviolet Light ☐ Other

58. If a chemical sterilant is used in the aseptic chamber or on containers, are spray volumes recorded in accordance with the scheduled process? ☐ N/A ☐ Yes ☐ No

59. Does the firm test for residual sterilant on packaging material? ☐ N/A ☐ Yes ☐ No

60. If the firm uses Hydrogen Peroxide as the sterilant, is the residual Hydrogen Peroxide level in compliance with part 178.1005(d)? ☐ N/A ☐ Yes ☐ No

Residual hydrogen peroxide levels must be below 0.5 ppm to be in compliance with 21 CFR 178.1005

61. If the firm is using other sterilants, is the residual level tested and in compliance with the manufacturer's specifications? ☐ N/A ☐ Yes ☐ No

UV does not leave a residual. Review MSDS sheets for other sterilants residual levels.

62. If pre-sterilized packaging materials are used are they received and maintained sterile prior to use? ☐ N/A ☐ Yes ☐ No

63. If the firm is using multiple aseptic container types or sizes have validation studies been performed on each container to ensure that they can be sterilized in the aseptic filler? ☐ N/A ☐ Yes ☐ No

For example, if a firm is using different aseptic bottle designs have studies been performed on all containers to ensure the container can be properly sterilized?

Aseptic Filler Equipment – 21 CFR 113.40(g)(2)(i)

64. Does the firm follow its SUP-SID and filed scheduled process for bringing the container and lid sterilization equipment to a condition of commercial sterility before production? ☐ Yes ☐ No

The SUP-SID will identify critical factors to:
(a) Bring the system to commercial sterility (b) Maintain commercial sterility during production.

Not all critical factors defined in the SUP-SID may be applicable during maintenance of sterility.

65. Are the container and packaging closure sterilization system instrumented to demonstrate that the required sterilization is being accomplished continuously? ☐ Yes ☐ No

66. Does the recording device capture sterilization media flow rates, temperatures, concentrations and other factors specified in the filed process for container sterilizing, filling and closing operations? ☐ Yes ☐ No

Not all critical factors may be present on the recording device. Some critical factors, for instance, hydrogen peroxide concentration, could be recorded manually and with sufficient frequency to ensure the critical factor is under control.

67. Is there a system that stops packaging operations or alternatively segregates any product packaged when conditions fall below the scheduled process? ☐ Yes ☐ No

68. Are the filling packaging machines designed to automatically shut down in the event of a failure to meet specified critical factors? ☐ Yes ☐ No

69. Does the firm record the proper residence time of the containers and closures in the sterilizing medium? ☐ N/A ☐ Yes ☐ No

70. Is there a method of preventing unauthorized changes in container and closure rates during aseptic filling operations? ☐ N/A ☐ Yes ☐ No

71. If sterile water is directed against containers to rinse containers prior to filling or after filling and prior to the lids closing are critical factors recorded to ensure the sterility of the water? ☐ N/A ☐ Yes ☐ No

72. Does the firm challenge alarms that automatically control the aseptic packaging system? ☐ Yes ☐ No

THERMAL PROCESSING ROOM OPERATIONS – 21 CFR 113.87

73. Is the system operated in the same state that was used during the last temperature distribution study? ☐ Yes ☐ No

74. Are scheduled processes posted in the aseptic processing room or readily available to the aseptic system operator? ☐ Yes ☐ No

21 CFR 113.87(a)

75. Are records maintained demonstrating that IT thermometers are properly calibrated? ☐ N/A ☐ Yes ☐ No

For direct steam injection, the temperature sensor prior to the steam injector is normally used to indicate the IT of the product.

76. Are thermal process timing devices (clocks, charts, stopwatches etc.) accurate? ☐ Yes ☐ No

CONTAINERS – 21 CFR 113.60

77. Do product codes comply with part 113.60(c)? ☐ Yes ☐ No

The code shall be permanently visible to the naked eye and shall identify the packer, product, year, day and period of packing. Describe the coding system including a code breakdown for products produced during this inspection.

78. Are regular observations performed during production for container defects? ☐ Yes ☐ No

79. Are records of visual and destructive tests of containers performed and documented by qualified individuals? ☐ Yes ☐ No

80. Are corrective actions for defects taken and recorded? ☐ Yes ☐ No

81. For metal cans, are destructive tests performed on cans from each seaming head by qualified individuals and are all required measurements documented? ☐ N/A ☐ Yes ☐ No

Collect supporting evidence for sealing closing parameters or specification values necessary for sealing/closing.

