HHS:PHS:FDA:CFSAN:OFS:DDEMP:MMPB

5001 Campus Drive
College Park, MD 20740-3835

M-I-17-2

March 15, 2017

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

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

SUBJECT: Application, Testing Options Flow Charts And Implementation Of Section VI. Test Methods For Non-Beta Lactams Residue Testing That Have Not Been Evaluated By FDA And Accepted By The NCIMS Within Appendix N. Drug Residue Testing and Farm Surveillance Of The Grade "A" Pasteurized Milk Ordinance

Proposal 213, which was passed at the 2015 NCIMS Conference, added Section VI. Test Methods For Non-Beta Lactam Residue Testing That Have Not Been Evaluated By FDA And Accepted By The NCIMS to Appendix N. Drug Residue Testing and Farm Surveillance of the 2015 Grade "A" Pasteurized Milk Ordinance (PMO). Section VI states:

"Provided, that until at least 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, and M-I-92-11 in raw milk, non-Beta lactam screening test methods, which have not been evaluated and accepted by FDA and the NCIMS, may be used for the initial screening, provided that the test method manufacturer's data indicates that testing sensitivity is at or below U.S. target testing/or tolerance levels."

NOTE: The non-Beta lactam drug test methods cited in M-a-85, latest revision, are Charm® FLUSLBL Flunixin and Beta Lactam Test, Charm® II Sulfa (Competitive) and Charm® II Tetracycline (Competitive) and Chloramphenicol as cited in M-I-92-11.

Section VI is broken down into the following two (2) Items:

- **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).**

- Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to **confirm** the presence of a non-Beta lactam drug residue with a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11.

- Within this Item there are two (2) options for when a non-Beta lactam drug residue is identified and when a test method evaluated by FDA and accepted by the NCIMS as cited in M-a-85, latest revision, and M-I-92-11 would be required to be used.

  NOTE: Please refer to the Flow Charts titled: 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) – OPTION 1 (Pages 5-6) and OPTION 2 (Pages 7-8).

- **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.**

  - Test methods not evaluated by FDA and accepted by the NCIMS may be used for screening and verifying bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues with the documented permission of the Regulatory Agency(ies). In advance of using such a test method, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to **verify** the presence of a non-Beta lactam drug residue.

  - Within this Item there is only one (1) option available to **verify** the presence of a non-Beta lactam drug residue.

NOTE: Please refer to the Flow Chart titled: 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 (Pages 9-10).

The following are questions related to the required prior documented agreement that shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies):

a) Where should this prior documented agreement(s) among the user of the test method, the milk supplier, and the Regulatory Agency(ies) be kept/retained?

The PMO does not specifically cite where the signed agreement(s) shall be kept/ retained. During ratings and check ratings of milk plants, receiving stations and transfer stations that utilize test methods not evaluated by FDA and accepted by the NCIMS for screening bulk milk pickup tankers and/or all raw milk supplies that have not been transported in raw milk bulk milk pickup tankers for non-Beta lactam drug residues, the Milk Sanitation Rating Officer (SRO) and FDA Regional Milk Specialist (RMS) will request to see and will review the documented agreement(s) at the milk plant, receiving station or transfer station and also during the official Regulatory Agency records review. Therefore, this required documented agreement(s) shall be kept/retained at the milk plant, receiving station or transfer station and in the official Regulatory Agency file of the milk plant, receiving station or transfer station. It is recommended that the milk supplier(s) should also keep/retain a copy on file.

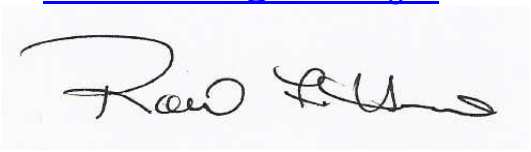
b) Does this prior documented agreement(s) among the user of the test method, the milk supplier, and the Regulatory Agency(ies) have to be signed by all three (3) parties?

Yes.

