

Docket No. FDA-2022-D-0099

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

**QUESTIONS AND ANSWERS REGARDING FOOD ALLERGENS, INCLUDING
THE FOOD ALLERGEN LABELING REQUIREMENTS OF THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT (Edition 5): DRAFT GUIDANCE FOR INDUSTRY**

January 30, 2023

Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, importers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, and other products.

The Food Allergen Labeling and Consumer Protection Act (FALCPA) was enacted in 2004.¹ FALCPA amended the Federal Food, Drug, and Cosmetic Act (FD&CA) by establishing a new labeling requirement² for foods that contain any of eight foods or food groups or, in general, any ingredient that contains protein derived from one of these foods or food groups (defined as a “major food allergen”) based on the legislature’s understanding that these eight foods and food groups “account for 90 percent of food allergies.” The foods identified in FALCPA as major food allergens include milk, eggs, wheat, peanuts, and soybeans; the food groups so identified are fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), and tree nuts (e.g., almonds, pecans, or walnuts)³. FALCPA’s food labeling requirement took effect on January 1, 2006.

In 2021, the Congress amended the statutory definition of “major food allergen” by adding sesame to the existing list of such foods. This was accomplished through enactment of the Food Allergy Safety, Treatment, Education, and Research Act (FASTER Act),⁴ which took effect on January 1, 2023.

On November 30, 2022, the Food and Drug Administration (FDA or the Agency) issued a Federal Register notice (the November 30 Notice)⁵ in which the Agency announced the availability of a draft guidance for industry titled “Questions and Answers Regarding

¹ Pub. Law 108-202, Aug. 2, 2004.

² 21 U.S.C. 343(w). Certain exceptions apply; a thorough analysis of this law is beyond the scope of these comments.

³ 21 U.S.C. 321(qq).

⁴ Pub. Law 117-11, Apr. 23, 2021.

⁵ 87 Fed. Reg. 73,561 (Nov. 30, 2022).

Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Draft Guidance for Industry” (Edition 5: Draft Guidance or the Draft Guidance). With the November 30 Notice, FDA also announced the availability of a final guidance entitled “Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Final Guidance for Industry” (Edition 5: Final Guidance). FDA described this Final Guidance as “includ[ing] the questions and answers from the currently issued guidance⁶ that remain substantively unchanged.” Both of these Edition 5 documents address both FALCPA and the FASTER Act.

AHPA’s members are engaged in the commerce of herbs and herbal products, which may include ingredients that require food allergen labeling under the FD&CA. AHPA’s members therefore have an interest in any FDA guidance on these labeling requirements, and these comments are submitted on behalf of AHPA’s members.

These comments are limited and address only certain of the elements of Edition 5: Draft Guidance. Absence of comments on any other element or section of this Draft Guidance should not be taken to mean that AHPA agrees with such element or section, unless such agreement is specifically stated. Also, these comments do not address Edition 5: Final Guidance, and AHPA has not reviewed the degree to which this Final Guidance remains substantially unchanged from the most recently issued prior version of this guidance (i.e., Edition 4, October 2006; hereinafter Edition 4: Final Guidance).

Stakeholders require further clarification on the applicability of food allergen labeling requirements to non-“nut” plant parts

The answer provided to question B.6 in Edition 5: Draft Guidance clarifies that the food allergen labeling requirements of the FD&CA that apply to a “tree nut” do not also apply to other plant parts of a plant species that produces a “tree nut” and that such other plant parts are not, in fact, major food allergens. In so doing, the Draft Guidance identifies examples of some, but not all, of the other parts of plants that may come into commerce; the examples listed specifically include, in the phrasing of both the question and the answer, the roots, leaves, stems, or barks of such plants. The answer also

⁶ Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance. October 2006. Availability announced in 71 Fed. Reg. 64,542 (Nov. 2, 2006).

includes the phrase “...or other parts that are distinct from the tree nut portion of the plant.”

