TO: Joint Committee on GMP for Dietary Supplements

FROM: Freddie Agyin, Chair of the Joint Committee

DATE: February 9, 2024

SUBJECT: Proposed revision to NSF/ANSI 455-2 - Good Manufacturing Practices for Dietary

Supplements (455-2i67r1)

Revision 1 of NSF/ANSI 455-2, issue 67 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by March 1, 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 4.5.42 language to clarify intent.

Background

The intent of 4.5.42 is to ensure that expired materials are not used in production. If the manufacturer extends shelf life, there must be testing and approval procedures in place. However, the current wording of the requirement may be misconstrued that retesting is required, even if the manufacturer does not extend shelf life. The language is being updated to reflect the actual requirement.

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



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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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4.5.42 Written procedures shall be in place for retesting of materials to extend shelf life. Procedures shall be established to ensure expired materials are not used in production. Where shelf life of materials is extended, procedures shall be in place for retesting and approval prior to use.

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