NOTE: For States that can legally enforce these new regulations based on the issuance of IMS-a-50 (Actions of the 2015 National Conference on Interstate Milk Shipments), the effective date was November 16, 2016. For the other States, these new regulations will become effective within one (1) year of the electronic publication of the 2015 PMO. The effective date for those States is March 15, 2017.

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



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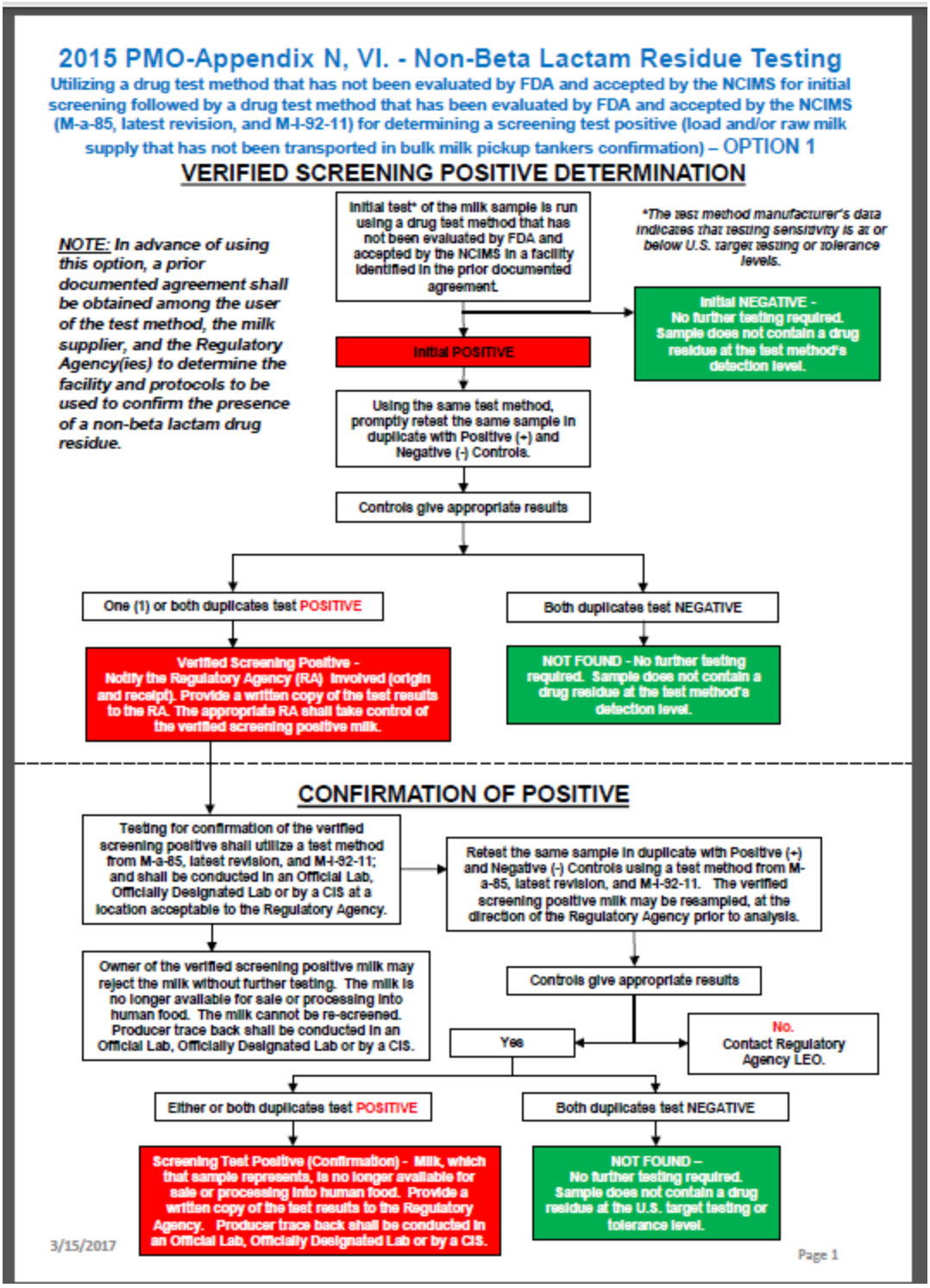
Milk and Milk Products Team


