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College Park, MD 20740-3835

M-I-18-7

January 30, 2018

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

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

SUBJECT: Neogen Corporation BetaStar® Advanced For Tetracyclines Assay

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the Neogen Corporation BetaStar® Advanced for Tetracyclines Assay for the detection of tetracyclines in raw, commingled cow milk.

The FDA evaluation of the data, presented by the Neogen Corporation, indicates that the performance of the Neogen Corporation BetaStar® Advanced for Tetracyclines Assay Test meets the standards established to determine the acceptance of a Test for use in raw, commingled cow milk. The acceptance of the Test for raw, commingled cow milk represents a claim for Chlortetracycline, Oxytetracycline and Tetracycline. The data has been evaluated in accordance with the standards established for the acceptance of screening tests for monitoring raw, commingled milk in accordance with the provisions of Appendix N-Drug Residue Testing and Farm Surveillance of the *Grade "A" Pasteurized Milk Ordinance*.

The Executive Board of the NCIMS voted on Proposal 220 from the 2017 NCIMS Conference to accept the use of this Test for Tetracyclines when used as labeled on October 12, 2017. Attached is the memorandum of acceptance from FDA's CVM.

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 State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Organizations, 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](mailto: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".

Robert F. Hennes, RS, MPH  
CAPT U.S. Public Health Service  
Milk and Milk Products Branch

Attachment: FDA CVM Memorandum of Acceptance of the Neogen Corporation  
BetaStar® Advance for Tetracyclines Assay Test



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## Memorandum

**To: CAPT Robert F. Hennes, RS, MPH  
Milk and Milk Products Branch**

**From: Philip James Kijak, Ph.D.**

**Date: January 26, 2018**

**Subject: Neogen Corporation BetaStar® Advanced for Tetracyclines**

Neogen Corporation has provided data to FDA supporting the use of the BetaStar® Advanced for Tetracyclines test for the detection of Oxytetracycline, Chlortetracycline and Tetracycline for raw, commingled cow milk. This data has been evaluated in accordance with the standards established for the acceptance of screening tests for raw, commingled cow milk to monitor milk in accordance to the provisions of Appendix N of the Pasteurized Milk Ordinance (PMO).

The 90/95 percent detection levels (ppb) and drug concentration responses are listed below:

<b>DRUG</b>	<b>90/95</b>	<b>Tolerance (ppb)<sup>1</sup></b>
<b>Chlortetracycline</b>	254	300
<b>Oxytetracycline</b>	190	300
<b>Tetracycline</b>	245	300

<sup>1</sup>The tolerance is established as the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline.

The Drug Concentration Response: (Displayed as percent positive based on 30 samples at each concentration.)

DRUG	Chlortetracycline	Oxytetracycline	Tetracycline
Tolerance (ppb)	300 ppb (Chlortetracycline + Oxytetracycline + Tetracycline)		
Drug Concentration (ppb)			
50	0	0	0
100	0	0	0
150	0	40	17
200	13	100	93
250	87	100	100
300	100	100	100

## RECOMMENDATION

Our evaluation of the data presented by the Neogen Corporation indicates that the performance of this test meets the standards established for acceptance of screening tests for monitoring raw, commingled cow milk for tetracyclines in accordance with the provisions of Appendix N of the PMO. We recommend that the appropriate announcement be issued to the Regulatory/Rating Agencies and the milk industry advising of the Agency's concurrence with the use of this test as labeled. A revision of M-a-85 and M-I-96-10 should be issued to reflect the acceptance of this test.



Philip James Kijak, Ph.D.  
 Director, Division of Residue Chemistry  
 CVM Office of Research

Attachment: Product Label BetaStar® Advanced for Tetracyclines (BSATET)