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

FROM: Dan Klassen, Chair of the Joint Committee

DATE: February 24, 2020

SUBJECT: Proposed revision to NSF/ANSI 455-4 – *Good Manufacturing Practices for Over the counter drugs* (455-4i13r1)

Revision 1 of NSF/ANSI 455-2, issue 13 is being forwarded to the Joint Committee for consideration. Please review the proposal and submit your ballot by March 16, 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 harmonization the standard format to match 455-2 GMP for Dietary Supplements, and 455-3 GMP for Cosmetics under the ISO Format.

**Background**

Changing the table of context and section, numbering to be consistent with both standards. Updated title 4.2, made some grammar change on clause 4.2.5, removed title 4.3 and renumbered section 4.3 under 4.2 to harmonization for OTC is the table of contents for audit requirements.

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

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Chair, Joint Committee on GMP for Over-the-Counter Drugs  
c/o Rachel Brooker  
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4 Audit requirements

4.2 Leadership and commitment

4.3 Organization roles, responsibilities, and authorities

4.3.1 4.2.6 A quality unit is defined – including quality assurance (QA) and quality control (QC) – that is independent of production. [21 CFR § 211.22]

4.3.2 4.2.7 Quality unit personnel have established roles and responsibilities covering requirements defined in 21 CFR Part 211, and procedures have been established to carry out these responsibilities. [21 CFR § 211.22 & 21 CFR § 211.184]

4.3.3 4.2.8 QA operations and authority have been established for manufacturing records. [21 CFR § 211.22 & 21 CFR § 211.184]

4.3.4 4.2.9 QA operations determine if all specifications have been met (raw material, components, in-process, final product specifications) and assign batch disposition (approve / release or reject) on each finished batch for distribution. [21 CFR § 211.22 & 21 CFR § 211.192]

4.3.5 4.2.10 Procedures exist for notifying responsible management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects, and related actions. [21 CFR § 211.180 & ICH Q10]

4.3.6 4.2.11 Procedures have been established that define work requirements for personnel to ensure hygienic practices have been implemented to prevent microbial contamination. [21 CFR § 211.28]
4.3.7  4.2.12 Procedures have been established to include appropriate protective garments, personal hygiene, hand washing and sanitization, etc., prior to starting work and at any time where personnel can become soiled / contaminated. [21 CFR § 211.28]

4.3.8  4.2.13 Personnel shall be qualified and have adequate training, experience and / or education necessary to perform job functions. [21 CFR § 211.25]

4.3.9  4.2.14 Personnel who are designated as supervisors have the education, training and experience or any combination thereof to perform assigned functions. [21 CFR § 211.25]

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