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 455-4ARG - *Audit Requirement Guidelines for Good Manufacturing Practices for Over-the-counter drugs* (455-4ARGi10r1)

Revision 1 of NSF 455-4ARG, issue 10 are 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 <www.standards.nsf.org>.

Please note that this is an ARG ballot only. ARG guidelines are denoted in italics and only the italic language is open for comments. While this ballot may include some suggested changes to the standard this ballot is NOT on those changes. They are only included so that you can see how those suggested changes impact the ARG. If you have any comments on the included standard changes you MUST make those comments on that issue paper's ballot. The link to the ballot is included in the comments in the ballot. Any comments on the suggested standard changes shown in this ballot will be considered nongermane and will not be addressed.

When adding comments, please use the comment template provided in the reference documents and upload it 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
Email: rbrooker@nsf.org

[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.]

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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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4.5.12 Manufacturing operations shall include the identification of all inprocess 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)]

*****The suggested change above is NOT part of this ballot.*****

4.5.12.1 *At a minimum, all processing lines and major equipment used in manufacturing should state product name, batch number and status.*

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