DIETARY SUPPLEMENTS JOINT COMMITTEE
VENETIAN HOTEL, LAS VEGAS
NOVEMBER 7, 2007
DRAFT MEETING SUMMARY

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GMPs (DS-2007-8)

Ed Wyszumiala reviewed the issue paper he submitted that recommended replacing much of section 8 of the Standard with a reference to the recently published 21 CFR § 111. He explained that when section 8 was first balloted for inclusion in the Standard, it was presumed that when the federal regulation was published, it would replace this section.

R. Upton stated that the current GMP requirement in 21 CFR § 111 does not require lot numbers, with which he disagreed. M. McGuffin agreed and stated that the lot number should be required to be disclosed on the finished product.

M. McGuffin pointed out that the three parts of section 8 that are proposed to be retained in the Standard are shelf life dating, handling/storage, and complaint files. He stated that complaint files are incorporated into 21 CFR § 111 so should be removed. E. Wyszumiala agreed. He also stated that after review, he would also propose that the shelf-life section be removed. J. Betz stated that the GMP outlines a minimum requirement; however, the JC has the opportunity to raise the bar. He suggested that if additional requirements add value, they should be maintained in the Standard. After some discussion, it was agreed that shelf life could be removed. K. Holt pointed out that the Standard is raising the bar with the addition of handling/storage requirements, lot numbers, and complaint files. V. Frankos clarified that the FDA requirement is that there is some means of designating batches, but it is not limited to lot numbers.

> **Motion:** R. Upton moved to require lot numbers to be on the finished product package. M. McGuffin seconded.
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> **Vote:** All in favor (V. Frankos abstained).
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> ***Motion passed.***

The Committee then discussed the proposed implementation date. E. Wyszumiala stated that the proposal is that this would become effective when the regulation becomes effective, January 1, 2008. However, companies will have until June 2008 to comply. S. Eisner argued that this was not a feasible compliance date for all manufacturers.

> **Motion:** M. McGuffin moved that an implementation date be incorporated into the Standard specifying a date by which products shall comply with 21 CFR § 111.
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> **Discussion:** S. Kozanecki clarified that the Standard cannot (in the normative sections) include any references to implementation dates. K. Levanseler suggested that a footnote could be included to specify a specific date, however. E. Wyszumiala pointed out that section 8 is consistent with 21 CFR § 111; therefore the implementation date is not an issue. K. Holt stated that the Standard references the regulation, and in NSF's certification policies an implementation date would be specified.
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> ***M. McGuffin withdrew his motion.***

Motion: M. McGuffin moved to ballot the proposed substitution of section 8. K. Levanseler seconded.

Discussion: S. Eisner stated that she disagrees with the FDA's justification and would not vote in favor of this change. M. McGuffin stated that this change would go above the regulation to also make ingredient suppliers comply with 21 CFR § 111. K. Levanseler suggested that the language could be changed such that for ingredients, the current section 8 requirements would remain. K. Holt indicated that auditing to two sets of GMP requirements would be difficult to manage and execute. V. Frankos spoke from the perspective of the FDA. He stated that the qualification aspect is what is important. Since ingredients assist finished products in meeting the final standard, compliance of the ingredients makes them more attractive to manufacturers. The group continued discussing whether the GMPs should apply to ingredient suppliers, and agreed that they should not.

M. McGuffin argued that the requirement for complaint files does not need to remain. Those present agreed. M. McGuffin also posited that the proposed section on handling/storage was also unnecessary. K. Levanseler stated that this section was viewed as unique from 21 CFR § 111 since it previously specified for aflatoxin testing, however, the wording was in the process of being changed per Issue 14. The newly accepted language should be reviewed against 21 CFR § 111 to determine if the requirements are over and above the regulations.

The group discussed keeping section 8 to the reference to 21 CFR § 111 plus a lot number requirement.

Vote: All in favor.

Motion passed.

E. Wyszumiala suggested that the bioterrorism and AER sections (both currently in section 8) should also remain.

Motion: M. McGuffin moved to reestablish the current section 8.9 (bioterrorism section). Jo Ann Peterson seconded.

Vote: All in favor.

Motion passed. All language changes will be balloted.

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