TO: Joint Committee on GMP for Over-the-counter drugs

FROM: Angela Diesch, Chair of the Joint Committee

DATE: February 2, 2024

SUBJECT: Proposed revision to NSF/ANSI 455-4 – *Good Manufacturing Practices for Over-the-counter drugs* (455-4i45r1)

Revision 1 of NSF/ANSI 455-4, issue 45 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by February 23, 2024** via the NSF Online Workspace <https://standards.nsf.org/home>.

Please review all ballot materials. When adding comments, please include the section number applicable to your comment and add all comments under one comment number whenever possible. If you need additional space, please use the attached blank comment template in the reference documents and upload online via the browse function.

Purpose

The proposed revision will add missing references to align with CFR 211.105(a) and CFR 211.105(b); identification of container/equipment content, and record equipment identification in batch record.

Background

Sec. 211.105 Equipment identification.
(a) All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch.
(b) Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code.

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

Angela Diesch
Chair, Joint Committee on GMP for Over-the-counter drugs
c/o Rachel Brooker
Joint Committee Secretariat
Tel: (734) 827-6866
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[Note – the recommended changes to the standard which include the current text of the relevant section(s) indicate deletions by use of ~~strikeout~~ and additions by grey highlighting. Rationale Statements are in *italics* and only used to add clarity; these statements will NOT be in the finished publication.]

NSF/ANSI Standard
for GMP for Over-the-counter drugs –

Good Manufacturing Practices for Over-the-counter drugs

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4 Audit requirements

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4.5 Operations

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4.5.11 Procedures and programs have been established for maintaining equipment. [21 C.F.R. § 211.67, 211.105(b)]

4.5.12 Manufacturing operations shall include the identification of all in process containers, process lines and major equipment used during manufacturing to indicate their contents and when necessary, the phase of manufacturing. [21 C.F.R. § 211.105(a)]

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4.5.35 The batch record follows the master record and each step is performed appropriately. [21 CFR § 211.188, 21 CFR § 211.105(b)]

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