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**PREAMBLE**

# *FDA 21 CFR Part 111 Proposed Regulation Changes (Blue Text Indicates ALI Suggested Modifications)*

## PREAMBLE CHANGES AND COMMENTS

### SUBPART E: PRODUCTION AND PROCESS CONTROLS

#### 111.35 WHAT PRODUCTION AND PROCESS CONTROLS MUST YOU USE?

**Recommended Changes: Preamble p12180 (column 1, 1<sup>st</sup> paragraph:** In addition, some dietary supplements contain raw (unprocessed and uncooked) brain tissue or glands (Ref.49) that have a high risk of containing the infective agent that causes bovine spongiform encephalopathy (BSE) if the originate from an animal infected with the disease (Ref.37).

**Recommended Changes: Preamble p12180 (column 2, 1<sup>st</sup> paragraph:** To prevent use of BSE agent-contaminated components, dietary ingredients, or dietary supplements, requirements for foreign supplier certifications from BSE positive countries would likely include certification:

- Of the species of animal
- Of the geographic origin (born, raised, and/or slaughtered?) of the animal.  
.....etc.

Such designations are currently not available from the USDA or United States slaughterhouse facilities! Does the FDA propose providing such requirements of United States based slaughterhouses? If not, such regulations on United States based facilities are baseless and should be eliminated from 21CFR111.

**Recommended Changes: Preamble p12180 (column 2, (3): There should be no exceptions in permitting animal-derived products from BSE countries to enter the United STATES!**

**Recommended Changes: Preamble p12180 (column 3, last 3 sentences & p12181 (column 1, 1<sup>st</sup> paragraph: Please refer to Appendix Two, our literature supported position is to eliminate any consideration of including CBER guidances 50244 and 51074 as part of 21CFR111.**

#### 111.60 WHAT REQUIREMENTS APPLY TO LABORATORY OPERATIONS?

**Recommended Changes: Preamble p.12209, 111.60(d):** would require that you identify and use appropriate manufacture established testing method to use for each manufacturer established specification for which testing is required to determine whether the specification is met.

### SUBPART H RECORDS AND RECORD KEEPING

#### 111.125 WHAT REQUIREMENTS APPLY TO RECORDKEEPING?

**Recommended Changes to Preamble p12218, 111.125(a):** would apply to all records covered by the proposed rule and would require that you keep those records ~~for 3 years beyond the last date of manufacture of the last batch~~ for one (1) year beyond the product label stated life or two years beyond the specific batch or lot manufactured of dietary ingredients or dietary supplements associated with those records. Retention for ~~3 years~~ for one (1) year beyond the product stated life or two (2) following the manufacture of that specific batch or lot would be appropriate for follow-up of consumer complaints received during the manufacturer batch or lot number marketing period.

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**Recommended Changes to Preamble p12218, 111.125(c):** would require that you make your records available for inspection and copying for us when requested. ~~We sometimes need to copy records when our field inspectors need guidance or additional expertise from our headquarters staff; if we were unable to copy records, our inspections would become more complicated and longer duration, particularly if the inspection involved a complex scientific or technical issue that normally would be handled at FDA headquarters.~~ This suggestion violates all current rights to privacy of corporate manpower, trade secrets for material sources, manufacturing processes, testing processes, and distribution records.