AHPA suggests that, for clarity, FDA amend Question B.6 to add as examples all other plant parts, such as flowers,⁷ pollen,⁸ husks and hulls,⁹ and sap and other exudates.¹⁰

Question B.6 also clarifies that the federal food allergen labeling requirements do not apply to wheatgrass or coconut sugar from coconut sap. AHPA suggests that this question also clarify that honey made from the flowers of nut tree species, such as almond flowers,¹¹ is also not subject to allergen labeling.

Finally, AHPA suggests that, when identifying all non-“nut” plant parts and derivatives or commodities of any plant that bears “tree nuts” as outside the scope of the food allergen labeling requirements of the FD&CA, FDA do so bluntly and redundantly to clarify the limits of these requirements and to protect against frivolous private lawsuits.

⁷ The male strobilus of some *Pinus* species are recorded as a source of food; see Smith HH. 1932. Ethnobotany of the Ojibwe Indians, pp. 407-408. *Bulletin of the Public Museum of the City of Milwaukee* 4(3):327-525.

⁸ Pine pollen is an ingredient in several marketed dietary supplements. At least six brands of pine pollen, derived from *Pinus massoniana* (Masson pine) or *P. sylvestris* (Scotch pine), are listed as “on market” in the Dietary Supplement Label Database maintained by the National Institutes of Health, Office of Dietary Supplements (accessed January 26, 2023).

⁹ Walnut hulls are recorded with food and traditional herbal uses. For the former, see McKennie M (trans. from P Duplais). 1871. *A treatise on the manufacture and distillation of alcoholic liquors*, p. 435 (“Tincture of walnut hulls”). Philadelphia: HC Baird. For the latter, an early English language record is Lyte H (trans. from R Dodoens). 1578. *A nieuwe herball or historie of plantes*, p. 731. London: Gerard Dewes; or Grieve M. 1931. *A modern herbal*, Volume II, p. 844. London: Jonathan Cape. Contemporarily, a review of “on market” labels listed in the Dietary Supplement Label Database maintained by the National Institutes of Health, Office of Dietary Supplements, returned 30 results with a search for “black walnut hull” and 45 with a search for “black walnut hulls” (accessed January 29, 2023).

¹⁰ Edition 5: Draft Guidance gives “coconut sugar from coconut sap” as an example of a food that does not require allergen labeling. Also recorded is the use of the sap of the English walnut (*Juglans regia*) tree to make sugar (see Hedrick, UP (ed.). 1919. (Ed.). 1919. *Sturtevant’s notes on edible plants*, p. 319. Albany, NY: J.B. Lyon Company, State Printers) and the use of the sap of the inflorescence or other parts of oil palm (*Elaeis guineensis*) to make palm wine (see Dalziel JM. 1937. *The useful plants of West Tropical Africa*, p. 506. London: The Crown Agents for the Colonies).

¹¹ Almond flower honey is readily available in the U.S. market.

Should FDA accept these suggestions, AHPA suggests revising Question B.6 as follows, with proposed new language underlined and two words struck through to indicate their proposed removal:

Are foods, including dietary supplements, derived from roots and other underground plant parts (e.g., rhizomes, tubers, etc.), leaves, stems and branches, flowers and other pollen-bearing parts, husks and hulls, sap and other exudates, pollen, wood, or bark, or any other part of a plant that is distinct from the tree nut portion of the same plant that bears tree nuts subject to the food allergen labeling requirements of the FD&C Act? What about wheatgrass or coconut sugar or honey made from the flowers of a plant that bears tree nuts?

