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M-I-17-6

December 5, 2017

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

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

SUBJECT: Clarification Of The Testing Requirement And Procedure For The Clearance Sample For Reinstatement Due To A Confirmed Positive Using An Approved Test Method To Allow The Sale Of Milk For Human Food, When A Representative Sample From The Dairy Producer's Milk, Prior To Commingling With Any Other Milk, Is No Longer Positive For Drug Residues

At the October 11-12, 2017 meeting of the National Conference on Interstate Milk Shipments (NCIMS) Executive Board held in St. Louis, MO, FDA was requested to issue an M-I clarifying the clearance testing requirements and procedure for reinstatement due to a confirmed positive using an approved test method to allow the sale of milk for human food, when a representative sample from the dairy producer's milk, prior to commingling with any other milk, is no longer positive for drug residues.

Appendix N-Drug Residue Testing and Farm Surveillance of the PMO states the following:

Permit Suspension and the Prevention of the Sale of Milk: Any time milk is found to test as a confirmed positive using an approved test method, the Regulatory Agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues. Upon official notification to the Regulatory Agency and milk producer of a confirmed positive, future farm pickups by bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers and/or farm use of the violative individual producer's milk are prohibited until subsequent testing reveals the milk is free of drug residue.

Reinstatement: When the permit has been suspended as required, the Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

Dairy Producer Clearance Sample Testing for Reinstatement:

FDA has always stated that dairy producer clearance sample testing for reinstatement is to be conducted in the same manner as what is required for dairy producer confirmation testing. The same test method or an equivalent test method as cited in the latest revision of M-I-96-10 (Drug Residue Test Methods for Confirmation of Presumptive Positive Results and Initial Producer Trace Back) shall be used to clear the dairy producer for reinstatement as was used to initially confirm the dairy producer. Also, the testing procedures required to initially confirm the dairy producer shall be used to clear the dairy producer for reinstatement.

The dairy producer's clearance sample for reinstatement, collected prior to commingling with any other milk, is to be analyzed at the Regulatory Agency's discretion in an Official Laboratory, Officially Designated Laboratory or by a certified industry supervisor (CIS).

Procedure for Dairy Producer Clearance Sample Testing for Reinstatement:

1. Initial result is reported as **NOT FOUND (NF)**, no further testing is required. Following notification to the Regulatory Agency and the dairy producer, the dairy producer is reinstated.
2. Initial result is **POSITIVE** (dairy producer presumptive positive), that same sample is then tested in duplicate using the same test method as was used to obtain the dairy producer presumptive positive. This testing is performed with positive (+) and negative(-) controls.
 - If the controls **DO NOT** give the appropriate results, contact the Regulatory Agency and/or Laboratory Evaluation Officer (LEO).
 - If the controls give the appropriate results and both of the duplicates test **NEGATIVE**, the dairy producer sample result is reported as **NOT FOUND (NF)**. Following notification to the Regulatory Agency and the dairy producer, the dairy producer is reinstated.
 - If the controls give the appropriate results and either or both of the duplicates are **POSITIVE** (dairy producer confirmed positive), following notification to the Regulatory Agency and the dairy producer, the dairy producer is not reinstated.

Appendix N of the PMO also states the following:

Prevention of the Sale of Milk: Any time milk is found to test as a verified screening positive for a drug residue using test methods not evaluated by FDA and accepted by the NCIMS without additional confirmation required the Regulatory Agency shall immediately take effective measures to prevent the sale of the milk containing drug residues.

Dairy Producer Clearance Sample Testing for Regulatory Agency Authorization to Sell Milk (Appendix N, Section VI (2015 PMO). Also, refer to Option 3 (Proposal 226/2017 Conference) incorporated into IMS-a-51 and the 2017 PMO):

FDA has stated that dairy producer clearance sample testing for Regulatory Agency authorization to sell milk is to be conducted in the same manner as what is required for a dairy producer verified screening positive. The same test method or an equivalent test method that has not been evaluated by FDA and accepted by the NCIMS shall be used to clear the dairy producer for Regulatory Agency authorization to sell milk as was used to initially verify the dairy producer (verified screening positive). Also, the testing procedures required to initially verify a screening positive for the dairy producer shall be used to clear the dairy producer for Regulatory Agency authorization to sell milk.

The dairy producer's clearance sample for Regulatory Agency authorization to sell milk, collected prior to commingling with any other milk, is to be analyzed by Industry at the direction of the Regulatory Agency as cited in the prior documented agreement.

Procedure for Dairy Producer Clearance Sample Testing for Regulatory Agency Authorization to Sell Milk:

1. Initial result is reported as **NOT FOUND (NF)**, no further testing is required. Following notification to the Regulatory Agency and the dairy producer, the Regulatory Agency will authorize the dairy producer to sell milk.
2. Initial result is **POSITIVE**, that same sample is then tested in duplicate using the same test method as was used to obtain the initial positive. This testing is performed with positive (+) and negative(-) controls.
 - If the controls give the appropriate results and both of the duplicates test **NEGATIVE**, the dairy producer sample result is reported as **NOT FOUND (NF)**. Following notification to the Regulatory Agency and the dairy producer, the Regulatory Agency will authorize the dairy producer to sell milk.
 - If the controls give the appropriate results and either or both of the duplicates are **POSITIVE** (verified screening positive), following notification to the Regulatory Agency and the dairy producer, the Regulatory Agency will not authorize the dairy producer to sell milk.

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Regulatory/Rating Agencies, Milk Laboratory Evaluation Officers and Milk Sanitation Rating Officers. 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.

A handwritten signature in black ink, appearing to read "Robert F. Hennes". The signature is written in a cursive style with a large initial "R".

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Milk and Milk Products Branch