2015 PMO-Appendix N, VI. - Non-Beta Lactam Residue Testing
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) – OPTION 1
VERIFIED SCREENING POSITIVE DETERMINATION
NOTE: In advance of using this option, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to confirm the presence of a non-beta lactam drug residue.
Initial test* of the milk sample is run using a drug test method that has not been evaluated by FDA and accepted by the NCIMS in a facility identified in the prior documented agreement.
*The test method manufacturer's data indicates that testing sensitivity is at or below U.S. target testing or tolerance levels.
Initial NEGATIVE - No further testing required. Sample does not contain a drug residue at the test method's detection level.
Initial POSITIVE
Using the same test method, promptly retest the same sample in duplicate with Positive (+) and Negative (-) Controls.
Controls give appropriate results
One (1) or both duplicates test POSITIVE
Both duplicates test NEGATIVE
Verified Screening Positive - Notify the Regulatory Agency (RA) involved (origin and receipt). Provide a written copy of the test results to the RA. The appropriate RA shall take control of the verified screening positive milk.
NOT FOUND - No further testing required. Sample does not contain a drug residue at the test method's detection level.
CONFIRMATION OF POSITIVE
Testing for confirmation of the verified screening positive shall utilize a test method from M-a-85, latest revision, and M-I-92-11; and shall be conducted in an Official Lab, Officially Designated Lab or by a CIS at a location acceptable to the Regulatory Agency.
Retest the same sample in duplicate with Positive (+) and Negative (-) Controls using a test method from M-a-85, latest revision, and M-I-92-11. The verified screening positive milk may be resampled, at the direction of the Regulatory Agency prior to analysis.
Owner of the verified screening positive milk may reject the milk without further testing. The milk is no longer available for sale or processing into human food. The milk cannot be re-screened. Producer trace back shall be conducted in an Official Lab, Officially Designated Lab or by a CIS.
Controls give appropriate results
Yes
No. Contact Regulatory Agency LEO.
Either or both duplicates test POSITIVE
Both duplicates test NEGATIVE
Screening Test Positive (Confirmation) - Milk, which that sample represents, is no longer available for sale or processing into human food. Provide a written copy of the test results to the Regulatory Agency. Producer trace back shall be conducted in an Official Lab, Officially Designated Lab or by a CIS.
NOT FOUND – No further testing required. Sample does not contain a drug residue at the U.S. target testing or tolerance level.
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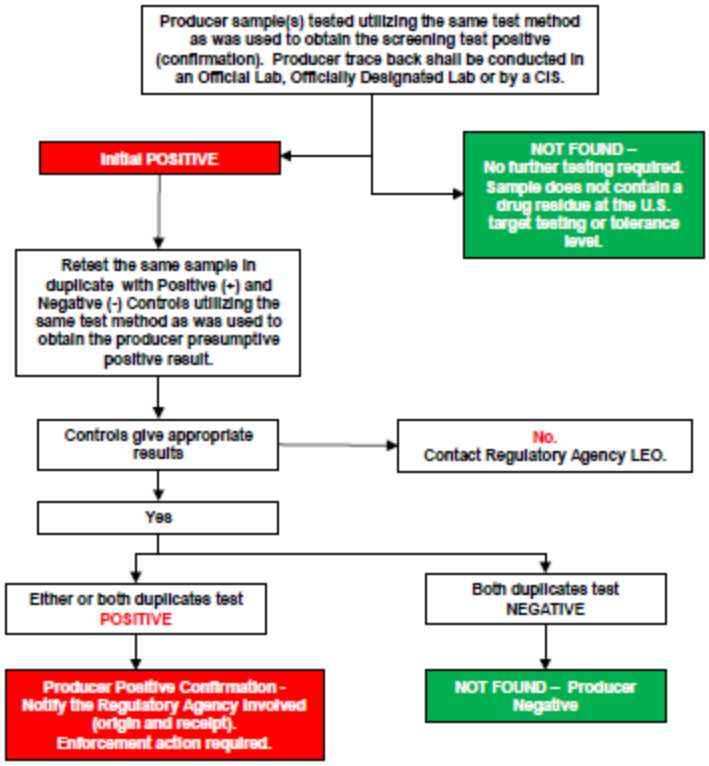
PRODUCER TRACE BACK