No. Other parts that are distinct from the tree nut portion of a ~~tree~~ plant species that bears tree nuts are not major food allergens, and the food allergen labeling requirements of the FD&C Act do not apply to any parts that are not the tree nut portion of any plant. For example, if a dietary supplement is derived from the leaves of the *Ginkgo biloba* L. plant, not the Ginkgo nut, and no other ingredients containing proteins derived from the Ginkgo nut or any other major food allergen were used to make the dietary supplement, the food allergen labeling requirements would not apply to the dietary supplement labeling. In the same way, the food allergen labeling requirements would ~~would~~ do not apply to wheatgrass or coconut sugar from coconut sap or honey made from the flowers of a plant that bears tree nuts.

FDA should accurately determine which specific “tree nuts” trigger the allergen labeling requirements

Edition 5: Draft Guidance includes the following as Question C.5: “For the purpose of complying with the food allergen labeling requirements of the FD&C Act, what are tree nuts?” This question is similar to Question 25 in Edition 4: Final Guidance, which asks, “Section 201(qq) of the Act defines the term ‘major food allergen’ to include ‘tree nuts.’ In addition to the three examples provided in section 201(qq) (almonds, pecans, and walnuts), what nuts are considered ‘tree nuts?’” The answers to these related questions, however, differ significantly between Editions 4 (Final) and 5 (Draft).

Botanical definition and common usage meanings of “nut.” To begin with, the answer to Question C.5 in Edition 5: Draft Guidance asserts that the Agency “...is aware that there is no universally accepted botanical definition of the term ‘tree nut.’” FDA further asserts that “[a]uthoritative botanical references use many different

botanical terms (e.g., berry, capsule, drupe, fruit, nut, and seed) to describe the embryo of a tree that can form into a dry, hard fruit considered to be a tree nut” and that, in some instances, “multiple, interchangeable botanical terms are used to describe the same tree nut.”

There is, in fact, a clear botanical definition of the part of a plant identified as a “nut.” In a section titled “The kinds of fruit” in his classic text on structural botany, no less a renowned expert than Asa Gray defined “nut” as follows:

A Nut is a hard, one-celled and one-seeded, indehiscent fruit, like an achenium, but larger, and usually produced from an ovary of two or more cells with one or more ovules in each, all but a single ovule and cell having disappeared during its growth; as in the Hazel, Beech, Oak, Chestnut, and the like. The nut is often enclosed or surrounded by a kind of involucre, termed a *Cupule*; such as the cup at the base of the acorn, the bur of the chestnut, and the leaf like covering of the hazel-nut.¹²

AHPA accepts, however, that the U.S. Congress did not have this narrow and precise botanical definition in mind when it included “tree nuts” as a major food allergen in FALCPA. A report issued in February 2004 by the Senate Committee on Health, Education, Labor, and Pensions (Senate HELP Committee) to accompany the legislation that would, upon its enactment, create the federal food allergen labeling requirements for major food allergens commented as follows on the intended meaning of “tree nuts” within this law:

For example, the term “tree nuts” refers to a variety of individual nuts, including almonds, Brazil nuts, cashews, chestnuts, filberts/hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts.¹³

It seems clear then that Congress intended for “tree nuts” in FALCPA to include the seeds of many plant species that do not meet the botanical definition of “nut” but that Americans commonly refer to as “nuts” for culinary purposes. These include, for

¹² Gray A. 1879. *Gray's botanical text-book (Sixth Edition) Vol. I. Structural botany*. New York and Chicago: Ivison, Blakeman & Company. pp. 295-296.

¹³ U.S. Senate, Committee on Health, Education, Labor, and Pensions Committee, Report 108-226, filed Feb. 12, 2004, to accompany S. 741: Minor Use and Minor Species Animal Health Act of 2003.

example, almonds (the seed of a drupe fruit), Brazil nuts (the seed of a capsule), and pine nuts (the seed of a cone).

In modifying its guidance on allergen labeling requirements, FDA must answer the following question: “Did the Congress intend for FDA to interpret FALCPA so expansively that the Agency would apply the allergen labeling requirements to every tree fruit that Americans might conceivably refer to in some context as a ‘nut?’” Based on the Draft Guidance, FDA seems to think it has such an obligation. AHPA, however, disagrees that such an expansive interpretation of FALCPA would prove necessary to protect Americans from “tree nuts” contribution to the “90 percent of food allergens” specifically identified in FALCPA or otherwise to effectuate Congressional intent.

