TO: Joint Committee on GMP for Dietary Supplements  
FROM: Brian Zamora, Chair of the Joint Committee  
DATE: September 18, 2020  
SUBJECT: Proposed revision to NSF/ANSI 455-2 – Good Manufacturing Practices for Dietary Supplements (455-2i8r1)

Revision 1 of NSF/ANSI 455-2, issue 8 – Shelf Life is being forwarded to the Joint Committee for consideration. Please review the proposal and submit your ballot by October 2, 2020 via the NSF Online Workspace <www.standards.nsf.org>.

When adding comments, please use the comment template provided in the ballot and upload it online via the browse function.

**Purpose**

The proposed revision is to align with FDA’s Response for shelf life/stability testing.

**Background**

Justification is to align with FDA’s Response for shelf life/stability testing as stated in the Preamble to 21 CFR Part 111 final rule § K. Comments on Shelf Life, excerpt included below:

__(Response) These comments do not provide data or information that would reduce the uncertainty about the feasibility of conducting tests to support an expiration date and, thus, do not persuade us to alter our position not to require that you establish an expiration date for your product. Indeed, the comments generally concur with that position. Because the final rule does not require that you establish an expiration date, we decline to offer guidance on the type of data that are acceptable to support an expiration date, other than to repeat that any expiration date that you place on a product label (including a ‘‘best if used by’’ date) should be supported by data.__
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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NSF/ANSI Standard for Joint Committee on GMP for Dietary Supplements –

Good Manufacturing Practices for Dietary Supplements

4 Audit requirements

4.6 Performance evaluation

4.6.27 For all products that bear an expiration date or a statement of product shelf life, the shelf life shall be supported by data. [Preamble to 21 CFR § 111 final rule]