MEMORANDUM

TO: NSF Joint Committee on Dietary Supplements

FROM: Sarah Kozanecki, Joint Committee Secretariat

DATE: February 25, 2008

SUBJECT: Changes to NSF/ANSI 173 – *Dietary Supplements*

Background:

In April and September 2007, ballots were sent to the Joint Committee proposing the following changes to Section 8:

- Issue 14 - Addition of the requirement of both identity testing and other testing of raw materials based on an established specification as part of a comprehensive raw materials acceptance program.

- Issue 22 - Incorporation of language that requires manufacturers to comply with new federal legislation on the reporting of adverse events from dietary supplements to the US FDA. Also, the addition of Annex D, an informative annex stating that the effective date for compliance to this requirement is December 22, 2007.

Both of these issues passed at the JC and the subsequent approval stage at the Council of Public Health Consultants and were adopted, but have not yet been published.

Issue:

The intent of the most recent ballot, 173i27, is to replace Section 8 of NSF/ANSI 173 with 21 CFR § 111. Additional requirements, including recall procedures and compliance with the 2002 Bioterrorism Act and the AER reporting system, which are not covered in 21 CFR § 111, are to remain. This change, though not explicitly stated in the ballot, will remove the language added by Issues 14 and 22. Therefore, unless any objections are received that this was not the intent of the language proposed in Issue 27, NSF International will editorially change the language so that the requirements added by Issues 14 and 22 will be overridden by that proposed by Issue 27.

Please contact me via e-mail at kozanecki@nsf.org by **March 10th** if you have any questions or concerns.

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