Not all “tree nuts” and other articles identified as culinary “nuts” qualify as “major food allergens.” Question C.5 in Edition 5: Draft Guidance also presents a list of plant species that FDA asserts produce “tree nuts” subject to the food allergen labeling requirements of the FD&CA; FDA identifies this list as “Table 1. Examples of Tree nuts with their Common or Usual names and Scientific Names” (Table 1). This table includes a few such species that FDA did not include in the similar list at Question 25 in Edition 4: Final Guidance. FDA also removed from that 2006 list one species, *Litchi sinensis* (a fruit sometimes identified by the common name “lichee nut” or “litchi nut” due to its dried form’s resemblance to a nut), a revision AHPA requested that FDA make to the Edition 4: Final Guidance list in comments submitted to Docket No. FDA–2017–N–5094 in 2018.¹⁴

AHPA does not believe, however, that FDA needs to identify as subject to the food allergen labeling requirements of the FD&CA all (i) true tree nuts or (ii) nut-like seeds, fruits, or other plant parts produced by a tree (or other tree-like plant) and with common names that include the term “nut” or that Americans may consider “nuts” in a culinary sense. Rather, in effectuating Congressional intent, FDA should apply additional criteria in providing guidance on the applicability of the food allergen labeling requirements to any “tree nut” not specifically identified in the cited 2004 Congressional record. Such criteria should include whether such additional articles are broadly used in food in the United States and, most obviously, whether there exists credible scientific evidence that

¹⁴ AHPA. Feb 5, 2018. Before the United States of America Food and Drug Administration – Comments of the American Herbal Products Association on FDA’s Request for Comments on Evaluation of Existing Regulations Relating to Products Regulated by CFSSAN (Center for Food Safety and Applied Nutrition).

any such article truly presents significant allergenicity to a degree that it should be classified as a major food allergen.

The list of articles presented in Table 1 under Question C.5 in Edition 5: Draft Guidance includes a number of species that were not cited in the Congressional record. These include several species retained from the similar list in Edition 4: Final Guidance: beech nut, butternut, chestnut, chinquapin, coconut,¹⁵ ginkgo nut, hickory nut, pili nut, and shea nut. AHPA notes that at least one comment submitted to FDA in 2013 requested, among other details, removal of all of these nine uncited species (and also “lichee nut”) from the representative list of “tree nut” species subject to food allergen labeling requirements.¹⁶ This request provided authoritative reviews of reports of allergic reactions to each of these nine foods, and it concluded that “there are insufficient data to support the inclusion” of the “nuts” of these nine tree species and that “[i]nclusions of ‘tree nuts’ that have either no history of sensitization and elicitation of allergic reactions (beech nut, butternut, chinquapin, ginkgo nut, hickory nut, pili nut, and sheanut), or only a few cases of mild and non-life threatening reactions (chestnut, coconut [and lichee nut]) contradict the intent of FALCPA and leads to an unnecessary elimination of food choices that are enjoyable, nutritious and convenient to allergic consumers.” AHPA has not confirmed whether the literature reviews presented to support this 2013 request remain reflective of the weight of the current scientific literature. Nevertheless, AHPA recommends that FDA do so now, prior to issuing Edition 5 as final guidance, and consider removing any of these extra-Congressional “tree nuts” from Table 1 that are not, in fact, major food allergens.

FDA should not add kola “nut” and palm “nut” to Table 1. Revised Table 1 in Edition 5: Draft Guidance also adds two entries: kola nut / kola nut (*Cola acuminata* and *C. nitida*) and palm nut (*Elaeis* spp.). AHPA is not aware of any data or information that indicates that either has sufficient allergenicity to qualify as a major food allergen.

