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College Park, MD 20740-3835

M-I-18-5

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 Beta lactam Assay Test And
BetaStar® Plus Beta lactam Test

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the Neogen Corporation BetaStar® Advanced Beta lactam Assay Test for raw, commingled cow milk. Neogen Corporation has indicated that the BetaStar® Advanced Beta lactam Assay Test will replace the current BetaStar® Plus Beta lactam Test.

The FDA evaluation of the data, presented by the Neogen Corporation indicates that the performance of the BetaStar® Advanced Beta lactam 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 Amoxicillin, Ampicillin, Ceftiofur, Cephapirin, Cloxacillin and Penicillin G. 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 219 from the 2017 NCIMS Conference to accept the use of this Test for Beta lactams when used as labeled on October 12, 2017. Attached is the memorandum of acceptance from FDA's CVM.

Neogen Corporation has indicated that the BetaStar® Plus Beta lactam Test will no longer be sold. The last lot of the BetaStar® Plus Beta lactam Test will expire March 28, 2018. Users of the BetaStar® Plus Beta lactam Test may continue to use the product until the test kit's expiration date.

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.

A handwritten signature in black ink, appearing to read "Robert Hennes", is centered on a light gray rectangular background.

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 Beta lactam Assay Test



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 Assay Test for Beta lactams

Neogen Corporation has provided data to FDA supporting the use of the BetaStar® Advanced assay test for Beta lactams for the detection of Amoxicillin, Ampicillin, Ceftiofur, Cephapirin, Cloxacillin and Penicillin G 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:

DRUG	90/95	Tolerance/Target Testing Level
Amoxicillin	9.2	10
Ampicillin	8.6	10
Ceftiofur	93	100
Cephapirin	18.1	20
Cloxacillin	9.0	10
Penicillin G	4.6	5

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

DRUG	Amoxicilli n	Ampicilli n	Ceftiofu r	Cephapiri n	Cloxacilli n	Penicilli n G
Tolerance/Target Testing Level (ppb)	10	10	100 ¹	20	10	5
Drug Concentration (ppb)						
1						0
2		0			0	0
3						0
4	0	0			0	90
5						100
6		27			0	
7	27	97				
8	73	100			50	
10	100	100			100	
14				33		
16				73		
18				100		
20				100		
50			0			
60			13			
80			80			
90			97			
100			100			

¹Total parent and desfuroylceftiofur related metabolites.

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 Beta lactams 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 Beta lactams (BSA002)