FDA's Draft "Guidance" OKs Clearly Illeg

by Pete Hardin

A recent draft Advisory from the federal Food and Drug Administration (FDA) signals that agency's continued sanctioning plant-based beverages as "milk" in product names and on packaging.

Yes, the FDA acknowledges that it will continue failing to follow the law when it comes to plant-based beverages that violate the law by being labeled as "milk."

Currently, the FDA is in the midst of a public comment period regarding that draft Advisory. This process is a meaningless sham. Why? The agency's proposed advisory is strictly "voluntary." If ultimately approved, the draft Advisory lacks regulatory teeth.

Thus, FDA's latest action shows no intent to deviate from more than two decades of failure to enforce labeling standards regarding plant-based beverages using the word "milk." Federal law – (un)enforced by the FDA – regards "milk" is a standardized term, which since 1973 has defined milk as "the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more cows."

That FDA draft Advisory admits that plant-based beverages labeled as "milk" do not conform to FDA rules for milk. But FDA's logic is that "milk" has become a "common use" phrase for plant-based beverages. Think about that illogic: +20 years of not enforcing the law on plant-derived beverages labeled as "milk" has (d)evolved to where that illegality is accepted by the agency as "common use."

The FDA's mission, according to this recent draft Advisory is: "… to improve dietary patterns in the United States to help reduce the burden of nutrition-related chronic diseases and advance health equity. We are committed to accomplishing this by promoting healthy starts through improved maternal, infant, and child health, creating a healthier food supply for all …."

FDA: Future intent to ignore "imitation" labeling laws

Under existing law, any plant-based beverages labeled "milk" that are not nutritionally equivalent to cow's milk should be required to prominently display the word "Imitation" on the containers' front panel. Clearly, in terms of protein content and unknown bioavailability of limestone (calcium carbonate) added to boost those products' calcium content, most plant-based "milk" products are nutritionally inferior to cow's milk.

Even so, FDA's draft Advisory clearly states that the agency may exercise "regulatory discretion" by not enforcing laws requiring such nutritionally inferior products to be labeled as "imitations."

Bad enough that FDA has failed to enforce milk-labeling laws for more than 20 years. But the recent draft Advisory signals FDA's intention to ignore another legal mandate in the future. Under existing statutes, manufacturers of products labeled with a standard of identity (such as milk) must prominently affix the word "Imitation" directly above the standard term being used, IF the product in question is nutritionally inferior to the standardized product whose name is used on the product.

By measures readily accessed on those products' nutritional profiles, most plant-based "milk" products contain far less protein than cow's milk products. Thus, plant-based products labeled "milk" are nutritionally inferior to cow's milk.

The bioavailability of calcium in plant-based "milk" products is also suspect. Virtually all plant-based "milk" products source their calcium content from calcium carbonate (finely-ground limestone). Indeed, the front panels of some such plant-based beverages claim to have "50% more calcium than cow's milk."

But is that added limestone actually available for persons consuming plant-based "milk" products? FDA's draft "Advisory" specifically states that no tests have been conducted on whether or not the calcium carbonate added to plant-based "beverages" is bioavailable.

The Milkweed has not witnessed FDA officials engaging in such eyes-wide-shut, bent-over-backwards denial of reality since August 1990, when that agency published its "human safety" findings regarding Monsanto's recombinant bovine growth hormone. (In the first five years of commercial use by dairy farmers of Monsanto's milk-stimulating, synthetic hormone veterinary drug, post-menopausal women's milk duct tissue cancers spiked 66% in the United States.")

Using FDA's own words in the draft Advisory, let's dig deeper into questions that cry out for better oversight than FDA's loose logic allowing continued sales of plant-derived beverages to be marketed as "milk."

Question: Does the FDA contend that plant-based "milk" beverages are nutritionally equivalent to cow's milk?

FDA quote: "While the nutritional value of milk and its role in healthy eating patterns is well-documented, the nutritional content of plant-based milk alternatives varies considerably across types (e.g., 'almond milk' vs. 'oat milk') and within the same type depending on the raw materials used, processing, fortification with vitamins and minerals, and addition of other ingredients, such as sugar and oil. (Refs. 5, 11, and 12). As noted above the *Dietary Guidelines, 2020-2025* includes soy beverages and soy yogurt alternatives that are fortified with calcium, vitamin A and Vitamin D in the Dairy Group because they have similar nutrient compositions and use in meals. However, the *Dietary Guidelines, 2020-2025* states that 'other products sold as "milks" but made from plants (e.g., almond, rice, coconut, and hemp milks') may contain calcium and be consumed as a source of calcium, but they are not included as part of the dairy group because their overall nutritional content is not similar to dairy milk and fortified soy beverages.) (Page 10.)