In addition, neither of these appears to meet the botanical definition of “nut.” For example, kola as an article of trade is defined as “the dried cotyledon of *Cola nitida*

¹⁵ AHPA notes that the plant that produces the coconut (*Cocos nucifera*) is not, in fact, a tree, and further notes that in proposing to add palm nut (from *Elaeis* spp.) to Table 1 FDA is extending its erroneous interpretation of a “tree” to include plant species that do not meet the botanical definition of a tree.

¹⁶ Grocery Manufacturers Association et al. May 13, 2013. Comments re: Docket No. FDA-2012-N-0711: Request for comments and information on initiating a risk assessment for establishing food allergen thresholds.

(Ventenat) Schott and Endlicher, or other species of *Cola* Fam. Sterculiaceae),”¹⁷ or as the seed of these species.^{18,19,20,21} Similarly, the relevant food article derived from *Elaeis guineensis*, a prominent commercial species in this genus, is the “nutlike fruit kernel” found within the plant’s fruit.²² Although food or drink recipes can be found that include each of these as ingredient, their identity as culinary “nuts” is, at most, related to very limited human food use in the United States. Neither is a “major food,” which should lead to the logical conclusion that neither could be a “major food allergen,” even if they were actually “tree nuts,” which they are not.

Summary of AHPA’s comments to Table 1 at Question C-5. In summary, AHPA requests that FDA revise Table 1 in Edition 5: Draft Guidance to, at the least, refrain from adding cola nut / kola nut (*Cola acuminata* and *C. nitida*) and palm nut (*Elaeis* spp.). AHPA also requests that the Agency give strong consideration to removing from Table 1 all plant species that were not specifically mentioned as representative “tree nuts” in Senate HELP Committee Report 108-226.

¹⁷ American Pharmaceutical Association. 1946. *The National Formulary*, Eighth Edition; p. 289. Note that the genus *Cola* is now classified in the Malvaceae family.

¹⁸ Hedrick, UP (ed.). 1919. (Ed.). 1919. *Sturtevant’s notes on edible plants*, p. 184-185. Albany, NY: J.B. Lyon Company, State Printers. The listing of *Cola acuminata* includes the following: “Under the name of cola or kolla or goora-nuts, the seed are extensively used ... [in] western and central tropical Africa and likewise ... in the West Indies and Brazil.”

¹⁹ Dalziel JM. 1937. *The useful plants of West Tropical Africa*, p. 102. London: The Crown Agents for the Colonies. (“The kola nut of commerce is the seed [of *Cola acuminata* or *C. nitida*] freed from its thin white covering, usually after soaking or by fermentation in broad leaves....”).

²⁰ Osol A and GE Farrar (eds.). 1955. *The dispensatory of the United States of America*, 25th edition, p. 1730. Philadelphia: JB Lippincott Company. (“The *Cola nitida* ... is largely cultivated in the West Indies and South America... for the sake of its seeds.”)

²¹ Furia TE and N Bellanca. 1971. *Fenaroli’s handbook of flavor ingredients* (edited, translated and revised), p. 141-142. Cleveland, OH: The Chemical Rubber Co. This authoritative food reference identifies the “seeds” as the part of “kola nut (cola nut) – *Cola acuminata* Schott and Endl. and other *Cola* species” used in flavoring.

²² The quoted description is in Davidson, A. 1999. *The Oxford companion to food*, p. 569. Oxford: Oxford University Press. See also Dalziel JM. 1937. *The useful plants of West Tropical Africa*, pp. 499-507. London: The Crown Agents for the Colonies.

FDA should exercise its authority to interpret ambiguous statutory language

Question C.5 in Edition 5: Draft Guidance also states, immediately preceding the Table 1 list of examples of “tree nuts,” the following disclaimer:

This list is not intended to be exhaustive because hundreds of types of tree nuts exist. Food manufacturers are responsible for knowing the identity and content of all ingredients they use to make their products and whether the ingredients are or contain tree nuts or their proteins.

