TO: Joint Committee on GMP for Dietary Supplements

FROM: Brian Zamora, Chair of the Joint Committee

DATE: September 22, 2022

SUBJECT: Proposed revision to NSF/ANSI 455-2 – *Good Manufacturing Practices for Dietary Supplements* (455-2i47r1)

Revision 1 of NSF/ANSI 455-2, issue 47 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by October 13, 2022** via the NSF Online Workspace <www.standards.nsf.org>.

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 purpose of this ballot is to ensure standard aligns with the reference in intent, to remove duplication, to move requirements to more appropriate sections and to add guidance to ARG where needed.

Background

4.2.3 standard and ARG: standard currently mixes requirements for Quality unit and tests and examinations. Separate QC Operations responsibilities for the lab with the test and examination requirements.
a. Add reference to 111.110 which describes QC Operation required for lab ops.
b. Move test and examination requirements to section 4.6 Performance Evaluation, specifically 4.6.13.
4.4.44 reference pertains to laboratory records, reword to clarify intent. Adding guidance to ARG.
4.6.12 Remove reference to 111.110
4.6.13 Combine requirement for 111.75(h) with 111.320 as they are similar. Adding tests and examination requirements from 4.2.3.

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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4.2 Leadership

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4.2.3 QC responsibilities for laboratory operations shall be defined and include approval of laboratory controls, assurance all tests and examinations are conducted and approval of test results. [21CFR111.110] ~~test methods and examinations used to test each specification requirement shall be defined, shall be appropriate for their intended use and shall be followed. Test methods and examinations shall be used according to established criteria. [21CFR111.320]~~

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4.4 Support

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4.4.44 ~~QC~~ ~~operations shall maintain appropriate records~~ ~~as required~~. Appropriate records shall be maintained for laboratory operations [21 CFR § 111.325]

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4.6 Performance evaluation

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4.6.12 QC laboratory operations and procedures shall be established.[~~21CFR111.110 &~~ 21CFR111.303]

4.6.13 Test methods and examinations shall be identified, ~~S~~scientifically valid and verified as appropriate for their intended use. Test methods and examinations shall ~~be used and~~ include at least one of the following: [21CFR111.75(h) and 21CFR111.320]

- gross organoleptic analysis;
- macroscopic analysis;
- microscopic analysis;
- chemical analysis; or

- another scientifically valid method.
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