TO: Joint Committee on GMP for Over-the-Counter Drugs

FROM: Dan Klassen, Chair of the Joint Committee

DATE: February 21, 2020

SUBJECT: Proposed revision to NSF/ANSI 455-4 – Good Manufacturing Practices for Over-the-Counter Drugs (455-4i17r1)

Revision 1 of NSF/ANSI 455-4, issue 17 is being forwarded to the Joint Committee for consideration. Please review the proposal and submit your ballot by March 17, 2020 via the NSF Online Workspace <www.standards.nsf.org>.

When adding comments, please use the comment template provided in the ballot and upload it online via the browse function.

Purpose

The proposed revision will add more clarity on what is required for traceability and mock recalls.

Background

Effectiveness of a traceability of mock recall can be evaluated against a predetermined criteria. This criteria is currently missing from the standard. The criteria recommended, of 99.5% to 101.5% recovery within four hours, is based on best industry practices and ensures an efficient mock recall system.

If you have any questions about the technical content of the ballot, you may contact me in care of:

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4.7.15 Procedures have been established to define the recall of a product, define traceability and mock recall exercises at a minimum of once a year to include trace forward and trace backward of finished products. All traceability exercises performed shall meet acceptable criteria of 99.5% to 101.5% recovery and shall be conducted within four (4) hours. Any additional mock recall exercises shall be completed within 24 hours. [21 CFR Part 7 Subpart C]