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 455-2ARG - *Audit Requirement Guidelines for Good Manufacturing Practices for Dietary Supplements* (455-2ARGi40r1)

Revision 1 of NSF 455-2ARG, issue 40 are 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 <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 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
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 Dietary Supplements –

Good Manufacturing Practices for Dietary Supplements

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4 Audit requirements

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4.6 Performance evaluation

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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]

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

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4.6.19.6 *All product complaints should 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.*

4.6.19.7 *The decision to investigate a complaint as well as the final decision as a result of the investigation, including corrective action, should be approved by QC personnel.*

4.6.19.8 *The investigation for a product complaint should be appropriately extended to other batches, products, processes, etc.*

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Commented [ER1]: This suggested change is 455-2i58r1. To vote or comment on this suggested change proceed to the 455-2i58r1 ballot at: https://standards.nsf.org/higherlogic/ws/groups/db501a6e-2381-412f-a5c0-018976f9bc62/ballots/ballot?id=8848