Mislabeled Food Hazards—Multiple Choices, One Answer
by Nathan Andersen, J.D., LL.M. Candidate

It is widely known that the Food and Drug Administration (“FDA”) has many powers to regulate producers and assure the public that “foods are pure and wholesome, safe to eat, and produced under sanitary conditions,” but also that the “packaging and labeling of these [food] products is truthful and informative.”¹ The FDA’s labeling oversight, specifically regarding standard nutrition information labels, is important for both the average consumer and those confronted with more vital, measured circumstances guiding their respective food choices. The following scenario will be used throughout this article to highlight a specific mislabeling circumstance, the potential harm and what FDA rules apply to prevent and redress such an error—when multiple food items are in one container, yet the nutrition information for only one of the items is reflected on the label.

The scene started pleasantly enough with my niece (hereinafter referred to as “E”) and me enjoying the evening, indulging in a snack from the quintessential gift of a three-flavored popcorn tin received over the holidays. E is a ten-year old girl who has Type I/juvenile diabetes—requiring blood sugar checks, as well as correspondent insulin injections based upon any elevated blood sugar levels, multiple times per day. E’s routine is to check her blood sugar level, portion out an evening snack based upon her sugar levels and dose properly with insulin to compensate for any carbohydrates in the snack, which are the key nutritional components contributing to blood sugar increases.² The snack that evening was the cheese popcorn variety from the tri-flavored tin, also containing two other options: butter and caramel. Popcorn is one of her regular snacks, so E drew up and injected the appropriate dose of insulin and sat down in the living room to watch a movie.

Later that night I awakened E to check her sugar levels, which were alarmingly high, requiring additional insulin and a 1-hour vigil before another sugar check to assure safe levels. An hour later, at midnight, E’s sugar levels had not dropped, so E drew and injected more insulin and fell back to sleep, leaving me to worry for another metabolic hour. Another hour passed and again I stood by E’s bed with her sugar checker and insulin, trying to soothe her irritation and exhaustion from being awakened to monitor and inject a third round of insulin. The night was endless; we battled through four additional, very emotional and taxing rounds/hours before sufficiently stabilized so she could wait until morning for another blood sugar check. By that point it was almost 5 a.m.—I was exhausted, but wired awake on concern-based adrenaline, falling into bed feeling horrible and thinking about why E’s blood sugar level was so elevated after properly dosing with insulin for popcorn, something she had many times previously.

Then it hit me to check the labeling. I discovered a seemingly standard nutrition information label. I thumbed up and down the data for carbohydrates several times. I

² See www.jdrf.org for scientific or metabolic guidance on Type I diabetes and/or carbohydrate consumption and relative effects on blood sugar levels.
found nothing on the label to differentiate carbohydrates for the three types of popcorn within—butter, cheese and caramel. I awakened E one final time to inquire about the nutrition information on the tin, learning that she’d failed to notice the label, instead using a standard carbohydrate count for butter popcorn since it was a regular snack. Moreover, based upon the carbohydrate count on the label and the insulin injected, E theoretically might have dosed for only approximately 50% of the required insulin, regardless to which of the popcorn varieties the label applied; after all, there was only one carbohydrate count present on the face of the label, yet three types of popcorn in the tin.

In 1990, Congress passed the Nutritional Labeling and Education Act (“NLEA”), leading to FDA rules standardizing the terms used on food labels, and reflecting the fact that the federal government was aware that “people should be informed about the food’s effect on their bodies.”3 To this end, the FDA specifically regulates producers by requiring an accurate nutrition information label on almost all food product packages and prohibits “the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.”4 Moreover, the definition of misbranded food includes “false or misleading label…if its labeling is false or misleading in any particular”5 (i.e., accurate carbohydrate counts).6

Upon notice of mislabeling, the FDA may enforce labeling rules and regulations through various measures, varying in both invasive extremes as well as civil and criminal penalties. For “minor violations”7 the FDA will issue a public warning and/or an administrative notice in the form of a warning letter to the food producer, defining the labeling violation, explaining the remedy and the potential for increased actions if such violations are not corrected.8 In fact, failure to correct the mislabeling after such notice allows an escalation of enforcement powers: seizure, injunction, civil fines and/or referral to the Department of Justice for criminal prosecution.9 Specifically, the applicable penalty provision provides that anyone who mislabels a food product “shall be imprisoned for not more than one year or fined not more than $1,000, or both.”10 With this stated, however, it is crucial to note that the FDA is not “required” to pursue any of the aforementioned civil or criminal actions against a food producer for mislabeling, should the Secretary of HHS deem such act[s] to be “minor violations of this Act,” and “believes that the public interest will be adequately served by a suitable written notice or warning.”11

