TO: Joint Committee on GMP for Dietary Supplements

FROM: Brian Zamora, Chair of the Joint Committee

DATE: September 16, 2022

SUBJECT: Proposed revision to NSF/ANSI 455-2: *Good Manufacturing Practices for Dietary Supplements* (455-2i43r1)

Revision 1 of NSF/ANSI 455-2, issue 43 is being forwarded to the Joint Committee for consideration. Please review the proposal and **submit your ballot by October 7, 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.

* Please note that this is a tri-JC issue. There are corresponding ballots open for the Joint Committee on GMP for Cosmetics and Joint Committee on GMP for Over-the-Counter Drugs. If you would like to see how those ballots correspond to this ballot, please see the reference documents.

Purpose

The proposed revision will update Sections 5.7.1-5.7.3 to clarify the intent of the requirements by adding new language and removing unclear and unnecessary verbiage.

Background

The purpose of the change in Section 5.7.1-5.7.3 is to clarify the intent of the requirements by adding new language and removing unclear and unnecessary verbiage. The clauses are wordy to the point where they are confusing, increasing the likelihood of misapplication. The statement regarding the CB communicating fees around potential additional audits is removed as it is out of place in the standard.

The requirement that corrective action against major nonconformances for a grade B is in place and effective before consideration for certification is removed. Verification of effectiveness can take months and will be reviewed at the next certification audit.

For 455-2, the reference to Appendix D was removed in issue paper 455-2i23r1 approved 5/18/22.

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

Tel: (734) 827-6866
Email: rbrooker@nsf.org

789 N. Dixboro Road, Ann Arbor, Michigan 48105-9723 USA
T +1 734 769 8010 | **F** +1 734 769 0109 | **www.nsf.org**

[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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5 Audit process

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5.7 Nonconformances and corrective action

5.7.1 Company provides a corrective action plan for all findings

The company ~~is responsible for generating~~ shall submit a corrective action plan ~~to address any~~ that includes implementation dates for each nonconformance~~s~~ within ten (10) business days of receipt the final audit report. If the Company requires additional time to ~~complete~~ submit the plan, the company shall request additional time ~~of~~ with the CB. ~~For each nonconformance, the applicant / auditee shall submit a corrective action plan together with timing for completion. The company is to document the plan using the online corrective action reporting system in the format of the template presented in Appendix D.~~ Depending on the grade received, a company may be required to submit objective evidence of completion for approved corrective action plans per section 5.7.3.

5.7.2 CB reviews the corrective action plan to ensure planned corrective actions are sufficient.

The CB reviews the corrective action plan within ten (10) business days of receipt to ensure planned corrective actions are sufficient. The proposed plan is reviewed by the technical reviewer and auditor, as applicable, for appropriateness. Each ~~line item~~ plan is independently reviewed and either approved, rejected, or additional information is requested. The submission of a corrective action plan does not change the grade assigned by the CB during this audit cycle. ~~Feedback on the corrective action plan shall be provided to the company.~~

5.7.3 CB determines next steps

CB determines next steps based on the grade as described below:

— a site with a grade of A and zero nonconformances is eligible for certification;

— a site with a grade of A with only minor nonconformances ~~shall submit a corrective action plan for all nonconformances. Once the plan is approved by the CB, the site~~ is eligible for certification once all corrective action plans are approved. ~~The site shall correct the minor nonconformances prior to the next certification audit.~~ The effectiveness of the corrective actions is reviewed at the next certification audit;

— a site with a grade of B with only minor nonconformances is eligible for certification once all corrective action plans are approved. ~~shall submit a corrective action plan for all nonconformances~~. ~~Corrective action against major nonconformances shall be closed with objective evidence to demonstrate the corrective action is in place and effective, before consideration for certification. A site with only minor nonconformances shall be considered for certification upon acceptance of the corrective action plan by the CB~~ The effectiveness of the corrective actions is reviewed at the next certification audit;

— a site with a grade of B with major nonconformance is eligible for certification once corrective action plans for all nonconformances are approved and objective evidence demonstrating corrective actions for major nonconformances are implemented and have been approved. The effectiveness of the corrective actions is reviewed at the next certification audit;

— a site with a grade of C ~~submit a corrective action plan for all nonconformances. A monitoring audit is required for grade of C. For a company who receives a grade of C in their initial certification audit~~ for an initial certification audit is eligible for certification once corrective action plans for all nonconformances are approved and corrective action against major nonconformances ~~shall be closed at the monitoring audit with objective evidence to demonstrate the corrective action~~ is demonstrated to be in place and effective at the monitoring audit. ~~, before consideration for certification. A company who has already received certification from a previous certification audit who receives a grade of C, does not lose their certification but shall have a monitoring audit prior to their next certification audit to verify that they have closed their major nonconformances. In both cases, the site is to close the minor conformances prior to the next certification audit.~~ A site with a recurring certification audit is eligible for recertification once corrective action plans for all nonconformances from the certification audit are approved. The completion and effectiveness of corrective actions against major nonconformances is reviewed at the monitoring audit. In both cases, the effectiveness of the corrective actions against minor nonconformances is reviewed at the monitoring audit or the next certification audit.

~~The CB shall determine and communicate any additional fees associated with a monitoring audit and related activities; and~~

— a site with a grade of D is not eligible for certification. A new certification audit is required. ~~but before that can take place, the site shall submit a corrective action plan and show completion of the corrective actions.~~

Corrective action for nonconformances identified from the previous audit that are not in place and effective at the next certification audit are deemed as repeat nonconformances. The classification of repeat nonconformances ~~identified from the previous audit will be reviewed, evaluated, reported, and~~ may be escalated based on the risk and severity. Technical reviewer shall review client's submitted objective evidence to ensure the classification recommended will remain as initially issued during the audit or elevate the nonconformance. ~~The CB shall require a monitoring audit for a grade of a C and may require a monitoring audit for a grade of an A or B.~~

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