

To: Steve Beam, Chair, NCIMS Executive Board

Subject: Implementation date for 2015 NCIMS Proposal 211 Pilot Program for Tetracyclines

Date: March 13, 2017

At the NCIMS Board Meeting in Grand Rapids on February 23, 2017, the Appendix N Modification Committee Chair stated that an implementation date for the Proposal 211 Pilot Testing Program for Tetracyclines would be dependent upon:

1. Receipt of FDA/CVM concurrence on the application of the Charm ROSA Tetracycline-SL test
2. The subsequent acceptance of the Charm ROSA Tetracycline-SL test methodology by the Appendix N Modification Committee
3. Receipt of FDA's formal response on test kit equivalence (test kits for confirmation, trace back and reinstatement) for the purpose of the pilot program
4. An implementation date of not less than 90 days after the first three items are achieved.

On the March 13, 2017 Appendix N Committee conference call, the criteria requests were met with the following:

1. FDA reviewed the data, found the report acceptable for the Charm ROSA Tetracycline-SL Test (Dilution Confirmation), and recommended the test for the pilot.
2. The committee voted and approved the Charm ROSA Tetracycline-SL Test (Dilution Confirmation) for the pilot
3. FDA provided a formal response on equivalence (test kits for confirmation, trace back and reinstatement) for the pilot program. (See attached document)
4. In consideration of all information above, the Committee voted to recommend an implementation date of July 1, 2017, for Tetracyclines to begin for the purpose of meeting the NCIMS Proposal 211 Pilot Program and such be provided for NCIMS Executive Board approval.

CONCLUSION

The Appendix N Committee recommended and voted unanimously to begin on July 1, 2017, with NCIMS Executive Board approval, for the purpose of meeting the NCIMS Proposal 211 Pilot Program with the use of the Appendix N Committee accepted Charm ROSA Tetracycline-SL Test (Dilution Confirmation) and the M-a-85 NCIMS approved Charm II Tetracycline test methods. Other methods would be brought into the pilot as they are evaluated by FDA and accepted by the Appendix N Committee for the Pilot Program, and after FDA has made recommendations of test kit equivalence. Participation would begin with users who have the Charm ROSA Tetracycline - SL (Dilution Confirmation) Test or the Charm II Tetracycline Test.

Roger Hooi
Appendix N Modification Committee – Chair

Roger Tedrick
Appendix N Modification Committee – Vice Chair