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 (455-2i57r1)

Revision 1 of NSF/ANSI 455-2, issue 57 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 4.4.8 and 4.5.17 language to clarify intent and to align with the referenced applicable regulation.

Background

4.4.8 pertains to facility construction and design while 4.5.17 pertains to facility sanitary condition. However, the requirements are worded similarly, which may lead to confusion. The language is updated to accurately reflect the intent of the 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

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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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4.4 Support

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4.4.8 Production area walls, floors, ceilings shall be adequately cleaned and shall be kept in good repair. [21 C.F.R. § 111.20(d1i)]

Facility walls, floors, and ceilings shall be designed and constructed in a manner that it can be adequately cleaned, kept clean, and in good repair. [21 C.F.R. § 111.20 (d1i)]

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4.5 Operation

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4.5.17 The production facility shall be maintained in a clean and sanitary condition and in a proper state of repair. [21 C.F.R. § 111.15 (b1, b2)]

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