82. For glass containers, are cold water vacuum tests for capper efficiency performed and recorded? ☐ N/A ☐ Yes ☐ No

Collect supporting evidence for sealing closing parameters or specification values necessary for sealing/closing

83. For other containers, are appropriate tests and detailed inspections performed to ensure a consistently reliable hermetic seal? ☐ N/A ☐ Yes ☐ No

Collect supporting evidence for sealing closing parameters or specification values necessary for sealing/closing

84. What type of container testing is performed?

Identify all that apply. For additional details on package integrity, refer to the FDA BAM (Bacteriological Analytical Manual)

☐ Abuse	☐ Air leak	☐ Burst	☐ Conductivity	☐ Dye	☐ Electrolytic
☐ Etching	☐ Gas leak	☐ Incubation	☐ Light	☐ Machine Vision	☐ Pull Up
☐ Peel (Tensile)	☐ Proximity	☐ Seam scope	☐ Security	☐ Sound	☐ Squeeze
☐ Teardown	☐ Torque	☐ Vacuum	☐ Visual	☐ Other	

POST PROCESS HANDLING – 21 CFR 113.60(d)

85. Are container handling procedures and conveyance equipment adequate to protect container bodies and seals from damage that could result in leakage and post-process contamination? ☐ Yes ☐ No

86. Are lots containing spoiled or swollen containers properly investigated? ☐ Yes ☐ No

Note that an acceptable level for can food spoilage in the LACF industry is 0.01% or 1 abnormal container per 10,000 containers – at levels above this the firm should perform a spoilage diagnosis including microbiological analysis to determine the cause of the spoilage. In addition, the firm should determine the cause of the problem and document this and any corrective action taken to prevent the problem from reoccurring.

PROCESS DEVIATIONS – 21 CFR 113.89

87. Does the firm maintain a separate file or log for documenting process deviations? ☐ Yes ☐ No

88. Did the firm properly handle all scheduled process deviations? ☐ Yes ☐ No

RECORDS – 21 CFR 113.100

89. Are all lots that are shipped in interstate commerce free from instances of public health significance and otherwise not injurious to health? ☐ Yes ☐ No

A commercial processor shall promptly report to the FDA any instances of spoilage or process deviations which indicate potential health significance when the lot of food has in whole or in part entered distribution.

90. Do operators document processing and production information on forms that include the product, code number, date, aseptic processing system, container size, approximate number of containers, initial temperature, actual processing time, TID readings, temperature recorder device readings and other appropriate processing data? ☐ Yes ☐ No

91. Is processing and production information recorded at the time it is observed by the aseptic processor or filler operator? ☐ Yes ☐ No

92. Are recording thermometer charts (analog, graphical or digital) identified by date, processing system and other data as necessary so that they can be correlated with the written record of lots processed? ☐ Yes ☐ No

93. Are processing and production records signed or initialed by the operator and reviewed for completeness and signed or initialed and dated by plant management within 1 working day after the actual process to assure that the product received the scheduled process? ☐ Yes ☐ No

94. Are all operators of thermal processing systems and container closure inspections under the operating supervision of a person who has attended a Better Process Control School (BPCS) or other school approved by FDA? ☐ Yes ☐ No

95. Does the firm have recall procedures on file that comply with 108.35(f)? ☐ Yes ☐ No

96. Does the firm maintain initial distribution records per 113.100(f)? ☐ Yes ☐ No

ASEPTIC PROCESSING AND PACKAGING RECORDS – 113.100(a)(4)

97. Before the start of aseptic processing operations are the product sterilizer and all product contact surfaces downstream brought to a condition of commercial sterility? ☐ Yes ☐ No

Records of the system sterilization must be maintained in accordance with the Supplemental SID as critical factors.

98. Do operators observe and document records at the following points to ensure that the process meets the parameters of the scheduled process.

