U.S. FOOD & DRUG ADMINISTRATION

July 8, 2025

Mr. Brian Wise, Chair
National Conference on Interstate Milk Shipments
Ohio Department of Agriculture
8995 E. Main Street
Reynoldsburg, OH 43068

Dear Mr. Wise:

The Proposal 101 Adulteration Study Committee was formed after the 2023 NCIMS Conference in response to reported consumer injuries and product recalls where chemical sanitizing solution was inadvertently packaged and distributed in fluid milk packages. The NCIMS Study Committee successfully concluded their work with the submission of a report and "*Best Practices: Preventing Accidental Adulteration of Milk and Dairy Products with Chemical Sanitizers*" to the NCIMS Executive Board earlier this year.

The "*Best Practices*" document from the Study Committee includes a recommendation for a "First Sellable Carton Check," to ensure products produced at the onset of marketable production meet quality and safety standards, specifically for chemical adulteration. This often occurs as a simple sensory evaluation or "flavoring" of the product by the line operator. The Study Committee discussed a potential conflict of this practice with cGMPs (21 CFR 117 "Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive Controls For Human Food"), which does not allow for eating food or drinking beverages in production areas. The Study Committee requested that FDA further examine this potential conflict.

FDA has reviewed the information presented by the Study Committee and concludes that such a practice is not in conflict with cGMPs (21 CFR 117.10(b)(8)), as the "flavoring" of product for QA purposes within the manufacturing environment is not personal food/drink. FDA expects that this procedure would be documented and established in the firm's SOPs and included within the firm's training materials for operators performing these quality checks, to include requirements that the "flavoring" is performed in a sanitary manner to prevent contamination of nearby surfaces. In addition to providing this communication to the NCIMS Executive Board, we also have provided this clarification to the Milk Specialists and have confirmed this is consistent with the training provided to FDA CSOs in FD 190 "Food Current Good Manufacturing Practice, Application, and Evidence Development."

We greatly appreciate the collaborative efforts of the Adulteration Study Committee to address this important dairy food safety issue. Please reach out if you have additional questions.

Sincerely,

U.S. Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
www.fda.gov

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JANET L. MCGINN -S

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