

Docket No. 2007N-0186  
RIN 0910-AB88  
FDA GMP Interim Final Rule – Comments  
From Bergstrom Nutrition

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Bergstrom Nutrition supports the new FDA GMP's and the desire to ensure that dietary supplements are safe for all consumers. Bergstrom also supports the flexibility that has been written into the regulations, particularly in the area of identity testing. In some cases, 100 percent identity testing is necessary, but there are many cases when 100 percent identity testing shouldn't be necessary. The Interim Final Rule allowing petition for exemption from 100 percent identity testing will be very helpful to the industry when finally incorporated into the Final Rule.

Bergstrom Nutrition appreciates the opportunity to comment on the Interim Final Rule.

#### Single product supplier

Some raw material ingredient suppliers manufacture only one product and supply that product to the dietary supplement manufacturer. It should be fairly easy to provide an exemption to the 100 percent identity testing for the combination of ingredient and supplier if the supplier manufactures only one product and that product has a very good history of quality production. The dietary supplement manufacturer should be reasonably assured that if well labeled raw material arrives from the single product manufacturer, it is indeed the raw material that is expected. Requirements for confirmation should be:

1. Label affixed to the container that clearly shows the raw material name and the name of the ingredient supplier. This may also include a marking directly on the container to identify the contents in the unlikely event that the label was missing.
2. Organoleptic testing to ensure that the contents of the container are what was expected, for instance checking to ensure that the contents are, in fact, a white powder with a certain odor. The raw material ingredient supplier will have supplied a certified sample to the dietary supplement manufacturer for organoleptic comparison.
3. A testing program to do periodic verification testing, such as periodic IR scan or GC.

#### Other factors

Other factors that should be taken into account when granting an exemption from 100 percent identity testing include:

1. Type of raw material ingredient. Some manufactured raw materials may be considerably easier to identify than most botanicals.
2. GMP certification. A third party certification of a raw material ingredient and manufacturing facility should be weighted heavily in the petition for exemption.
3. SIDI Protocol. The FDA should favorably consider a completed SIDI Protocol when reviewing exemption petitions. If the SIDI Protocol is on file with the

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- FDA, much of the relevant information about the product and the supplier will be readily available to the FDA.
4. History of raw material ingredient analytical. A multi-year history of excellent raw material ingredient final analysis should be factored into the petition exemption. This could be shown using common statistical methods, including control charts and/or capability studies. Analytical should include more than just identity testing. Also included in the historical analytical information should be heavy metals, using appropriate low-level testing, and microbiological testing.
  5. Competence/reputation of analytical lab. Analytical results from accredited/recognized labs should be favorably viewed. Some of the factors taken into account should be: lab accreditation from AAOC, type (specialization) of the lab, analytical techniques, FDA lab registration, and the use of validated testing methods.
  6. Certificate of Analysis. Part of the petition for exemption could/should include confirmation of the C of A. The C of A should be confirmed by periodically doing independent third-party testing on incoming material and comparing the results with the C of A.
  7. Periodic audit of the supplier. Even with GMP certification, supplement manufacturers should do their own audits of their suppliers.

Thank you for allowing our comments.

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