The Milkweed's analysis: In citing the USDA's current *Dietary Guidelines, 2020-2025*, FDA's draft Advisory reveals the agency's flawed logic. Soy-based "milks" are considered the nutritional equivalent of cow's milk and listed in the so-called "Dairy Group" of foods. That's despite soy "milk" products often containing lower levels of protein per serving than cow's milk. But other plant-based beverages are not listed in the "Dairy Group," because "their overall nutrition content is not similar to dairy milk and fortified soy beverages." **AHA! Right or WRONG, USDA's current *Dietary Guidelines, 2020-2025* lists only soy-based "milks" as nutritionally comparable to cow's milk. But that same document downgrades other plant-derived "milk" beverages, because of their nutritional inferiority. HOWEVER … FDA's draft Advisory makes no such differentiation on plant-based "milk" beverages other than soy.**

Question: Do consumers think that plant-derived "milk" is equally nutritious as cow's milk.

FDA's quote: "… several consumer studies submitted in response to the notice indicate that consumers, including consumers who purchase plant-based milk alternatives, **do not understand the nutritional differences between milk and plant-based alternatives**."

"The majority of consumers who purchase plant-based milk alternatives state they do so **because they believe the products are healthier than** milk."

"Further, a survey reported that **53 percent of its respondents believe that plant-based milk alternatives labeled with the term milk in their names have a nutritional content similar to milk.**" (Bold emphasis added. All above quotes from FDA draft Advisory, page 6.)

The Milkweed's analysis: The majority of consumers buying plant-based beverages are misinformed and ignorantly believe that plant-based "milk" products are nutritionally equivalent to cow's milk. In truth, cow's milk has superior nutritional attributes.

Question: If 53% of consumers buying plant-based "milk" mistakenly believe that such beverages have nutritional content similar to cow's milk, how does the FDA explain allowing such products to be called "milk"?

***FDA's* quote:** "Plant-based milk alternatives are not milk, they are made from plant materials rather than the lacteal secretion of cows. Consequently, under the FD&C Act they may not be offered for sale as "milk." Although many plant-based milk alternatives are labeled with names that bear the term 'milk' (e.g., 'soy milk") they do not purport to be nor are they represented as milk. … **consumers, generally, do not mistake plant-based milk alternatives for milk**." (Bold emphasis added. Quotes sourced from pages 7-8 of draft Advisory.)

The Milkweed's analysis: FDA contradicts its own statements. If slightly more than half of consumers (53%) buying plant-based alternatives mistakenly believe those products are nutritionally equivalent, how can FDA state that "consumers, generally, do not mistake plant-based milk alternatives for milk."?

Question: How *should* FDA regulate foods using a standardized name that are not nutritionally equivalent to the standardized food?

***FDA quote*:** "The FD&C Act also provides for labeling of a food product as an 'imitation' of another food. We have defined an imitation food as one that substitutes for and resembles another food and is nutritionally inferior to that food. Nutritional inferiority is defined in part as any reduction in the content of an essential nutrient that is present at a level of two percent or more of the Daily Reference Value or Reference Daily Intake, depending on the nutrient, per reference amount customarily contained." (Page 7.)

The Milkweed's analysis: Most plant-based products labeled as "milk" are nutritionally inferior to cow's milk in one or more important nutrients. Thus, those products should be labeled as "imitations" under FDA's rules.

Question: How does the FDA's draft Advisory address the fact that most plant-based beverages marketed as "milk" contain far less protein than a similar-sized serving of cow's milk?

***FDA's quote*:** "The Dietary Guidelines identify the Dairy Group as a key contributor of calcium, protein, vitamin A, vitamin DS, magnesium, phosphorus, potassium, riboflavin, vitamin B-12, as well as zinc, choline, and selenium." (Page 9.)

Appendix I "USDA's FNS Fluid Milk Substitutes Criteria" lists "Protein 8 Grams" per cup (8 fluid ounces). (Page 29.)

The Milkweed's analysis: The agency's draft Advisory avoids the fact that many plant-based beverages marketed as "milk" contain lower levels of protein than cow's milk. In fact, the only reference to actual protein content of plant-based beverages is on the last page – Appendix I – that cites USDA's Food Nutrition Service's rules that plant-based milk alternatives must have 8 grams of protein per 8-ounce serving. Trouble is: Most plant-based beverages contain fewer grams of protein — often only 1 or 2 grams — per 8-ounce serving. Further, plant-derived proteins are not "complete" proteins, in other words they do not contain the full array of nine amino acids. When measured by the amount of protein per recommended serving, as well as the inherent failure of plant-based beverages to provide complete proteins, one may logically conclude that such plant-based beverages are nutritionally inferior to cow's milk.