Enforcement Action: 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 and/or farm use of the violative individual producer's milk shall be immediately discontinued. A farm inspection by the Regulatory Agency or its agent shall be made to determine the cause of the residue and actions taken to prevent future violations. Any producer positive confirmation test using an approved test method will count towards the three (3) violations in a twelve (12) month period for permit revocation.

PRODUCER REINSTATEMENT

Future farm pickups and/or farm use of the violative individual producer's milk is prohibited until the producer(s) that test(s) Positive has (have) a Negative sample utilizing the same test method as was used to obtain the producer positive confirmation test.

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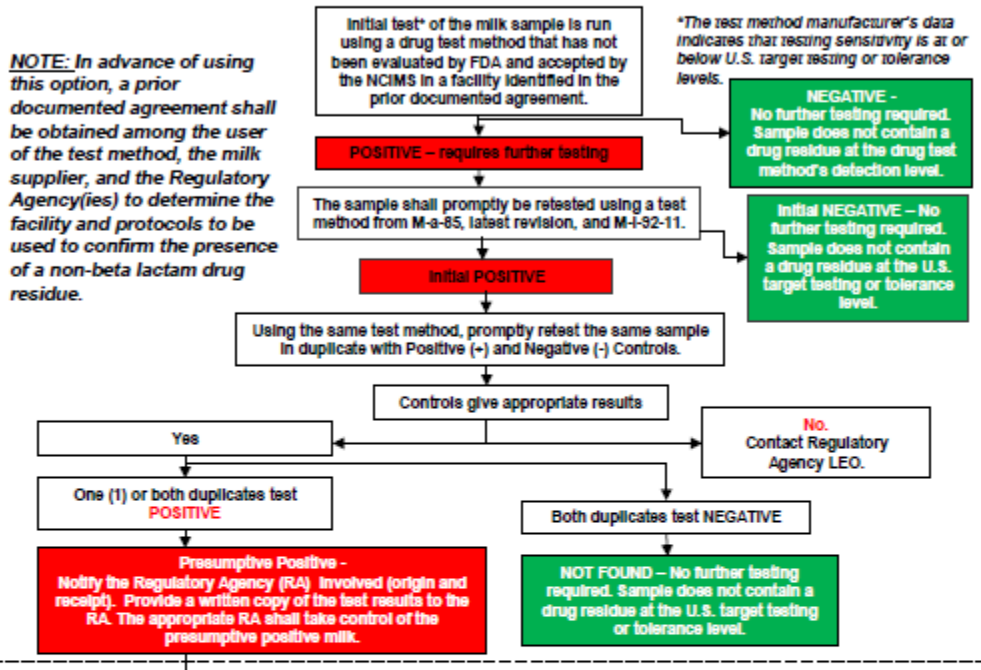
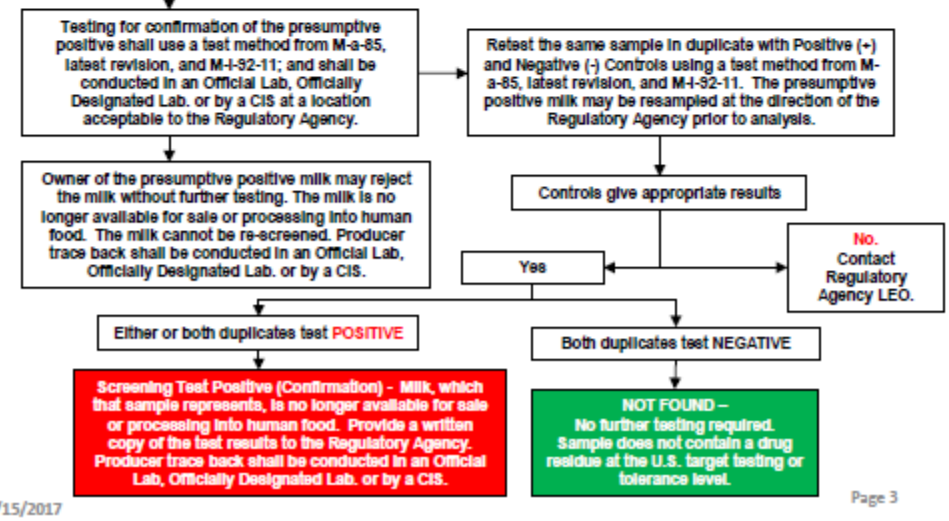
2015 PMO-Appendix N, VI. - Non-Beta Lactam Residue Testing

