

DBA

AnalyticalSM

An NSF International Company



Regulatory Support

At DBA Analytical, our scientists and regulatory specialists have the expertise to provide guidance on the regulatory framework for various manufacturers from the dietary supplement, food ingredient and food contact material industries. DBA Analytical's extensive professional staff can help clients to determine the appropriate steps towards regulatory approval, while assisting with the submission of the necessary paperwork to the FDA.

For further information, call us at +1 (734) 913-5734 or email Analytical@DBA-global.com

Regulatory Support, Regulatory Submissions and Safety Assessments

21 CFR Material Formulation Review

Review the material formulation to determine whether the ingredients are FDA compliant to 21 CFR regulations for the intended end use of the material. Identification of any associated testing or chemical purity specifications that may be required for such compliance.

21 CFR Migration and Exposure Testing

Our laboratories can conduct the appropriate laboratory analyses for food contact materials to determine potential leaching at varying conditions of exposure.

Food Contact Notifications (FCN)

Compilation and submission of a Food Contact Notification as a requirement of the Federal Food, Drug and Cosmetic Act and Title 21, Code of Federal Regulations (CFR) for indirect food additive and secondary additive substances that are not GRAS (Generally Recognized as Safe) or previously authorized by the FDA for the intended end use.

Food Additive Petitions (FAP)

Compilation and submission of a Food Additive Petition as a requirement of the Federal Food, Drug and Cosmetic Act and Title 21, CFR for direct food additive substances that are not GRAS or previously authorized by the FDA for the intended end use.

New Dietary Ingredient (NDI) Notifications

If a company is planning to use an ingredient that was not marketed in the United States in a product prior to October 1994, the FDA requires that the company submit a safety assessment (NDI Notification) verifying that the ingredient is safe for human use. This includes a review of the product use history and safety studies, development of toxicology data as appropriate and preparation and submission of the NDI Notification.

GRAS (Generally Recognized as Safe) Dossiers

Preparation of regulatory submissions or self-affirmation, as appropriate. Compilation of the necessary documentation based on generally available safety data and information about the use and manufacture of the substance. Coordination of an Expert Panel to determine whether there is consensus among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use.

Safety Assessments

Our experienced toxicologists can conduct safety and risk assessments on various substances through the review and evaluation of comprehensive scientific literature, identification and resolution of data gaps and application of various toxicology and exposure modeling tools to support risk management decisions.