



**TO:** Joint Committee on Dietary Supplements

**FROM:** Brian Zamora, Chairperson

**DATE:** May 23, 2019

**SUBJECT:** Proposed revision to NSF/ANSI 173 – *Dietary Supplements* (173i84r1)

Draft 1 for NSF/ANSI 173, Issue 84 is presented to the Joint Committee on Dietary Supplements for consideration. Please review the changes proposed to this standard and submit your ballot by **the due date of June 13, 2019** via the NSF Online Workspace <[www.standards.nsf.org](http://www.standards.nsf.org)>.

When adding comments, please include the section number applicable your comment and add all comments under one comment number whenever possible. If additional space is needed, you may upload a word or .PDF version of your comments online via the browser function.

**Purpose**

Update the definition of ‘dietary supplement’ to make it clearer.

**Background**

Both NSF 173 and NSF 455-1 have the same definition of ‘Dietary Supplement.’ When NSF 455-1 was balloted by the CPHC a new member voted negative because she felt that the definition was not clear. She stated that was unclear from the wording of the definition of dietary supplements (3.28) if all five of the sub-definitions need to be met in order to qualify as a dietary supplement. In particular, the last bullet appears to be a subset of dietary supplements and not applicable in all cases, while the first four bullets may be intended to collectively constitute the definition (?). She suggested to clarify the language by using "and", "or" "one or more" etc.

She eventually voted affirmative but only if an issue paper was opened to this JC. The JC decided to open a task group (TG) to discuss this. The TG met and since the definition was based off of the DSHEA definition they decided to only change the current definition in 173 to better mimic the DSHEA format. Due to the required format of the Standard, it cannot be placed in the exact same format. To try to make it a little easier to understand the last paragraph of the current definition is split into two and a footnote to DSHEA was added to the definition. (That is the superscript ‘11’ in the ballot.)

These changes have no impact to public health but rather related to administrative changes and or corrections.

**Public Health Impact**

These changes will have no negative impact on public health.



**NSF International**

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**Joint Committee Correspondence**

If you have any questions feel free to contact me.

A handwritten signature in black ink, appearing to read "Brian Zamora", written over a horizontal line.

Brian Zamora  
Chairperson, Joint Committee on Dietary Supplements  
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## NSF International Standard for Dietary Supplements —

### Dietary supplements

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### 3 Definitions

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**3.8 dietary supplement<sup>11</sup>:** A product (other than tobacco) that:

- is intended to supplement the diet and bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients;
- is intended for ingestion in pill, capsule, tablet, powder, or liquid form;
- is not represented for use as a conventional food or as the sole item of a meal or diet;
- is labeled as a “dietary supplement” or has the word “dietary” deleted and replaced by the name of the dietary ingredient/s in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins); ~~and~~
- includes an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351, of the Public Health Service Act (42 U.S.C. 262), and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary (U.S. Department of Health and Human Services, FDAP) has issued a regulation, after notice, and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f), ~~and~~
- does not include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) or an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful.

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