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

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Guidance for Milk Sanitation Rating Officers, Single-Service Consultants and FDA Regional Milk Specialists When Electronically Completing The Required Forms and Electronically Submitting IMS Certifications/Listings Or IMS FDA Audits, Respectively, For Single-Service Containers and/or Closures For Milk And/Or Milk Products Manufacturers For Inclusion On The IMS List

Proposal 309 that was passed at the 2015 NCIMS Conference was incorporated into the 2015 Revisions of the Grade “A” Pasteurized Milk Ordinance (PMO), Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (MMSR), and Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures). This Proposal addressed the regulation and certification/listing of single-service containers and/or closures for milk and/or milk products manufacturing plants. For a manufacturing plant to be certified and listed on the IMS List, the manufacturing plant shall obtain a Sanitation Compliance Rating (SCR) of eighty (80) or above conducted by:

- A FDA certified Milk Sanitation Rating Officer (SRO) for domestic manufacturing plants; or
- A FDA certified Single-Service Consultant (SSC) or a FDA certified SRO that is an employee of a Third Party Certifier (TPC) that is authorized under the voluntary NCIMS International Certification Program (ICP) for foreign manufacturing plants.

Recently, FDA has provided on their web site a means for SROs, SSCs and FDA Regional Milk Specialists (RMSs) to electronically complete the required Forms and electronically submit IMS certifications/listings or IMS FDA audits, respectively, for single-service containers and/or closures for milk and/or milk product manufacturers for inclusion on the IMS List. Following is guidance for the electronic completion of the required Forms and the electronic submission of the IMS certifications or IMS FDA audits:
MILK SANITATION RATING OFFICERS (SROS):

If you do not have an account as a SRO for this FDA web site, please request an account from Charlotte Epps at Charlotte.Epps@fda.hhs.gov.

EXISTING Domestic Single-Service IMS Certifications/Listings

- Login as a SRO;
- Click “Search Certified Domestic Single-Service Containers”;
- Click “Re-Certify” on the appropriate Domestic Single-Service Container Manufacturer;
- Fill out FORM FDA 2359d-Report of Certification (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15). New Items that were added and are required to be completed on this Form include:
  - Item 7.a.-Rating/Certification Personnel: New boxes were added to choose from. Check the appropriate box.
  - Item 7.c.-Sanitation Compliance Rating: This is the SCR that the SRO has calculated using the new FORM FDA 2359e-Status of Manufacturing Plants (Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15).

  **NOTE:** The SCR point value assigned to each inspectional Item is identified on FORM FDA 2359e.

  - Item 7.d.-Expiration Date: If the SCR is less than eighty (<80) as recorded in Item 7.c.-Sanitation Compliance Rating do not fill in/answer Item 7.d.-Expiration Date.
  - Item 11-Inspection Results: The inspectional Items listed on FORM FDA 2359c-Manufacturing Plant Inspection Report (Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15) are listed under this Item;

- Click “Save”;
- Fill out FORM FDA 2359c-Manufacturing Plant Inspection Report (Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15); and
- Click “Save” and the recertification/listing will automatically be forwarded to a RMS.

NEW Domestic Single-Service IMS Certifications/Listings

- Login as a SRO;
- Click “Create New Domestic Single-Service Container”;
- Fill out FORM FDA 2359d-Report of Certification (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15) as cited above;
- Click “Save”;
- Fill out FORM FDA 2359c-Manufacturing Plant Inspection Report (Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15); and
Click “Save” and the new certification/listing will automatically be forwarded to a RMS.

SINGLE-SERVICE CONSULTANTS (SSCs) OR A THIRD PARTY CERTIFIER’S (TPC) MILK SANITATION RATING OFFICER (SRO):

If you do not have an account as a SSC or SRO, respectively, for this FDA web site, please request an account from Charlotte Epps at Charlotte.Epps@fda.hhs.gov.

EXISTING Foreign Single-Service IMS Certifications/Listings

- Login as a SSC or SRO, respectively;
- Click “Search Certified Foreign Single-Service Containers”;
- Click “Re-Certify” on the appropriate Foreign Single-Service Container Manufacturer;
- Fill out FORM FDA 2359d-Report of Certification (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15). New Items that were added and are required to be completed on this Form include:

  - Item 7.a.-Rating/Certification Personnel: New boxes were added to choose from. Check the SSC or SRO, respectively.
  - Item 7.c.-Sanitation Compliance Rating: This is the SCR that the SSC or TPC’s SRO has calculated using the new FORM FDA 2359e-Status of Manufacturing Plant (Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15).

  NOTE: The SCR point value assigned to each inspectional Item is identified on FORM FDA 2359e.

  - Item 7.d.-Expiration Date: If the SCR is less than eighty (<80) as recorded in Item 7.c.-Sanitation Compliance Rating do not fill in/answer Item 7.d.-Expiration Date.
  - Item 11-Inspection Results: The inspectional Items listed on FORM FDA 2359c-Manufacturing Plant Inspection Report (Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15) are listed under this Item;

- Click “Recertify”;
- Fill out FORM FDA 2359c-Manufacturing Plant Inspection Report (Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15); and
- Click “Save” and the recertification/listing will automatically be forwarded to the Milk Safety Team (MST).

