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M-I-19-2

February 27, 2019

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

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

SUBJECT: Updated Information Related To Appendix N-Drug Residue Testing And Farm Surveillance, Section VI-Test Methods For Non-Beta Lactams Residue Testing That Have Not Been Evaluated By FDA And Accepted By The NCIMS Of The PMO

Proposal 226 passed at the 2017 NCIMS Conference incorporated the following text within Section VI-Test Methods For Non-Beta Lactams Residue Testing That Have Not Been Evaluated By FDA And Accepted By The NCIMS, Appendix N-Drug Residue Testing And Fam Surveillance of the PMO:

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR INITIAL SCREENING FOLLOWED BY A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) FOR DETERMINING A SCREENING TEST POSITIVE (LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS CONFIRMATION): ...

“One (1) year after two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85 (latest revision) or as cited M-I-92-11, in raw milk, one (1) of the following two (2) options (1 or 2) shall be used for confirmation:”

UTILIZING A DRUG TEST METHOD THAT HAS NOT BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS FOR THE INITIAL SCREENING AND DETERMINING A VERIFIED SCREENING POSITIVE LOAD AND/OR RAW MILK SUPPLY THAT HAS NOT BEEN TRANSPORTED IN BULK MILK PICKUP TANKERS WHEN A DRUG TEST METHOD THAT HAS BEEN EVALUATED BY FDA AND ACCEPTED BY THE NCIMS (M-a-85, latest revision, and M-I-92-11) IS NOT AVAILABLE: ...

“One (1) year after two (2) test methods are found acceptable by FDA and the NCIMS for detecting a particular drug or drug family, other than Beta lactams, as cited in M-a-85, latest revision, or M-I-92-11 in raw milk, Option 3 shall not be used for non-Beta lactam screening or verification.” ...in raw milk, Option 3 shall not be used for screening or verification of this non-Beta lactam family.”

Tetracyclines

The following tetracycline drug test kits (methods) have been evaluated by FDA and accepted by the NCIMS:

- CHARM® II Tetracycline Drug Test (Competitive Assay)
 - M-I-96-11 (Tetracycline Test Method for Chlortetracycline, Oxytetracycline and Tetracycline), issued 12/20/1996.
 - M-I-96-10 (Revision #1), issued 12/20/1996.
 - M-a-85 (Revision #6), issued 7/14/1997.
 - M-I-98-8 (Tetracycline Test Method)-Replaces M-I-96-11, issued 12/11/1998.
 - M-a-85 (Revision #7), issued 5/21/1999.
- CHARM® ROSA® SL Tetracycline SL (Dilution Confirmation)
 - M-I-18-6, issued 1/30/2018.
 - M-a-85 (Revision #16), issued 12/20/2018.
- Neogen BetaStar® Advanced for Tetracyclines Assay
 - M-I-18-7, issued 1/30/2018.
 - M-a-85 (Revision #16), issued 12/20/2018.
- CHARM® TRIO Test for Tetracyclines Only (screening only)
 - M-a-85 (Revision #16), issued 12/20/2018.

This brings the total of tetracycline drug test kits (methods) to four (4); therefore, Options 1 and 2 are required to be used, and Option 3 shall not be used for tetracycline testing under Appendix N. Section VI of the PMO

Sulfonamides

The following sulfonamide drug test kits (methods) have been evaluated by FDA and accepted by the NCIMS:

- CHARM® II Sulfa Drug Test (Competitive Assay)
 - M-a-85 (Revision #5), issued 7/31/1996.
 - M-I-96-10 (Revision #1), issued 12/20/1996.
- CHARM® ROSA® SULF Test
 - M-I-18-20, issued 11/27/2018.
 - M-a-85 (Revision #16), issued 12/20/2018.
- CHARM® TRIO Test for Sulfonamides Only (screening only).
 - M-I-18-21, issued 11/27/2018.
 - M-a-85 (Revision #16), issued 12/20/2018.

This brings the total of sulfonamides drug test kits (methods) to three (3); therefore, starting on 11/27/2019, Options 1 and 2 are required to be used and Option 3 shall not be used for sulfonamide testing under Appendix N of the PMO.

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Milk Regulatory/Rating Agencies, 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 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 Monica.Metz@fda.hhs.gov.

A handwritten signature in black ink, appearing to read "Monica Metz", with a stylized flourish at the end.

Monica Metz, Chief
Milk and Milk Products Branch