Therefore, FDA ought to require plant-based beverages using the phrase "milk" to be labeled as imitation. Buried deep in the draft Advisory, the FDA admits that protein content of plant-based milk alternatives "may" not be equivalent to cow's milk. The agency states: "Calcium and vitamin D-fortified plant-based milk alternatives are alternatives to milk to consider, **but they may vary in other potentially important nutrients (e.g., protein, magnesium, phosphorus, and potassium).** (Bold emphasis added. Quote from page 11 of the draft Advisory.

Questions: What about calcium? Calcium is an important nutrient provided by cow's milk. Most calcium contained in plant-based "milks" is "calcium carbonate" – finely-ground limestone. Is that finely-ground limestone bioavailable for folks drinking "fake" milk products?

***FDA's quote*:** "FDA also identified calcium, vitamin D, and potassium as nutrients of public health significance, requiring them to be declared on the updated Nutritional Facts label. The Dairy Group in the *Dietary Guidelines, 2022-2025* includes soy beverages fortified with calcium, vitamin A and vitamin D … (Page 9.)

"Inadequate consumption of calcium and vitamin D can result in impaired peak bone mass accrual, low bone mass, and osteoporosis. Although calcium and vitamin D are important across the lifespan, calcium and vitamin D are critically needed during the time period when peak bone mass is still actively accruing (adolescence through 30 years of age, and, for women, in the post-menopausal period when bone remodeling occurs.") (Page 10.)

gal Labeling of Plant-Beverages as "Milk"

"The analysis demonstrated that, while individuals can consume these nutrients from sources other than milk, the number of potential alternatives to provide sufficient calcium would provide too many calories and/or be a large amount to consume daily. … **The question of bioavailability of calcium in non-dairy products was not addressed in the modeling analysis."** (Bold emphasis added. Quotes from pages 10-11.)

The Milkweed's analysis: In contrast to mentions of protein content in plant-based beverages, FDA's draft Advisory goes to great lengths to cite the need for adequate calcium in the human diet — particularly for infants, children and adults up to age 30, when bone mass is being developed. Further, the draft Advisory notes that post-menopausal women need adequate dietary calcium. Is the calcium in plant-based fake "milk" — calcium carbonate, or finely-ground limestone – actually bioavailable? FDA admits that question has not been researched.

Question: If plant-based alternative beverages are inferior in protein content to cow's milk, why doesn't the FDA require labeling those as "imitation" products?

FDA's quote: "As previously discussed, we have defined an imitation food under the FD&C Act as one that substitutes for and resembles another food and is nutritionally inferior to that food. Not all plant-based milk alternatives meet this definition, but to the extent that they do, based on our current understanding, **we intend to exercise enforcement discretion with respect to section 403(c) of the FD&C Act (21 U.S.C. 343(c)."** (Bold emphasis added.)

The Milkweed's analysis: The FDA has clearly failed to enforce existing laws, and telegraphs intent to continue ignoring labeling of nutritionally inferior plant-based "milk" products as "imitation" in the future. In the quoted material directly above, the FDA admits that some plant-based "milk" alternatives are nutritionally inferior to cow's milk. That's clearly the case for protein content. But FDA is failing to require such products to be labeled as "imitation." "Enforcement discretion" is the FDA's classic excuse for knowingly failing to enforce existing laws! That's the same d****d excuse that FDA used for nearly 20 years in failing to disallow use of Milk Protein Concentrate (MPC) in foods. From the mid- or late-1990s, until about 2016, MPC had not been declared as a "Generally Recognized As Safe" (GRAS) food ingredient. Lacking GRAS, MPC use in foods was technically illegal. But FDA "exercised regulatory discretion" and continued allowing Kraft Foods to use MPCs in several dozen non-standardized food products.)

Other cow pies along the way …

"Voluntary nutrient statement" – The draft Advisory ***suggests*** that manufacturers of plant-based beverages that use the word "milk" in their name(s) "and have a nutritional composition that is different than milk" should ***voluntarily*** affix a front-panel, nutrient statement on the product about the nutrient level. FDA recommends a statement such as:

"*Contains lower amounts of [nutrient name(s)] than milk."

What baloney! No consumer product marketer is ***voluntarily*** going to declare its product(s) to be nutritionally inferior, even if true.

What about federal nutrition programs' requirements for protein?

