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5100 Paint Branch Parkway
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M-I-06-14

August 29, 2006

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Tetra Pak's Vacuum Thermal Instant Sterilizer (VTIS) Higher-Heat-Shorter-Time (HHST) Pasteurizer and Aseptic Processing System Vacuum Chambers F-Series (F-30, F-20, F-16, F-12, F-8, and F-4) Vessel Modifications

Background

On December 31, 2001, Milk Safety Team (MST) issued M-I-01-5 describing the vacuum chamber in Tetra Pak's VTIS HHST and aseptic steam injection milk and milk product processing systems that were observed to have serious construction and cleaning problems. M-I-01-5 also provided recommendations to the States regarding the inspection and continued use of this equipment.

Since early 2002, Tetra Pak has been working to redesign these vacuum chambers to be more easily inspected. With these new redesigned chambers, product enters straight into the vacuum chamber rather than being directed up an enclosed product inlet and distribution passage. FDA has been working with Tetra Pak to assure that the new design can be readily dissembled and all surfaces inspected without having to use a scope to view and videotape the condition and cleanliness of the product inlet and distribution passages.

FDA has agreed that the most current redesign (F-series: F-30, F-20, F-16, F-12, F-8, and F-4) when designed and installed as outlined in this M-I will meet this criterion.

However, approximately thirteen (13) vacuum chambers with an interim design were produced, sold and installed between late 2001 and the present, which will be required to be corrected to meet the most current redesign.

Purpose

This M-I sets forth the modifications that will need to be made in these interim designed vacuum chambers.

1. The F-Series Vacuum Chamber's baffle plate and mounting pins at the product inlet on the interior of the vacuum chamber shall be removed.

2. The most current redesign of the F-Series Vacuum Chamber includes an inspection port located in the top of the vessel. The inspection port on F-30, F-20 and F-16 vessels is to be not less than 300 mm (11.8 inches) in diameter. The F-12 and F-8 vessels shall have an inspection port of not less than 200 mm (7.87" inches) in diameter. The F-4 vessel may be equipped with sight glasses only.

Early versions of the F-Series Vacuum Chamber, which were shipped before this redesign began, may not have the required inspection port or may have a smaller inspection port than specified above.

NOTE: In lieu of modifying the inspection ports on these vessels, Tetra Pak has committed to working with the State Regulatory Agencies and FDA to provide means to assure adequate inspection of these vessels.

3. The product inlet line shall be readily removable to allow for the direct inspection of the product inlet area.

4. The manufacturer's installation manual shall recommend installation and placement to preclude overhead obstruction of the sight glasses and inspection port in order to assure that all product contact surfaces are visible and accessible for inspection. In existing installations, any overhead obstruction needs to be removed.

If questions arise concerning the inspectability or cleanability of any Tetra Pak F-Series Vacuum Chamber, the State Regulatory Agency may contact Tetra Pak to work out an acceptable procedure for the appropriate inspection and cleaning of these vessels.

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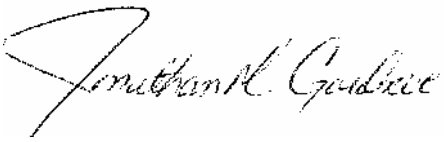
NOTE: All provisions of M-I-01-5 (Tetra Pak's Vacuum Thermal Instant Sterilizer (VTIS) Higher Heat Shorter Time (HHST) Pasteurizer and Aseptic Processing System Vacuum Chambers), issued December 31, 2001, shall continue to be applicable to VTIS Vacuum Chamber manufactured between 1989 and 2001.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies and State Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web site at http://www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.



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