TO: Joint Committee on GMP for Dietary Supplements

FROM: Freddie Agyin, Chair of the Joint Committee

DATE: February 23, 2024

SUBJECT: Proposed revision to NSF/ANSI 455-2 – *Good Manufacturing Practices for Dietary Supplements* (455-2i58r1)

Revision 1 of NSF/ANSI 455-2, issue 58 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by March 15, 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 update the scope of requirement for 4.5.33 and 4.6.18 and add language in 4.6.19 for clarity.

Background

4.5.33 Add requirement for QC operations that was moved from 4.6.18
4.6.18 Removed reference to deviations/unplanned occurrences and move to 4.5.33 where it is more appropriate.
4.6.19 Added language to clarify intent.
4.6.20-22 Removed and combined with 4.6.19 as they are related and elements of the investigation process. Added the applicable regulation 21 C.F.R. § 111.560 as reference in 4.6.19. Moved language as guidance in ARG under 4.6.19.

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

Freddie Agyin
Chair, Joint Committee on GMP for Dietary Supplements
c/o Rachel Brooker
Joint Committee Secretariat
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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 Dietary Supplements –

Good Manufacturing Practices for Dietary Supplements

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4 Audit requirements

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4.5 Operation

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4.5.33 Procedures that include QC operations shall be established ~~that includes~~ to ensure proper handling of both planned deviations and unanticipated occurrences. [21 C.F.R. 111.75 (b2), 21 C.F.R. 111.113 (a2, a3), & 21 C.F.R. 140 (b3i, b3ii, b3iv)]

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4.6 Performance evaluation

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4.6.18 QC operations shall ensure product complaints ~~and deviations / unplanned occurrences~~ are handled properly. [21 C.F.R. § 111.135]

4.6.19 Product complaint ~~p~~rocedures shall be established and include provisions for how ~~product~~ complaints will be received, investigated, and documented and, if necessary, for reporting of serious adverse events. [21 C.F.R. § 111.553, 21 C.F.R. § 111.570 (b2ii), & 21 U.S.C § 379 (aa-1) & 21 C.F.R. § 111.560]

~~**4.6.20** All product complaints shall be reviewed by a qualified person to determine if the complaint was the result of a failure of the dietary supplement to meet any of its specifications or quality. [21 C.F.R. § 111.560(a)]~~

~~**4.6.21** The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, shall be approved by QC personnel. [21 C.F.R. § 111.560(b)]~~

~~**4.6.22** The investigation for a product complaint shall be appropriately extended to other batches, products, processes, etc. [21 C.F.R. § 111.560(c)]~~

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