Federal nutrition programs include the National School Lunch Program (NSLP), the School Breakfast Program (SBP), the Child and Adult Care Food Program (CACFP), and the Women, Infants, and Children Program (WIC). The NSLP requires that milk substitutes must be nutritionally equivalent to milk and meet nutritional standards set by the U.S. Department of Agriculture. The other food programs have similar requirements. However, virtually all plant-based beverages (whether called "milk" or not) contain less protein than cow's milk.

What about plant-based cheeses & yogurt?

FDA's draft Advisory strategically avoids any mention "fake" cheeses using standardized dairy names such as "Cheddar" or "Mozzarella." Abuse of standardized cheese names by plant-based products' manufacturers widely occurs. FDA has taken no action on such blatant abuse. And major dairy states — including Wisconsin and New York — have copycatted FDA's inaction.

Public May Comment on FDA's Draft Advisory

Interested persons may submit their comments on the recent FDA draft Advisory regarding labeling of plant-based "milk" products. The deadline for filing comments is late April 2023. Persons may submit their comments either in writing or by email. Important that comments reference "Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry."

All comments should be identified with the docket number: FDA-2-23-D-0451

To submit comments by email: https://www.regulations.gov

Written comments should be mailed to:
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

Want a few helpful hints for comments?

1) Note that FDA's draft Advisory fails to enforce existing law that defines milk as being from cows.

2) Note that most plant-based beverages labeled as "milk" do not have comparable levels of protein as does milk. Therefore, such products should be labeled "imitation."

3) There are no studies about the bioavailability of calcium in plant-based milk. How can FDA assure that plant-based beverages labeled "milk" are nutritionally equivalent to cow's milk?

"Silk next milk™" Danone's Latest Insult

Ingredients List for whole fat "Silk next milk™"

Oatmilk (Filtered Water, Oat Concentrate), Coconut Milk (Filtered Water, Coconut Cream), Coconut Oil, Soy Protein Isolate, Chicory Root Extract, Cane Sugar, Sunflower Oil, Vitamin and Mineral Blend (Calcium Carbonate, Vitamin A Palmitate, Vitamin D2, Riboflavin[B2], Sea Salt, Locust Bean Gum, Gellan Gum, Sunflower Lecithin, Soy Lecithin, Natural Flavor.

A consumer would have to squint closely at the fine print at the bottom of the package to ascertain that "Silk next milk"™ is in fact not milk. That product's use of the seemingly unqualified phrase "milk" is in technical violation of the federal Food and Drug Administration's standards for products called "milk." Trouble is: "Silk next milk"™ and similar products abusing the protected name of "milk" fall in the deep rabbit hole dug by the FDA's decades of non-enforcement.

Danone – the global food and water marketer based in France – has announced intentions to sell its Horizon line of products sold in the United States. (In the U.S. market, Danone is commonly referred to as Dannon.) Horizon includes the Whitewave products. Horizon's holdings include both conventional and organic dairy and food products. The Silk line of plant-based beverages was established back in the 1990s as one of the first plant-based beverages.

In recent years, Dannon has behaved like an out-and-out illegitimate in its treatment of organic dairy produces whose milk its Horizon subsidiary has marketed. Several years ago in the Northeast, Horizon turned over producer relations to the low-lifes at Small Farms, LLC – related to the Kalona Organics firm based in Kalona, Iowa. About a year ago, Horizon gave notice that it would be discontinuing marketing of farm milk for about seven dozen organic producers in New England and eastern/central New York. That deadline was extended, amid many complications and still-unfulfilled promises from Horizon/Danone.

"Silk next milk"™ – clearly labeled as "milk" – contains zero ingredients that ever came from a cow. The back of the package crows that the contents are "FREE FROM DAIRY" (among other items). In relatively obscure type towards the bottom of the consumer package, one may squint to read the phrases "plant-based" and "oat milk & plant-based blend." The words "plant-based" also appear at the top of the carton, near the pour spout. Curiously, the container of "Silk next milk"™ – which appears to be half-gallon sized – in fact only contains 59 fluid ounces – five ounces shy of an honest half-gallon.

By any measure, "Silk next milk"™ violates FDA rules regarding the use of a standardized term – "milk" – since "Silk next milk"™ contains no dairy ingredients. FDA rules specify that beverages identified as "milk" must be sourced only from cows.

Protein content of "Silk next milk"™ is 4 grams per 8-oz serving. That's only half the protein content of cow's milk.

Buried deep in the fine print of a side panel is the phrase:

"NOT TO BE USED AS INFANT FORMULA."