



How FDA's Program Alignment Affects the Dietary Supplement Industry

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Benefits of Alignment

- Increased understanding of dietary supplement cGMPs among inspectors
 - Based on *expertise* rather than geographic location
 - Allows inspectors to develop expertise in the manufacturing of a particular class of products, such as dietary supplements
 - Fosters increased collaboration between inspectors and the industry in addressing dietary supplement GMP challenges
- Consistency, uniformity, and regulatory certainty
- Increased consumer protection and product safety
 - More efficient, targeted inspections
 - All firms must be prepared as FDA moves beyond the basics of GMP compliance...



Warning Letter to Vita Pure Inc. (11/8/17)

- *Your firm failed to conduct at least one appropriate test or examination to verify the identity of a component that is a dietary ingredient, prior to its use, as required by 21 CFR 111.75(a)(1)(i).*
 - Although the firm stated that it relied on Fourier transform infrared spectroscopy (FTIR) for identity testing for dietary ingredients, according to FDA “FTIR may be used to confirm that the supplier is consistent in sending the same product, FTIR does not ensure that the product received is what it is claimed to be. To verify the identity of a component that is a dietary ingredient, you must first authenticate that the ingredient is what it is stated to be, and then you may use that FTIR as a secondary authentication spectrum.”
 - <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm585616.htm>
- Demonstrates FDA’s focus on “next level” GMP compliance and the **scientific validity** of tests used to verify ingredients

Industry Support for Program Alignment

CRN Applauds FDA's Implementation of Program Alignment



Washington, D.C., May 17, 2017—In response to FDA's announcement of the implementation of its Program Alignment, the Council for Responsible Nutrition (CRN), the leading trade association for the dietary supplement and functional food industry, issued the following statement:

Statement by Steve Mister, president & CEO, CRN:

"CRN commends FDA Commissioner Scott Gottlieb and the agency for announcing the implementation of its Program Alignment, a major initiative that will help strengthen FDA's ability to protect public health. CRN has long urged FDA to move to commodity-based inspections so that the agency could become more efficient and effective in overseeing dietary supplement manufacturing operations, and we are hopeful that the Program Alignment will achieve this.