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College Park, MD 20740-3835
M-I-18-20

November 27, 2018

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

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

SUBJECT: Charm Sciences, Inc. CHARM® Rapid One Step Assay (ROSA®) SULF
Test for Sulfonamide Drugs

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the Charm Sciences, Inc. CHARM® ROSA® SULF Test for the detection of sulfonamides in raw, commingled cow milk.

The FDA evaluation of the data, presented by Charm Sciences, Inc., indicates that the performance of the CHARM® ROSA® SULF 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 Sulfamethazine and Sulfadimethoxine. 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 NCIMS Executive Board voted to accept the use of this Test for Sulfonamides when used as labeled on January 29, 2018. 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 monica.metz@fda.hhs.gov.



Monica Metz, Chief
Milk and Milk Products Branch

Attachment: FDA CVM Memorandum of Acceptance of the Charm Sciences, Inc.
CHARM® ROSA® SULF Test



Memorandum

**To: Monica Metz, Chief
Milk and Milk Products Branch**

From: Philip James Kijak, Ph.D.

Date: November 26, 2018

Subject: Charm® ROSA® SULF Test

Charm Sciences, Inc. has provided data to FDA supporting the use of the Charm® ROSA® SULF test for the detection of Sulfamethazine and Sulfadimethoxine in 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 Charm® ROSA® SULF test is an eight-minute raw, commingled raw milk lateral flow screening test for the detection of sulfonamides. The test validation data package contained all the test results required by the FDA protocol for validation of tests for sulfonamides and the results met the requirements for use in as an approved test. Charm Sciences, Inc. submitted data for both sulfonamide drugs (Sulfamethazine and Sulfadimethoxine) that FDA requires a test to detect for acceptances.

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

DRUG	90/95	Tolerance/Target Testing Level (ppb)
Sulfamethazine	7.8	10
Sulfadimethoxine	7.7	10

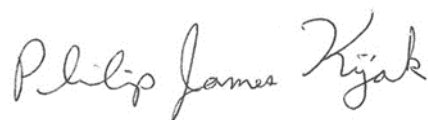
The Drug Concentration Response: (Displayed as percent positive based on 30 samples at each concentration.)

**CHARM® SULF TEST: Sulfonamides
DRUG CONCENTRATION RESPONSE**

DRUG	Sulfamethazine	Sulfadimethoxine
Tolerance/Target Level (ppb)	10	10
Drug Concentration (ppb)		
2	0	3
4	50	67
6	83	83
8	100	93
10	100	97

RECOMMENDATION

Our evaluation of the data presented by Charm Sciences, Inc. indicates that the performance of this test meets the standards established for acceptance of screening tests for monitoring raw, commingled cow milk for sulfonamides. 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