This language differs significantly from FDA’s description of the similar list of plant species presented at Question 25 in Edition 4: Final Guidance. In that document, FDA stated:

The following are considered ‘tree nuts’ for purposes of section 201(qq). ... The ... list reflects FDA’s current best judgment as to those nuts that are ‘tree nuts’ within the meaning of section 201(qq). ... FDA further advises that, as with any guidance, the list may be revised consistent with the process for revising guidance documents in our regulation on good guidance practices in 21 CFR 10.115.

In other words, in 2006, FDA apparently considered the plant species listed in the table at Question 25 in Edition 4: Final Guidance an exhaustive list of species that produce “‘tree nuts’ for purposes of section 201(qq)” – that is, the statutory definition of food articles that require food allergen labeling under FALCPA – and retained for itself the responsibility and the authority to revise this list if necessary. On the other hand, the Agency now proposes to shift this responsibility to industry such that food manufacturers must now determine whether any food ingredient is one of, or shares characteristics with, the “hundreds of types of tree nuts” the Agency references in the revised guidance.

AHPA believes it is the responsibility of FDA to determine what is and what is not a “major food allergen,” as FDA is much better positioned and has more timely access to the data needed to make this determination than industry.

The proposed shift of responsibility from FDA to industry is unacceptable, and is likely to be counterproductive. It will unfairly burden industry with expensive risk analysis exercises that will leave the door open to frivolous lawsuits, which in turn will lead to industry over-warning the public about substances that do not actually present a

significant allergen risk. This in turn will unfairly limit the access of allergen-sensitive individuals to many foods that are not, in fact, dangerous for them to consume, and will undermine the importance of the warnings in the mind of consumers, which will lead to increased public health risk and will contravene the intent of the law.

That FDA seems to interpret the term “tree nuts” far more expansively than Congress intended to include many articles that do not qualify botanically as nuts, that are not produced by plants that botanically qualify as trees, that are not commonly used as foods in the United States, and that have no established allergenicity leaves industry members in an impossible situation. The ambiguities and uncertainties FDA has created via its own guidance raise significant vagueness and enforceability issues.

For this reason, AHPA strongly suggests that FDA revert to its prior approach of publishing and implementing a singular, positive list of “tree nuts” that accords with Congressional intent. Otherwise, inconsistent approaches to the question of what qualifies as a “tree nut” for these purposes may abound in product labeling to the detriment of consumers. Continued uncertainty on this subject may also incentivize a new wave of frivolous private litigation to the detriment of industry. Further, the absence of a positive list may lead to numerous, inefficient, and contentious administrative compliance and enforcement proceedings to the detriment of the Agency.

Should FDA decide not to accept this suggestion, and therefore place the responsibility on industry to know which ingredients not listed in Table 1 qualify as “tree nuts” for these purposes, then the Agency must provide precise guidance on exactly what criteria industry would use to make such determinations. Such criteria must include clear definitions of the terms “tree” and “nut” along with the factors that industry should use to otherwise assess whether an article would trigger the labeling requirements as an ingredient in the class of “major food allergens,” in a manner that is consistent with Congressional intent. The trigger should be based on an objective, unambiguous measure such as X serious adverse event reports per Y unit of U.S. population.

Summary

AHPA appreciates the opportunity to present comments on FDA's draft guidance, Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Draft Guidance for Industry. AHPA staff and counsel will make themselves available at any mutually convenient time to further discuss any of the topics addressed herein. Please feel free to contact us if clarification or additional engagement is needed on the issues raised in these comments.

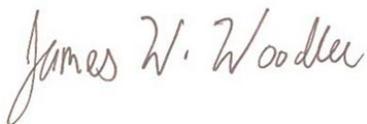
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