To: State Regulatory Dairy Partners

From: NCIMS Appendix N Modification Committee

Date: October 31, 2023

Subject: Multi-Drug Residue Raw Milk Monitoring Project – Request for State Participation

Since 2019, the NCIMS Appendix N Modification Committee has been working cooperatively with FDA CFSAN to develop and implement a new approach to expand monitoring for additional animal drug residues in the nation's raw milk supply. As you know, we currently have a robust sampling program (as required by the PMO) for beta-lactams. By implementing a multi-drug residue raw milk monitoring project, our knowledge of the potential of drug residues in milk beyond the traditional beta-lactams will improve. This additional data will allow NCIMS and FDA to evaluate the overall effectiveness of our current drug residue program and implement modifications as necessary. This will further assure consumers that FDA, states, and industry are continuing to work together to minimize the risk of drug residues in milk.

NCIMS and FDA are reaching out again to seek your participation in collecting raw milk samples from Grade "A" bulk milk pickup tankers at IMS listed facilities and shipping them to a third-party central location to generate data for this monitoring project. The number of samples each state will be requested to collect will be based on their proportion of U.S. milk production. Timing and frequency of sample collection will be left to the discretion of each state. This project will be implemented specifically for data gathering purposes only, with no intent or means for traceback, trace forward or enforcement action. This project began in January 2023 and will continue for 3 years.

Project Specifics include:

1. This is a non-enforcement drug residue monitoring project for data gathering purposes only.
2. Raw milk samples will be double blinded to ensure anonymity.
3. No traceback or trace forward of sample results will occur.
4. Samples will be collected from Grade "A" bulk raw milk pickup tankers at the receiving milk plants
5. Samplers will be State samplers who have been certified to collect official samples for regulatory purposes and/or State Certified Industry Plant Samplers
6. Approximately 600 milk samples will be collected nationwide each year for three years
7. 19 drugs will be included in the testing regimen
8. Samples will be tested in two FDA labs
9. Methodology to be used: Liquid-Chromatography – Mass Spectrometry (LC-MS)
10. FDA will provide sample collection bottles, labels, temperature control bottles, and prepaid UPS labels for shipping. In addition, the states will be able to request $41 per sample to offset any other costs.

The goal for this effort is for NCIMS and FDA to continue to work together to gather additional residue prevalence data to evaluate the overall effectiveness of the current drug residue program and to make decisions that are data-driven. State milk regulatory programs serve a vital role in this project and your

State's participation would be sincerely appreciated. Together, we can explore better solutions to protect public health and further strengthen food safety in a way that creates shared value.

Your response to our request for participation in Year 2 sample collection would be appreciate by **November 3, 2023. Please respond to FDA at Kathryn.bennett@fda.hhs.gov.**

Around the first week in December the sample collection instructions, shipping labels and supplies will be sent to you at the address(es) you provided.

If you have any questions, please contact FDA at Kathryn.bennett@fda.hhs.gov. Thank you for your time and consideration of this project again.

Roger Hooi

NCIMS Appendix N Modification Committee, Chair

Attachments:
Multi-Drug Residue Raw Milk Monitoring Project Flow Diagram