\[4\] 21 U.S.C. §301 et al.
\[5\] 21 U.S.C. §343(a)(1)
\[6\] 21 U.S.C. §343(q)(D)
\[7\] 21 U.S.C. §336
\[8\] For sample language from actual Warning Letter--http://www.fda.gov/foi/warning_letters/s6595c.htm, pursuant to 21 U.S.C. §336
\[9\] See 21 USC §§331, 332, 333, 334, 335, & 337.
\[10\] 21 U.S.C. §331(a)(1)
\[11\] 21 U.S.C. §336
One fairly recent mislabeled food event occurred in May 2007—*FDA Warning on Mislabeled Monkfish*—where the FDA cautioned the public about a Chinese importer’s improperly labeled puffer fish as monkfish, thereby exposing consumers to a “potentially deadly toxin called tetrodotoxin” found in certain organs of the puffer fish, and otherwise requiring strict adherence to special rules to import same.\(^{12}\) Furthermore, FDA analysis of the misbranded fish noted life-threatening levels of the toxin, citing at least two illnesses and one hospitalization as a result of roughly 6200 lbs. of mislabeled fish.\(^{13}\) Though it was noted in the public warning that the “FDA is examining all entries from the Chinese supplier and will take additional action, if warranted,”\(^{14}\) there was never an FDA “Warning Letter” issued to the food importer for the mislabeled monkfish and no ‘additional action[s]’ for civil or criminal sanctions have been taken to date.\(^{15}\) Perhaps the concept of mislabeling a deadly toxin circulating in the stream of commerce warrants only “minor violation” status in the eyes of the FDA.

Referring back to the example of E and her cheese popcorn, the undefined carbohydrate count on the popcorn label might not seem as dangerous as the toxin found in the mislabeled puffer fish, but for a type I diabetic, mislabeled carbohydrates pose similar and potentially deadly effects. Just as fish should be properly labeled to ensure consumer safety, carbohydrate counts required by the FDA inform absolutely crucial decisions for those such as E, demanding strict adherence to FDA rules.\(^{16}\)

Turning back to E’s case facts and assuming she read and followed the carbohydrate count on the tin, and this count related to cheese popcorn, she would have properly dosed with insulin and both her blood sugar and the night would have been relatively tranquil. Now assume the carbohydrate count on the popcorn tin was for caramel popcorn, considerably higher in carbohydrates than cheese popcorn.\(^{17}\) Following the carbohydrate counts under this circumstance, E would have actually overdosed with insulin, which is far more dangerous than dosing with less than sufficient insulin. In effect, E would have risked hypoglycemic shock, coma and even death.\(^{18}\) Yes, mislabeling is a “big deal.”

The FDA obviously contemplated such a scenario by implementing the following regulation: “a variety pack…a product having two or more compartments with each compartment containing a different food, shall provide nutrition information for each variety of food.”\(^{19}\) Therefore, unless an exception applies, this producer should have accurately listed each type of popcorn within the variety pack, allowing one to discern the exact amount of carbohydrates for each type of popcorn from the label attached.

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\(^{12}\) http://www.fda.gov/bbs/topics/NEWS/2007/NEW01639.html (last accessed 2-22-08)

\(^{13}\) Id.

\(^{14}\) Id.

\(^{15}\) http://www.fda.gov/foi/warning.htm (no warning letter was found addressing the importer of mislabeled monkfish)

\(^{16}\) 21 U.S.C. §343(q)(D) (specifically, “…total carbohydrates…”).

\(^{17}\) Id.


\(^{19}\) 21 C.F.R. 101.9(b)(4)
Although the FDA does exempt a few packaged food producers from the general nutrition information label requirements (i.e. businesses which conduct a fairly low-level of interstate commerce), such exemption is only applicable, “Provided, that the food bears no nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section.” Thus, even if the exemption requiring nutrition information labeling could have applied to the popcorn manufacturer, the mere presence of any nutrition information on the label expressly secures the accuracy and accountability of such label’s nutrition information under the auspices of FDA nutrition information label requirements.

Though E’s popcorn scenario offers a first-hand view of a clear food mislabeling case, it would most likely merit only concerned comments from the local FDA district office and/or possibly a warning letter to the food producer. After all, the deadly puffer fish toxin in the mislabeled monkfish package received nothing more than a mere warning to the public from the FDA, even though several people were actually harmed and there was significant potential for more widespread and serious injury.

Consuming mislabeled food generally only raises minimal diet concerns for most individuals, but there are those for whom very serious health consequences attach to mislabeled food items, such as those with Type I diabetes and other nutritionally sensitive health conditions. In fact, E’s life is a series of carefully defined choices, based upon the information revealed on food labels, each and every food item contributing to the person she will become—carbohydrate by carbohydrate. The FDA food labeling regulations are obviously well intentioned and fairly expansive, as noted from the required content of labels to the civil and criminal enforcement options available to address violations. However, through serving health concerns for all individuals, from mundane to monumental, the FDA’s enforcement of these regulations must be sincere, effective and consistent to assure the foods we consume are accurately labeled.

When a food item is mislabeled, the FDA should actively assess the actual and potential harm from such errors and, when appropriate, demand civil fines (or criminal penalties) that accurately reflect the producer’s liability, their ability to pay and an amount (or sentence) to assure continued and future producer compliance. Consumers risk their health and safety on the assumed accuracy of food labels, thus the FDA should act commensurately when approaching mislabeled foods by applying the rules and regulations to the full force for which they were designed—to promote producer integrity and protect the public. While there might be circumstances that truly merit “minor violation” status, there should be no compromise when it comes to public health and safety concerns surrounding mislabeled food.

In closing, it is undeniable that neither E nor I followed the nutrition information label on the popcorn tin, but this was chance fortune rather than chance failure. The popcorn was mislabeled with regard to accurate carbohydrate counts mandated by the FDA—possibly contributing to an overdose of insulin and E suffering severe medical distress or death

had we followed it. One would hope this type of mislabeling would be considered far
greater than a “minor violation,” and should be redressed with much more than a public
notice or warning letter from the FDA.

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