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) – OPTION 2

PRESUMPTIVE POSITIVE DETERMINATION



CONFIRMATION OF POSITIVE



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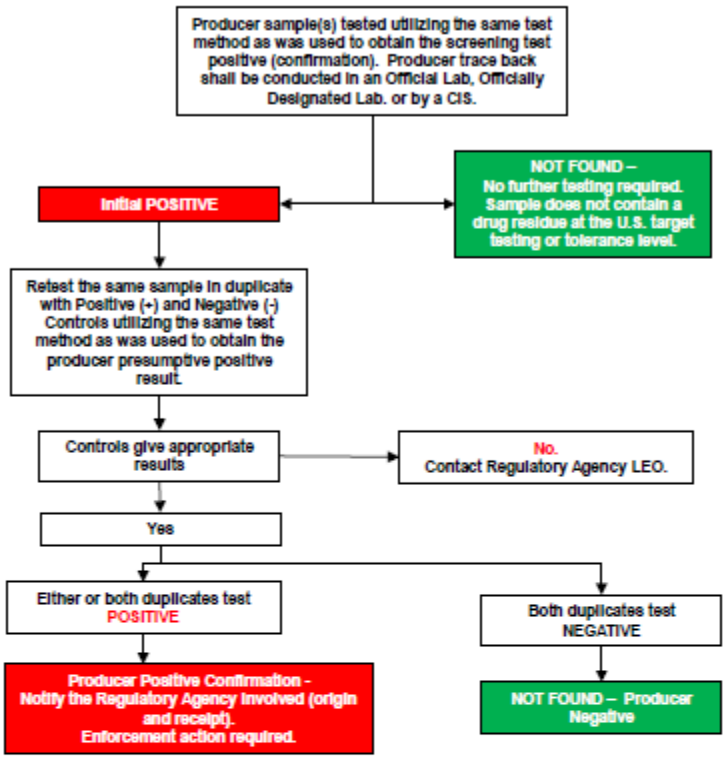

Enforcement Action: The Regulatory Agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues. Upon official notification to the Regulatory Agency and milk producer of a confirmed positive, future farm pickups and/or farm use of the violative individual producer's milk shall be immediately discontinued. A farm inspection by the Regulatory Agency or its agent shall be made to determine the cause of the residue and actions taken to prevent future violations. Any producer positive confirmation test using an approved test method will count towards the three (3) violations in a twelve (12) month period for permit revocation.

PRODUCER REINSTATEMENT

Future farm pickups and/or farm use of the violative individual producer's milk is prohibited until the producer(s) that test(s) Positive has (have) a Negative sample utilizing the same test method as was used to obtain the producer positive confirmation test.