99. Temperature Indicating Device in the holding tube outlet. ☐ Yes ☐ No

100. Temperature recorder in the holding tube outlet. ☐ Yes ☐ No

101. Differential pressure recorder if a product regenerator is used. ☐ N/A ☐ Yes ☐ No

102. Product flow rate as determined by the metering pump or as determined by filling and closing rates. ☐ Yes ☐ No

103. Was the flow controlling device operating properly to assure no more than the maximum product flow rate (proper residence time) in the holding tube? ☐ Yes ☐ No

104. Aseptic surge tank sterile air over-pressure or other protective means. ☐ N/A ☐ Yes ☐ No

105. Proper performance of steam seals or similar devices. ☐ Yes ☐ No

Temperature Drop in the Holding Tube – 113.40(g)(1)(ii)(b)

106. Were there any incidences of temperature drops in the holding tube below that specified in the scheduled process? ☐ Yes ☐ No

107. If there were any incidences of temperature drops in the holding tube below that specified in the scheduled process, was the product properly handled as a process deviation? ☐ N/A ☐ Yes ☐ No

108 If there were any incidences of temperature drops in the holding tube below that specified in the scheduled process, was the aseptic system returned to a state of commercial sterility before product flow was resumed? ☐ N/A ☐ Yes ☐ No

109. If there were any incidences of temperature drops in the holding tube below that specified in the scheduled process, was all affected product that was filled into containers properly segregated? ☐ N/A ☐ Yes ☐ No

Pressure Loss in a Product to Product Regenerator – 113.40(g)(1)(ii)(c)

110. Do records indicate pressure on the sterile side of the regenerator is greater than the pressure on the non-sterile side of the generator? ☐ N/A ☐ Yes ☐ No

In a product to product regenerator, sterilized product pressure must be greater than 1psi (6.9 kpa) than un-sterilized product. This requirement ensures that any leakage in the regenerator is from the sterilized product into the unsterilized product.

111. If there were any incidences of loss of pressure in product to product regenerator, was the system returned to a state of commercial sterility before resuming product flow? ☐ N/A ☐ Yes ☐ No

112. If there were any incidences of loss of pressure in product to product regenerator (<1 psi or 6.9 kpa), was affected product properly segregated? ☐ N/A ☐ Yes ☐ No

Loss of Sterile Air Pressure in Aseptic Surge Tanks – 113.40(g)(1)(ii)(d)

113. Were there any incidences of loss of sterile air or other protective means for the aseptic surge tank? ☐ N/A ☐ Yes ☐ No

114. If there were any incidences of loss of sterile air pressure, was potentially contaminated product removed from the tank prior to resuming product flow? ☐ N/A ☐ Yes ☐ No

115. If there were any incidences of loss of sterile air pressure, was the tank returned to a state of commercial sterility prior to resuming product flow into the surge tank? ☐ N/A ☐ Yes ☐ No

ASEPTIC FILLER RECORDS – 113.100(a)(4)

116. Do operators observe and record measurements of all critical factors during aseptic filling operations? ☐ N/A ☐ Yes ☐ No

Not all critical factors may be present on the automatic recording device. Some critical factors, for instance, hydrogen peroxide concentration, could be recorded manually and with sufficient frequency to ensure the critical factor is under control.

117. Does the firm observe and document records at the following points to ensure that the process meets the parameters of the scheduled process:

118. Media flow rates ☐ N/A ☐ Yes ☐ No

119. Temperatures at all critical locations ☐ Yes ☐ No

120. Container and closure flow rates thru the sterilization system ☐ N/A ☐ Yes ☐ No

121. Sterilization conditions for batch systems ☐ N/A ☐ Yes ☐ No

122. Are records for all critical sensors on the aseptic filling system identified in the SUP-SID generated and recorded? ☐ Yes ☐ No

123. Are all critical factor sensors and recording devices calibrated and functioning properly? ☐ Yes ☐ No

Critical Factors – 113.40(g)(4)

124. Are all critical factors defined in the scheduled process measured and recorded at intervals of sufficient frequency to ensure the process is under control? ☐ Yes ☐ No

TID and Reference Device Records - 113.100(c) and 113.100(d)

125. Do the TID calibration records include: A reference to the tag or seal, the name of the manufacturer, the ID of the reference device, NIST traceability, ID of the person who performed the test, the date and results of the testing including adjustments, and the date the next test is to be performed? ☐ Yes ☐ No

126. Do the reference device calibration records include: A reference to the tag or seal, the name of the manufacturer, the ID of the reference device, NIST traceability, ID of the person who performed the test, the date and results of the testing including adjustments, and the date the next test is to be performed? ☐ Yes ☐ No

Container Integrity Records – 113.100(e)

127. Do container closure records include the product code, date, time, measurements and corrective actions taken? ☐ Yes ☐ No

128. Are container integrity records signed and dated by the inspector and reviewer? ☐ Yes ☐ No

129. Are container integrity records reviewed with sufficient frequency to ensure containers are hermetically sealed? ☐ Yes ☐ No

COMMENTS