NEW Foreign Single-Service IMS Certifications/Listings

- Login as a SSC or SRO, respectively;
• Click “Create New Foreign Single-Service Container”;
• Fill out FORM FDA 2359d- Report of Certification (Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15) as cited above;
• Click “Add”;
• Fill out FORM FDA 2359c- Manufacturing Plant Inspection Report (Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15); and
• Click “Save” and the new certification/listing will automatically be forwarded to the Milk Safety Team (MST).

REGIONAL MILK SPECIALISTS (RMSs):

IMS FDA Audits

If the SCR from an IMS FDA audit of a single-service containers and/or closures for milk and/or milk products manufacturer is eighty (80) or above “No Action is Necessary” and the current listing is justified.

If the SCR from an IMS FDA audit of a single-service containers and/or closures for milk and/or milk products manufacturer is seventy-nine (79) or below the “Immediate Withdrawal of Certification/Listing” is required and the current listing is not justified.

• Login as a RMS;
• Click “Search Certified Domestic Single-Service Containers”;
• Select a Region and a State:
• Click “Single-Service Audit (Form 2359c)” on the appropriate Domestic Single-Service Manufacturer;
• Fill out FORM FDA 2359c- Manufacturing Plant Inspection Report (Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15);
• Click “Update”;
• Click “Audit Report (Form FDA 2359f)” on the appropriate Domestic Single-Service Manufacturer;
• Fill out FORM FDA 2359f- Audit Report of IMS Listed Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers (11/15). This is a new Form which is similar to FORM FDA 2359h- Interstate Milk Shipper’s Check Rating Report:

  ➢ Date, Listed Certification: Record the date that the current IMS Certification/Listing was conducted.
  ➢ Date, Audit: Record the date(s) that the IMS FDA audit was conducted.
  ➢ Single-Service Manufacturer, Listed Certification: Record the SCR* from the current IMS Certification/Listing.
  ➢ Single-Service Manufacturer, Audit: Record the SCR* from the IMS FDA audit.

  *NOTE: This is the SCR that the RMS has calculated using the new FORM FDA 2359e- Status of Manufacturing Plant (Single-Service Containers and/or Closures for
Milk and/or Milk Products) (11/15). The SCR point value assigned to each inspectional Item is identified on FORM FDA 2359e.

- Items of Sanitation Debited: The inspectional Items listed on FORM FDA 2359c-Manufacturing Plant Inspection Report (Single-Service Containers and/or Closures for Milk and/or Milk Products) (11/15) are listed under this Item. Check the appropriate inspectional Item(s) on FORM FDA 2359c that was/were debited on the IMS FDA audit.
- Check the appropriate box under “The results of this audit conducted by PHS/FDA…”:

* Click on “Add” and the IMS FDA audit will automatically be forwarded to the Milk Safety Team (MST) database.

**Review of Submitted SRO Domestic Certifications/Listings**

- Login as a RMS;
- Click “Approve Domestic Single-Service Containers”; 
- Click “Approve” on the appropriate Domestic Single-Service Manufacturer;
- Review SRO submitted FORM FDA 2359d;
- Click “View SRO (Form 2359c)”;
- Review SRO submitted FORM FDA 2359c;

  - Click “Reject” if there is an error(s) identified on FORM FDA 2359d and/or FORM FDA 2359c and the certification/listing will automatically be returned to the SRO that submitted the certification/listing.
  - If FORM FDA 2359d and FORM FDA 2359c are completed correctly and are accurate, on FORM FDA 2359d complete:

    ✓ Item 14-Date Received,
    ✓ Item 15-Publication of Rating Recommended, and
    ✓ Item 16-Date Transmitted.
    ✓ Item 17-Signature will be automatically self-populated with the name of the RMS.

  - Click “Approve” on the Domestic Single-Service Containers and the certification/listing will automatically be forwarded to the IMS List Administrator.

**MILK SAFETY TEAM (MST):**

**Review of Submitted SSC and/or TPC’s SRO Foreign Certifications/Listings**

- Login as MST;
- Click “Approve Foreign Single-Service Containers”;
- Click “Approve” on the appropriate Foreign Single-Service Manufacturer;
• Review SSC or SRO submitted FORM FDA 2359d;
• Click “View SSC (Form 2359c)”;  
• Review SSC or SRO submitted FORM FDA 2359c;

➢ Click “Reject” if there is an error(s) identified on FORM FDA 2359d and/or FORM FDA 2359c and the certification/listing will automatically be returned to the SSC or SRO that submitted the certification/listing.
➢ If FORM FDA 2359d and FORM FDA 2359c are completed correctly and are accurate, on FORM FDA 2359d complete:

  ✓ Item 14-Date Received,
  ✓ Item 15-Publication of Rating Recommended, and
  ✓ Item 16-Date Transmitted.
  ✓ Item 17-Signature will be automatically self-populated with the name of the RMS.

• Click “Approve” on the Foreign Single-Service Containers and the certification/listing will automatically be forwarded to the IMS List Administrator.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, Milk Regulatory/Rating Agencies and Milk Sanitation Rating Officers in your region and to Single-Service Consultants. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will 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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Milk and Milk Products Branch