New York Attorney General Questions Certain Herbal Dietary Supplements – But Scientists, Experts Say the AG Used the Wrong Test

The New York State Attorney General's (AG) office commissioned an outside laboratory to conduct DNA barcode testing of several popular store brand herbal dietary supplement products. Based on those tests, the AG's office has asserted that the products do not contain the herbs listed on the label, and also contained some other food ingredients that were not on the label. In addition to the Attorney General's threatened legal actions in New York, the AG's letters to the retailers and the ensuing media coverage have caused some in Congress to question the adequacy of the federal laws and regulations that govern the manufacturing of dietary supplements. But scientific experts familiar with herbal products and their testing methods maintain that the DNA barcode test is not an appropriate method to determine what is in an herbal dietary supplement, thereby making these results likely inaccurate and irrelevant.

Does FDA Regulate Dietary Supplements?

Yes. Dietary supplements are regulated by the federal Food, Drug & Cosmetic Act, as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA). DSHEA authorized FDA to issue Good Manufacturing Practice (GMP) regulations to cover all aspects of supplement manufacturing and the FDA released those rules in 2007 (21 CFR Part 111). These regulations address all aspects of manufacturing dietary supplements, including procuring ingredients, the manufacturing process, holding and distribution operations and packaging and labeling of the products.

Among those requirements, manufacturers must conduct "at least one appropriate test or examination" to verify the identity of any ingredient, 21 CFR §111.75(a), and must also test their finished products to assure they meet the products' specifications for identity, purity, strength and composition, 21 CFR §111.75(c). In addition, DSHEA requires that dietary supplement labeling accurately represents the identity and quantity of the ingredients. In other words, what's in the bottle must accurately be identified on the label; if not, the product is adulterated and misbranded and is subject to seizure, recall or detention by the FDA.

What is an Appropriate Test?

Manufacturers routinely conduct a variety of analytical test methods (e.g., microscopy, various chromatographic tests, mass spectrometry, etc.) to assure their products do in fact contain the appropriate ingredients, including phytochemicals from herbs, and they keep records of these

test results to satisfy the requirements of these federal regulations. The FDA inspects dietary supplement facilities for compliance with these federal requirements.

Every analytical method that can be used to identify herbs and herbal products can be applicable in some situations but not in others. For example, a microscope can be a very effective tool to identify an herb in a form in which its microscopic features are intact if these features are unique to a specific plant, but once a liquid extract is made with that plant the microscope is useless for identification.

The FDA does not mandate any specific method to be used for authentication, but only requires the chosen method to be "scientifically valid." Thus, the FDA does not specify the use of a DNA barcode test. In fact, the FDA has stated that "We [FDA] currently use chemical markers or fingerprints for ingredient verification."

DNA Barcode Analysis is Not Appropriate for Testing Extracts

DNA barcode tests can be effective for verifying the identity of a whole plant right out of the ground or unprocessed plant materials, since the barcode tests will be able to locate intact DNA unique to the plant species in these forms. But processing of these same plant raw materials can alter DNA markers so that they are no longer detectable or leave them behind as part of the extracted, unused plant residue. Although there are exceptions (which would require extensive validation procedures), DNA barcode tests are not likely to be "scientifically valid" for use in authenticating the botanical source of the extracted raw material–there are simply no detectable and identifiable intact DNA markers left behind for authentication.

Many of the herbal supplements tested by the New York AG were made from plant extracts, not the whole, unprocessed plant. In the extract manufacturing process, the naturally-occurring constituents—phytochemicals—are extracted from the plant cells while the DNA is damaged or left behind. Therefore, a DNA test of these herbal finished products may not detect the plant DNA even though the plant's phytochemicals are present.

What About the Other Ingredients the AG Says Were Found?

In addition to questions about the general validity of DNA testing for finished products, the allegations that other undisclosed ingredients were discovered is also suspect. Extensive regulations for labeling of all food (including dietary supplements) require the disclosure of all ingredients in a product. Some manufacturers permissibly use such ingredients as rice bran as "flowing agents" or other excipients in their products and label them appropriately. However, in the case of trace amounts of other botanical material, there are well-established legal thresholds that allow for trace amounts of some ingredients that are not considered harmful or required on labels. Separate allergen labeling regulations from the FDA identify the top eight allergens and require labeling statements to indicate the presence of such allergens unless a permissible threshold has been set. Dietary supplements are subject to these same allergen rules mandated for all foods and are tested for the presence of possible allergens.

What Claims Can Be Made for a Dietary Supplement?

The New York AG has also questioned the claims that are made for these herbal supplements. The Federal Food Drug and Cosmetic Act and Title 21 of the Code of Federal Regulations permit dietary supplements to make "structure/function claims" on their label and in labeling and advertising, provided the marketer has substantiation to support the claims it makes. A structure/function claim is a claim that describes the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body. The Federal Trade Commission (FTC), which regulates dietary supplement advertising, requires "competent and reliable scientific evidence" to back up these claims. All of the herbal supplements tested by the New York AG have long histories of traditional use and a substantial body of research supports the structure/function claims that are made on their labels and in labeling and advertising.

For more information, please contact any one of these associations:
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