TO: Joint Committee on GMP for Dietary Supplements

FROM: Brian Zamora, Chair of the Joint Committee

DATE: September 30, 2022

SUBJECT: Proposed revision to NSF 455-2ARG - *Audit Requirement Guidelines for Good Manufacturing Practices for Dietary Supplements* (455-2ARGi18r1)

Revision 1 of NSF 455-2ARG, issue 18 are being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by October 21, 2022** 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 purpose of this ballot is to add guidance that supports the reference.

Background

ARG – adding guidance that supports the reference.

Sec. 111.60 What are the design requirements for the production and process control system?
(a) Your production and in-process control system must be designed to ensure that the dietary supplement is manufactured, packaged, labeled, and held in a manner that will ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record; and (b) The production and in-process control system must include all requirements of subparts E through L of this part and must be reviewed and approved by quality control personnel.

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

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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 gray highlighting. Rationale statements are underlined and only used to add clarity; these statements will NOT be in the finished publication.]

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Audit Requirements Guideline for NSF/ANSI 455-2 – 2021

Good Manufacturing Practices for Dietary Supplements

4 Audit requirements

4.3 Planning

4.3.3 Production and processes shall be designed to ensure the quality of the product and the QC unit has approved the control systems. [21 CFR § 111.60]

4.3.3.1 *Production and process control systems include Quality, Components, MMR, BPR, Laboratory, Manufacturing and Packaging and Labeling. These systems together should be designed to ensure dietary supplements are manufactured, packaged, labeled and held in a manner that ensure the quality of the finished dietary supplement.*

4.3.3.2 *Together these systems ensure the dietary supplement is packaged and labeled as specified in the MMR.*

4.3.3.3 *Production and process controls are reviewed and approved by quality control personnel.*