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.
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 Ordnance (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 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:

<table>
<thead>
<tr>
<th>DRUG</th>
<th>90/95</th>
<th>Tolerance/Target Testing Level (ppb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethazine</td>
<td>7.8</td>
<td>10</td>
</tr>
<tr>
<td>Sulfadimethoxine</td>
<td>7.7</td>
<td>10</td>
</tr>
</tbody>
</table>
The Drug Concentration Response: (Displayed as percent positive based on 30 samples at each concentration.)

**CHARM® SULF TEST: Sulfonamides**

**DRUG CONCENTRATION RESPONSE**

<table>
<thead>
<tr>
<th>DRUG</th>
<th>Sulfamethazine</th>
<th>Sulfadimethoxine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolerance/Target Level (ppb)</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Drug Concentration (ppb)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>50</td>
<td>67</td>
</tr>
<tr>
<td>6</td>
<td>83</td>
<td>83</td>
</tr>
<tr>
<td>8</td>
<td>100</td>
<td>93</td>
</tr>
<tr>
<td>10</td>
<td>100</td>
<td>97</td>
</tr>
</tbody>
</table>

**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