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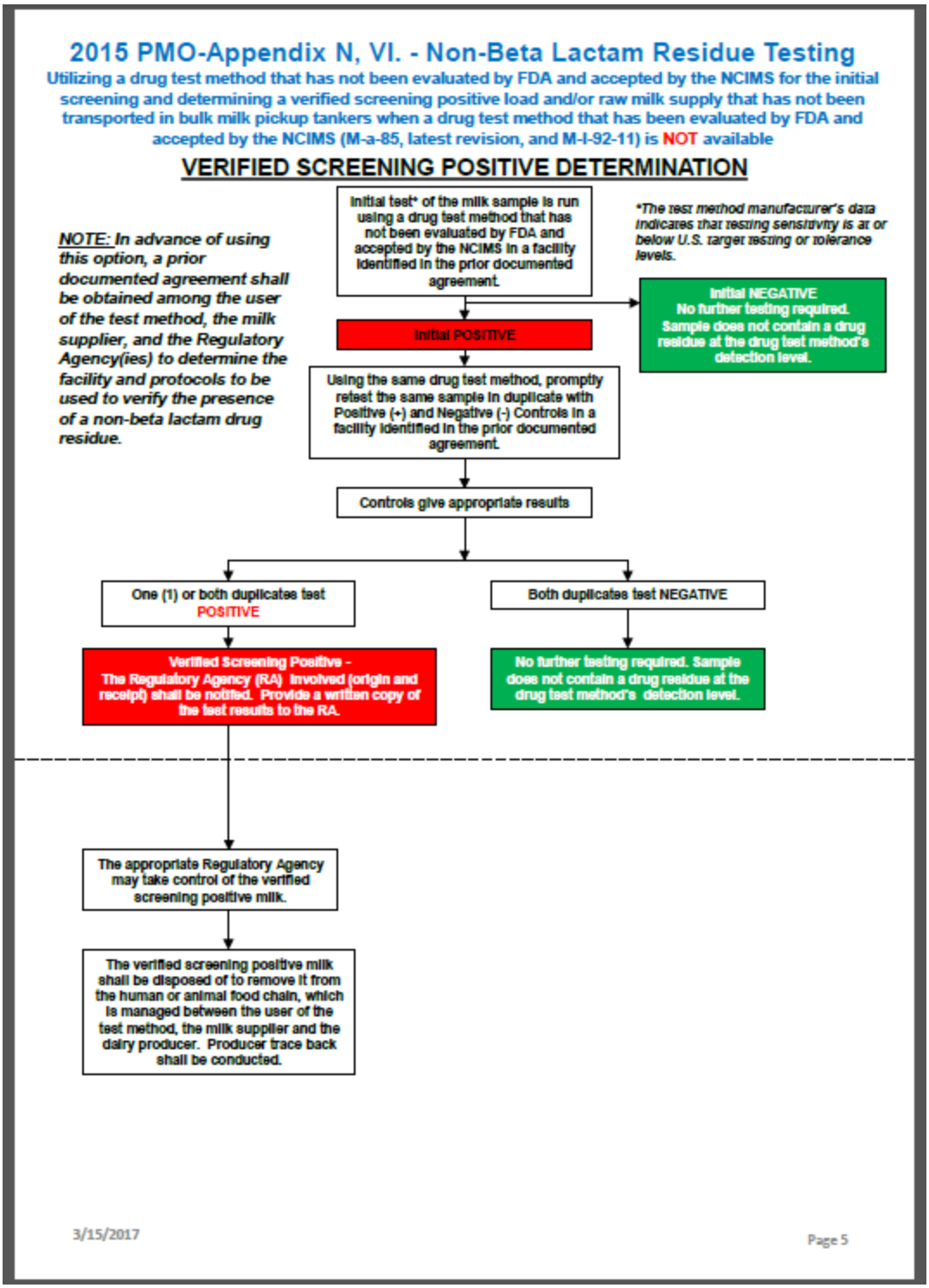
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VERIFIED SCREENING POSITIVE DETERMINATION
NOTE: In advance of using this option, a prior documented agreement shall be obtained among the user of the test method, the milk supplier, and the Regulatory Agency(ies) to determine the facility and protocols to be used to verify the presence of a non-beta lactam drug residue.
Initial test* of the milk sample is run using a drug test method that has not been evaluated by FDA and accepted by the NCIMS in a facility identified in the prior documented agreement.
*The test method manufacturer's data indicates that testing sensitivity is at or below U.S. target testing or tolerance levels.
Initial NEGATIVE
No further testing required. Sample does not contain a drug residue at the drug test method's detection level.
Initial POSITIVE
Using the same drug test method, promptly retest the same sample in duplicate with Positive (+) and Negative (-) Controls in a facility identified in the prior documented agreement.
Controls give appropriate results
One (1) or both duplicates test POSITIVE
Both duplicates test NEGATIVE
Verified Screening Positive -
The Regulatory Agency (RA) involved (origin and receipt) shall be notified. Provide a written copy of the test results to the RA.
