

Joint Committee Issue Document

NOTE: An issue document may be submitted at any time – it comprises two parts: the cover sheet (this page) and a description of the issue to be submitted to the Joint Committee (following page). A separate issue form is required for each issue submitted. Issue papers include proposals for modification of a standard, information reports and (of current research, etc.). An issue paper shall be categorized as being for ACTION or for INFORMATION. Submitters should limit the Issue Paper to 1 or 2 pages – attachments detailing full recommendations or background information may be attached with supplementary information. The Chairperson of the appropriate Joint Committee will respond within 30 days of receipt of the issue document advising what steps will be taken. Any issue document intended for discussion at a Joint Committee meeting must be received at least 21 days prior to the meeting to ensure inclusion in the agenda.

Submit to:

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Signature of Submitter * _____

Date _____

**Type written name will suffice as signature*

Please insert a check (X) in the appropriate place to indicate if you wish the item to be considered as an action item or as an information item.

Action X Information

NSF Standard(s) Impacted:
NSF 173

Issue Statement:

Provide a concise statement of the issue, which reference as appropriate any specific section(s) of the standard(s) that are related to the issue.

With the publishing of 21 CFR § 111 NSF International would like to propose that we replace Section 8 of NSF/ANSI 173 with 21 CFR § 111. We will also highlight additional requirements, including Recall procedures, compliance with the 2002 Bioterrorism Act, and AER reporting system, which are not covered in 21 CFR § 111.

Background:

Provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc, and any other reason why the issue should be considered by the Committee.

After 21 CFR § 111 was published in it's final form, NSF decided that it would be best if we referenced this document directly in NSF/ANSI Standard 173 in Section 8. NSF feels that the additional requirements that were not covered in this document are essential when evaluating Good Manufacturing Practices, so our manufacturing customers must be in compliance with these as well.

Recommendation:

*If action by the Joint Committee is being requested, clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of ~~strike-out~~ and additions by **highlighting** or underlining; e.g., reference of the issue to a Task Force for detailed consideration; etc. If recommended text changes are more than a half page, please attach a separate document.*

8 Good Manufacturing Practices

The manufacture and handling of dietary supplements and dietary supplement ingredients shall meet all applicable regulatory requirements set forth by 21 CFR § 111, with the following additional requirements, which are already stated in Section 8 of the standard.

8.1 Written recall procedures

Procedures shall be established and followed that define the recall of a product(s) should it become necessary

Written procedures shall be established and followed.

8.2 Compliance with Public Health and Security and Bioterrorism Preparedness and Response Act of 2002

Manufacturers of Dietary Supplements shall submit application to USFDA for registration, receive a Registration Number, and provide the Registration Number upon request.

8.3 Compliance with the Dietary Supplement and Non Prescription Drug Consumer Protection Act.

Written procedures shall be established and followed for reporting serious adverse events to the USFDA in accordance with the Dietary Supplement and Non Prescription Drug Consumer Protection Act.

Supplementary Materials (photographs, diagrams, reports, etc.):

If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

Submitter _____

Date _____