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College Park, MD 20740-3835

M-b-370

August 15, 2013

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

FROM: Dairy and Egg Branch/Milk Safety Team (HFS-316)

SUBJECT: Carlson Engineering, Inc., Electronic Data Collection, Storage and Reporting System

In accordance with M-I-00-2, *Milk and Milk Product Equipment – A Guideline for Evaluating Construction*, FDA's Pacific/Southwest Region Milk Specialists and CFSAN's Dairy and Egg Branch/Milk Safety Team have specifically evaluated the Carlson Engineering, Inc., Electronic Data Collection, Storage and Reporting System, and have validated and confirmed the technical information submitted by Carlson Engineering, Inc. and the review findings of the Pacific/Southwest Region Dairy Equipment Review Committee (PSRDERC).

When the Carlson Engineering, Inc., Electronic Data Collection, Storage and Reporting System is installed, operated and maintained as described in the Engineering Design and Technical Construction File (EDTCF) PR-12-02, electronic data collection, storage, and reporting for CIP records; and raw and heat-treated milk and/or milk product storage tank temperature and cleaning requirements have been determined to meet the applicable provisions of the *Grade "A" Pasteurized Milk Ordinance* (PMO). Compliance with the PMO is based upon installation, operation, usage and maintenance as described in the following provisions:

1. Customers or vendors installing the Carlson Engineering, Inc., Electronic Data Collection, Storage and Reporting System shall protect the Carlson Plant Control server with an Uninterruptable Power Supply (UPS) providing twenty (20) minutes of electrical power in case of a power failure.
2. The milk plant is instructed to maintain a written record of the changes and updates to the Carlson Engineering, Inc., Electronic Data Collection, Storage and Reporting System, software, drivers, networking and/or servers. Milk plant personnel should be trained on the applicable devices, computers, servers, and software that require this log and the procedure for recording any changes

and/or updates. This documentation of change control is instructed to be a separate record and shall be available for review by the Regulatory Agency and the FDA.

3. On initial installation, the installer is instructed to print all reports for seven (7) consecutive days to assure that the system is functioning properly, accurately and error free before it becomes a compliant record system. The installer shall correct any anomalies before the end of this seven (7) day period and furnish a signed copy to the customer (milk plant), or a cover letter with their signature. These seven (7) days of reports shall be kept on file at the milk plant and a copy shall be provided to the Regulatory Agency and/or FDA when requested.
4. The customer (milk plant) is instructed that when changes, updates, or anomalies are observed, they shall be investigated and corrections shall be addressed. These investigations and corrections shall be recorded and signed by the person performing them.
5. The milk plant shall have a procedure to back-up the database for the Carlson Engineering, Inc., Electronic Data Collection, Storage and Reporting System every twenty four (24) hours

The technical information concerning the Carlson Engineering, Inc., Electronic Data Collection, Storage and Reporting System constitutes the PSRDERC's EDTCF PR-12-02. The Table of Contents for this EDTCF is attached and is also on file with the PSRDERC. The material in the EDTCF is the property of the manufacturer and may be shown at their discretion.

For additional information regarding this equipment and to request copies of the documents listed, please contact:

Carlson Engineering, Inc.
505 N.E. 37th Street
Fort Worth, Texas 76106
Attn: Brett Allen
Phone: (817) 877-3815
Email: brett.allen@cenginc.com

FDA's review and acceptance of the Carlson Engineering, Inc., Electronic Data Collection, Storage and Reporting System does not constitute FDA or Regulatory Agency endorsement or approval. Any representation on a label or in printed literature citing or indicating as "FDA Approved" would be considered as false and misleading.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, Milk Regulatory Agencies and Milk Sanitation 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.



Randy Elsberry
FDA Regional Dairy Specialist
Pacific Region



Robert Hennes, RS, MPH
CAPT U.S. Public Health Service
Dairy and Egg Branch

Attachment: PSRDERC's EDTCF PR-12-02 - Table of Contents

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