No further testing required. Sample does not contain a drug residue at the drug test method's detection level.
The appropriate Regulatory Agency may take control of the verified screening positive milk.
The verified screening positive milk shall be disposed of to remove it from the human or animal food chain, which is managed between the user of the test method, the milk supplier and the dairy producer. Producer trace back shall be conducted.
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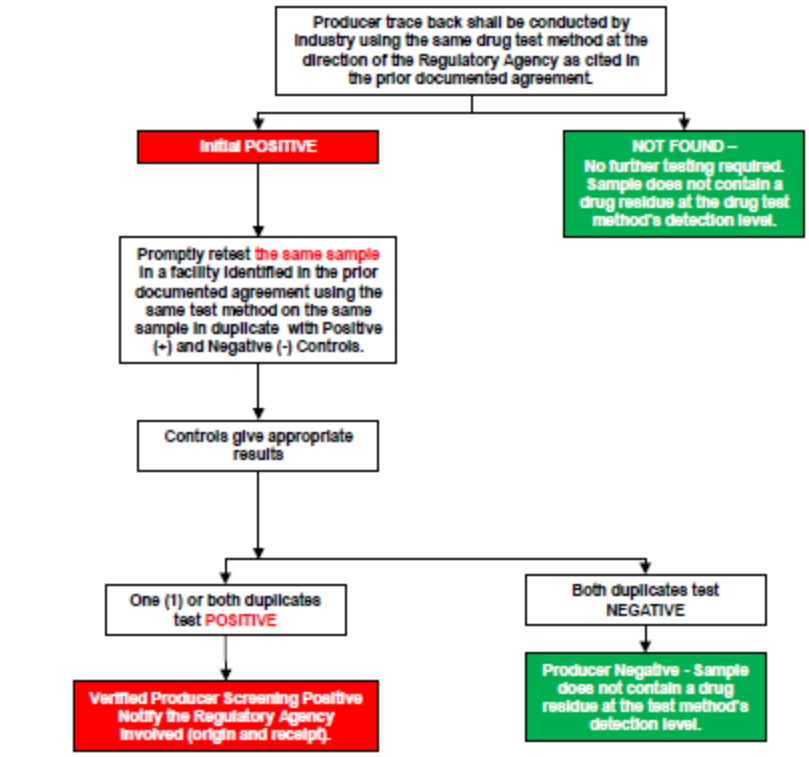
PRODUCER TRACE BACK



Enforcement Action: Producer permit suspension action is not required. Upon official notification to the Regulatory Agency and milk producer of a verified producer screening positive, future farm pickups and/or farm use of the violative individual producer's milk shall be immediately discontinued. A farm inspection by the Regulatory Agency or its agent may be made to determine the cause of the drug residue and actions taken to prevent future violations.

PRODUCER REINSTATEMENT

Future farm pickup(s) and/or use of the violative individual producer's milk is (are) prohibited until the producer(s) that test(s) Positive has (have) a Negative sample utilizing the same drug test method as was used to obtain the verified producer screening positive or an equivalent drug test method as cited in the prior documented agreement.

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