

January 30, 2023

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

RE: Docket No. FDA-2022-D-0099 “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Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Draft Guidance for Industry.”

The Consumer Healthcare Products Association (CHPA)¹ and members of our Dietary Supplements Committee appreciate the opportunity to comment on the recently released Draft Guidance² outlining FDA’s approach to food allergen labeling. Our comments pertain to the information provided in the Draft Guidance related to determination of whether a food or dietary supplement contains an ingredient considered a tree nut³ and would thus require allergen labeling under the Federal Food, Drug, and Cosmetic Act.

However, the current Draft Guidance provided by the Agency creates confusion regarding the classification of tree nuts and leads to the potential for non-compliant and inconsistent food allergen labeling. Below, we cite apparent discrepancies between the current Draft Guidance and additional information available from an FDA website as it relates to the definition of a tree nut, highlight the potential impact this may have on interpreting allergen labeling requirements, and request clarity from FDA regarding these topics.

Table 1 in the current Draft Guidance (‘Examples of Tree nuts with their Common or Usual names and Scientific Names’) provides examples of tree nuts, noting that the list is “*not intended to be exhaustive...*”. As the current list does not represent a full accounting of what the Agency considers a tree nut, we are concerned that differing interpretations of what does constitute a tree nut amongst manufacturers and ingredient suppliers may result in inconsistent allergen declarations on labeling.

Further, several statements in the Draft Guidance also have the effect of promoting an open-ended definition of a tree nut, including:

“[m]anufacturers are responsible for knowing ... whether the ingredients are or contain tree nuts ...”

¹ The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

² 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

³ See Question C.5 (“Food Sources”) which states, “For the purpose of complying with the food allergen labeling requirements of the FD&C Act, what are tree nuts?”

“...there is no universally accepted botanical definition of the term ‘tree nut’” and

“Authoritative 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”.

In earlier information provided to stakeholders,⁴ the Agency adopted a seemingly clear approach to what was considered a “tree nut”. For example, text above the Table notes that “*The following are considered “tree nuts” for the purposes of section 201 (qq)*”, and further describes the list as “comprehensive”.

Given this apparent discrepancy between a previous list of tree nuts described as “comprehensive” and the current Draft Guidance where manufacturers are responsible for determining if something is a tree nut, we also request clarity on how to approach the inclusion (or exclusion) of tree nut examples in the current Draft Guidance as they relate to allergen labeling. Cola nut (Kola nut) and Palm nut are included as examples of tree nuts in the new Draft Guidance but were not included on FDA’s “comprehensive” list of tree nuts referenced earlier.⁴ It is unclear what manufacturers should do if they currently have a marketed product containing Cola nut (Kola nut) or palm nut which does not include an allergen labeling statement. This new Draft Guidance brings into question whether food and dietary supplement companies would be required to declare these nuts as mandatory allergens moving forward, despite a long history of these nuts not being considered as mandatory allergens. Would a company be out of compliance if the currently marketed product containing Cola nut (Kola nut) and/or Palm nut proteins did not include an allergen labeling statement?

In addition, lichee nut was previously included in an earlier version of the Draft Guidance and is listed on the FDA website as an example of a tree nut. However, lichee nut is not included in the current version of the Draft Guidance. FDA should clarify whether the removal reflects simply the “non exhaustive” nature of the list or if the Agency no longer considers the lichee nut to be an allergen.

Lastly, the newly proposed FDA definition of tree nuts for the purposes of allergen labeling are highly inconsistent with several international food allergen requirements, namely Health Canada and the European Commission.

For the purposes of allergen labeling in Canada, Tree Nuts are clearly defined as follows:

almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts.⁵

For the purposes of food labeling within the European Union, the European Commission details “nuts” as the following:

almonds (*Amygdalus communis L.*), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil

⁴ 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?” available at <https://www.fda.gov/industry/fda-basics-industry/section-201qq-act-defines-term-major-food-allergen-include-tree-nuts-addition-three-examples>; Content current as of February 1, 2016

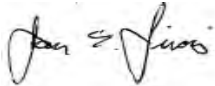
⁵ <https://www.canada.ca/en/health-canada/services/food-allergies-intolerances/avoiding-allergens-food/allergen-labelling.html>

nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof...⁶

Commonly, Coconut (*Cocos nucifera*) has generally not been considered as a Tree Nut in the majority of international markets.

CHPA seeks greater clarity from the Agency on a standard definition for a tree nut to ensure that industry compliance with allergen labeling requirements is consistent and consumers are adequately protected from major food allergens.⁷ We believe that FDA should provide additional opportunity for stakeholders to comment on how to determine whether something is a tree nut to ensure that the universe of “tree nuts” is adequately captured.

CHPA and the members of our Dietary Supplement Committee thank you for considering these comments.



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⁶ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF> (See page 304/43)

⁷ Lack of clarity in the regulatory definition of tree nuts also creates an opening for unnecessary litigation and trial courts across the country reaching different definitions of the term, which does not help consumers.