



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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### **FDA's New Compliance Program for Dietary Supplements is Both Controversial and Useful**

By [Wes Siegner](#)

Direct link to the News/Story:-

<http://www.fdalawblog.net/fda-law-blog-hyman-phelps/2010/05/fdas-new-compliance-program-for-dietary-supplements-is-both-controversial-and-useful.html>

FDA recently posted a [compliance program](#) for dietary supplements that provides useful insights on where the agency is likely to focus its enforcement resources in the coming year. Illustrating FDA's institutional biases, the agency prioritizes inspections to focus more on "non-traditional" products and less on vitamins and minerals. The document also lists deviations from GMP requirements (among others) that can be expected to result in the issuance of a warning letter, quoted verbatim below:

- Lack of master manufacturing records or significant requirements not included;
- Lack of finished product release criteria or failure to test (all or subset of finished batches) or meet finished product release criteria critical to product safety and quality;
- For significant dietary ingredients, e.g. those that make up the bulk of the product, failure to establish specifications for incoming material or failure to conduct identity testing;
- No quality control review procedures or significant quality control procedures not implemented;
- No batch records;
- Significant physical plant deficiencies.

FDA also states that it will not examine labeling claims for the purpose of determining whether they include the disclaimer provided in FDCA section 403(r)(6) because "there are unresolved policy issues regarding the use of the disclaimer" - perhaps an oblique reference to the fact that there is a [pending citizen petition](#) that was filed in February 2000 that addresses this issue as well as the issue of claim notification.

In addition to addressing enforcement priorities, the document contains some new interpretations of regulatory requirements that should have first been communicated to industry through the issuance of guidance in compliance with the agency's Good Guidance Practices regulation in 21 C.F.R. Part 115. For example, the document states that a new dietary ingredient notification "only applies to the specific product of the manufacturer/distributor who submits the notice." This means that an NDI notification would have to be submitted even if the dietary ingredient that is the subject of the notification is identical to a dietary ingredient that has been the subject of a prior notification. This position directly conflicts with FDCA section 413 and is therefore unauthorized by law.

As an additional example, the document appears to acknowledge that the statement of identity requirement can be fulfilled simply by the term “dietary supplement” or by statements other than "dietary supplement" (e.g., "herbal supplement"). (For a discussion of FDA’s acknowledgement that previous guidance on this issue is incorrect, see our previous post [here](#).) Given the agency's willingness to address these issues in a compliance program, it would not be surprising if the agency soon issues guidance for industry that explains the agency's thinking in greater detail.

Industry should remember that guidance such as this is not legally binding on FDA or industry. Nonetheless, the new guidance is further evidence of a much stronger focus on dietary supplement inspections and imports, and signals increased FDA enforcement in this area