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By Electronic Submission

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Proposed Rule; Revocation of Methods of Analysis Regulation; FDA-2020-N-1383-0001

The Council for Responsible Nutrition (CRN)[1] is the leading trade association for the dietary supplement and nutritional products industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements, many of which are multinational and already actively exporting and selling ingredients, finished products and services globally.

CRN respectfully submits these comments to the U.S. Food and Drug Administration (FDA), in response to the published "Revocation of Methods of Analysis Regulation"; FDA-2020-N-1383-0001, which would revoke FDA's current policy to use AOAC International (hereafter termed AOAC) methods of analysis as published in the 1980 edition of the "Official Methods of Analysis of the Association of Analytical Chemists" for its enforcement programs if the method of analysis is not prescribed in a regulation.

With this revocation, CRN is concerned that transparency would be lost if in lieu of AOAC Official Methods of Analysis, FDA first and foremost relies on internal agency-developed methods of analysis that may not be developed and validated through the current AOAC standard method performance requirements (SMPR) and systematic evaluations and laboratory validation processes.

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 200 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

Further, CRN finds it counterproductive for U.S. government agency actions to be so diametrically opposed. In 2013, the National Institute of Health's (NIH) Office of Dietary Supplements (ODS) funded a 5-year Dietary Supplement Analytical Methods and Reference Materials Program (AMRM), with the goal of producing 25 SMPR and 16 Official Methods for priority dietary supplement ingredients. The program was coordinated by AOAC with many scientists from relevant trade associations, standard-setting organizations, and industry, as well as the FDA, working collaboratively. Resulting SMPR and analytical methods were published in the *Journal of AOAC INTERNATIONAL and Official Methods of Analysis*, and have been beneficial for multiple stakeholders, including regulators, academics, researchers, and industry.

Food and dietary supplement industries need to have reliable, scientifically valid, fit-for-purpose methods to ascertain quality parameters of the ingredients and final formulations. Such methods should be published and meet rigorous standards for method development and validation. Having key primary reference sources for analytical methods help to create consistency for both regulators and industry in testing quality. With that in mind, we recommend that FDA leave the current 21 CFR 2.19 in place as written or revise to the text as follows:

"Where the method of analysis is not prescribed in a regulation, it is the policy of the Food and Drug Administration in its enforcement programs to utilize the methods of analysis of the AOAC INTERNATIONAL (AOAC) *or any other official compendial method or other published validated method, developed with the same rigor as Official Methods of Analysis of AOAC International that are available when such methods are suitable for intended purpose for the products under investigation.* ~~as published in the latest edition (13th Ed., 1980) of their publication "Official Methods of Analysis of the Association of Official Analytical Chemists," and the supplements thereto ("Changes in Methods" as published in the March issues of the "Journal of the Association of Official Analytical Chemists"), which are incorporated by reference, when available and applicable. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*~~ In the absence of an AOAC method, the Commissioner will furnish a copy of the particular method, or a reference to the published method, that the Food and Drug Administration will use in its enforcement program. Other methods may be used for quality control, specifications, contracts, surveys, and similar nonregulatory functions, but it is expected that they will be calibrated in terms of the method which the Food and Drug Administration uses in its enforcement program. Use of an AOAC method does not relieve the practitioner [sic] of the responsibility to demonstrate that he can perform the method properly through the use of positive and negative controls and recovery and reproducibility studies."

Revoking 21CFR 2.19 could impact the industry and even public health as the regulation applies to FDA's sample analysis in their enforcement program. We believe that is important for FDA to use latest AOAC methods of analysis or published methods that were developed with the same rigor as

AOAC Official Methods of Analysis, as these have gone through rigorous validation process to minimize variance in the accuracy and precision and have been created for "fit for purpose," which is critical for both the industry and enforcement agency to use reliably and consistently. This will minimize any confusion from industry and enforcement agency on the standard expected for scientifically valid analytical methods to protect public health.

In summary, **revision** of the 21 CFR 2.19 and **not revocation** of 21 CFR 2.19 would better serve industry, the agency, and public health. Updating the regulation would avoid potential disruption that would undermine the validity and necessity of the numerous AOAC analytical methods of analysis currently used by the dietary supplement industry, contract laboratory services, academics, researchers, and regulators not only in the United States, but also globally.

Respectfully submitted,

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