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

FROM: Dan Klassen, Chair of the Joint Committee

DATE: February 25, 2020

SUBJECT: Proposed revision to NSF/ANSI 455-4 – Good Manufacturing Practices for Over-the-Counter Drugs (455-4i19r1)

Revision 1 of NSF/ANSI 455-4, issue 19 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 harmonize the standard format to match 455-2 GMP for Dietary Supplements, and 455-3 GMP for Cosmetics under the ISO Format.

Background

Harmonization the standard format to match 455-2 GMP for Dietary Supplements, and 455-3 GMP for Cosmetics under the ISO Format.

Section 5.2 a) under audit preparation should state review and understand section in order to harmonize the standards under the Audit and certification process outline.

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

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5 Audit process

5.2 Audit and certification process outline

a) Educate / inform


— audit preparation shall include, but not be limited to:

— audit types (certification audit, monitoring audit);
— self-assessment of compliance with the Standard;
— selection of a CB; and
— determine the scope of the audit.