MEMORANDUM

TO: Joint Committee on GMP for Dietary Supplements

FROM: Brian Zamora, Chair of the Joint Committee

DATE: August 18, 2022

SUBJECT: Proposed revision to NSF/ANSI 455-2 – *Good Manufacturing Practices for Dietary Supplements* (455-2i37r1)

Revision 1 of NSF/ANSI 455-2 issue 37 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by September 8, 2022** via the NSF Online Workspace <www.standards.nsf.org>.

Please review all ballot materials. When adding comments, please identify the section number/name for your comment and add all comments under one comment number where 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

To ensure standard aligns with the reference in intent, to remove duplication, to move requirements to more appropriate sections.

Background

1. Move all requirements for calibration to 4.5 operations section as calibration is part of operations not support (4.4.20-4.4.23)
2. (previous) 4.4.20 – Remove wording in the standard around maintenance as there are separate maintenance requirements (4.5.5, 4.5.6, 4.5.15).
3. (previous) 4.4.22 and 4.4.23 – Adding appropriate references to standard.

111.27 What requirements apply to the equipment and utensils that you use? (b) You must calibrate instruments and controls you use in manufacturing or testing a component or dietary supplement. You must calibrate: (1) Before first use; and (2) At the frequency specified in writing by the manufacturer of the instrument and control; or (3) At routine intervals or as otherwise necessary to ensure the accuracy and precision of the instrument and control.

111.30 What requirements apply to automated, mechanical, or electronic equipment? (c) Routinely calibrate, inspect, or check the equipment to ensure proper performance. Your quality control personnel must periodically review these calibrations, inspections, or checks;

Sec. 111.35 Under this subpart D, what records must you make and keep?
(b) You must make and keep the following records: (3) Documentation of any calibration, each time the calibration is performed, for instruments and controls that you use in manufacturing or testing a component or dietary supplement. In your documentation, you must: (i) Identify the instrument or control calibrated; (ii) Provide the date of calibration; (iii) Identify the reference standard used including the certification of accuracy of the known reference standard and a history of recertification of accuracy; (iv) Identify the calibration method used, including appropriate limits for accuracy and precision of instruments and

controls when calibrating; (v) Provide the calibration reading or readings found; (vi) Identify the recalibration method used, and reading or readings found, if accuracy or precision or both accuracy and precision limits for instruments and controls were not met; and (vii) Include the initials of the person who performed the calibration and any recalibration. (4) Written records of calibrations, inspections, and checks of automated, mechanical, and electronic equipment;

Sec. 111.113 What quality control operations are required for a material review and disposition decision? (4) Calibration of an instrument or control suggests a problem that may have resulted in a failure to ensure the quality of a batch or batches of a dietary supplement; or

Sec. 111.117 Quality control operations for equipment, instruments, and controls must include: (a) Reviewing and approving all processes for calibrating instruments and controls; (b) Periodically reviewing all records for calibration of instruments and controls; (c) Periodically reviewing all records for calibrations, inspections, and checks of automated, mechanical, or electronic equipment; and (d) Reviewing and approving controls to ensure that automated, mechanical, or electronic equipment functions in accordance with its intended use.

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

Brian Zamora
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 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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~~**4.4.20**~~ **4.5.10** Procedures and programs shall be established for ~~maintaining~~ ~~equipment including for~~ calibration of all instruments, controls, automated, mechanical, laboratory, and electronic equipment, etc. [~~21 CFR § 111.25~~ 21 CFR § 111.27(b) & 21 CFR § 111.35(ab) & 21 CFR § 111.130(c)]

~~**4.4.21**~~ **4.5.11** Instruments and controls that are important to product quality and safety shall be accurate and precise, adequately maintained, and adequate in number. [21 CFR § 111.27(a6)]

~~**4.4.22**~~ **4.5.12** Complete records shall be made and kept of any calibration of instruments and controls that are important to product quality and safety. [21 CFR § 111.35(b3)(b4) & 21 CFR § 111.113 (a4)]

~~**4.4.23**~~ **4.5.13** QC operations shall review and approve all processes and procedures for calibrating equipment, instruments, and controls, including the periodic review of calibration records, etc. [21 CFR § 111.113(a4) & 21 CFR § 111.117]

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