Adapting to change is the name of the game

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Earlier this year, proposed changes to the Nutrition and Supplement Facts panels started coming into mandatory compliance. This article discusses these changes to regulations governing dietary supplements, their impact on nutritional information and claims, and the possible ramifications of non-compliance.

This year has brought a number of changes to the food and supplement industries, with perhaps none greater than the changes to the regulations governing the labeling of dietary supplements, food, and beverages. While changes to the look and feel of the Nutrition Facts labels for food and beverages, such as increased text size of “calories” and other information, have drawn the most attention, the revisions to the information displayed in the Supplement Facts panel have had great effect on the dietary supplement industry as well.

Time for change

The Food and Drug Administration (FDA) first proposed changes to the regulations mandating the display of information on the labels for dietary supplements, food, and beverages in 2014, announced revisions to those changes in 2015, and finalized the proposed changes in 2016 with two final rules, “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” and “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” [1].

Both final rules came into effect on July 26, 2016, meaning that companies could have implemented changes to product labeling based on those revisions starting on that day. The initial mandatory compliance dates were July 26, 2018, for companies with annual sales of $10 million or more and July 26, 2019, for companies with less than $10 million in annual sales. The agency, however, pushed the deadlines to January 1, 2020, and January 1, 2021, respectively. After numerous sectors of the food and supplement industries asserted that the FDA had not allowed enough time to implement the required changes, the agency further indicated that it would exercise enforcement discretion on those com-
companies subject to the January 2020 deadline and not take any action before July 1, 2020. So, now that the deadline has passed, how have these changes affected dietary supplement companies?

**Small changes that pack a punch**

As mentioned, the look of the Nutrition Facts label has significantly changed under the new regulations. The type size of certain elements has increased, some substantially, while the order of some nutrients has also changed [2]. Dietary supplement companies don't have to worry about similar changes to the format of the Supplement Facts panel. Some more subtle changes to the Supplement Facts panel were contemplated, but ultimately the FDA decided to preserve the format and size parameters.

While there were no changes to the size of information in the Supplement Facts panel, new panels may display some different information or omit nutrition information previously displayed. For example, the FDA no longer deems “Calories from Fat” particularly helpful or necessary for consumers, so Supplement Facts panels are no longer required to, and should not, display that information. “Fluoride” was added as a voluntary declaration unless a claim is made about it, in which case it is a mandatory declaration. “Sugars” must now be declared as “Total Sugars.” Perhaps the biggest change is the addition of "Added Sugars", which have a daily reference value (DRV) of 50 grams. Companies must declare any sugars that are added (i.e. not naturally occurring in the product's ingredients) as "Added Sugars." This includes “sugars (free, mono-, and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type” [3].

While a few extra words here and an extra line there may not seem like much, the implications for the nutraceutical industry are far reaching. For dietary supplement companies, the changes that could have the most impact on their labels look moving forward are the changes to the DRVs and recommended daily intakes (RDIs) that were established by the revisions to 21 CFR 101.9 and 21 CFR 101.36. Likely, the new DRVs and RDIs will change the daily value (DV) percentage declared in the nutrition information and could, in turn, affect the nutrient content claims made and other nutrition information provided.

Previously, the DRV for Total Fat was 65 grams, but it has now increased to 78 grams. Because the DRV is higher, the DV percentage for the same amount of Total Fat will now be less than it was before. A product with 10 grams of Total Fat had a 15 percent DV based on the old DRV. Now, 10 grams of Total Fat has a DV of about 13 percent. Conversely, the DRV for Total Carbohydrate was reduced to 275 grams from 300 grams. So, while 30 grams of Total Carbohydrate would have yielded a 10 percent DV, it now yields a DV of about 11 percent. A table of those new DRVs for macronutrients is included in 21 CFR 101.9 [3].

The RDIs for many more of the vitamins and minerals have also changed. A few of the RDIs increased, such as vitamin C from 60 to 90 milligrams, calcium from 1,000 to 1,300 milligrams, and potassium from 3,500 to 4,700 milligrams. This means that the DV percentage will decrease for the same amount of the vitamin or mineral since the RDI is higher. However, more of the RDIs decreased, such as B vitamins like riboflavin (1.7 to 1.3 milligrams), niacin (20 to 16 milligrams), and biotin (300 to 30 micrograms). This will have the effect of increasing the DV percentages for the same amount of these vitamins and minerals. Without any alterations to the formulations of these products, manufacturers must update the information on the Supplement Facts panels to accurately reflect these new percentages.

**Claims department**

While it is clear that the Supplement Facts panel for many products is likely to change pursuant to the revisions to the labeling regulations, the new rules will also affect product marketing claims. Nutrient content claims are defined in 21 CFR 101.13(b) as claims that “expressly or implicitly characterize the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36” [4]. Certain claims can be made based on the amount of a particular nutrient in the product. For example, 21 CFR 101.54(b) authorizes use of the words “high in,” “rich in,” or “excellent source of” if the referenced nutrient represents a 20 percent or greater DV. Meanwhile, 21 CFR 101.54(c) authorizes the claims “contains”, “provides”, or “good source of” to be used in reference to nutrients with a 10 to 19 percent DV [5].

So, knowing this, let’s see how the changes to the various DRVs and RDIs may impact the viability of certain claims. As indicated, if you have a 20 percent or greater DV of vitamin C, you can make a claim like “excellent source of vitamin C.” Under the regulations in place before the revisions, the RDI for vitamin C was 60 milligrams. That means that a manufacturer could include the claim “excellent source of vitamin C” on a product with 12 milligrams or more of vitamin C per serving. However, the DV percentage for 12 milligrams of vitamin C is now only 13 percent based on the RDI of 90 milligrams, so the claim “excellent source of vitamin C” is no longer accurate for that same amount of vitamin C. The manufacturer would need to either remove the claim, revise the claim to “good source of vitamin C,” or reformulate to at least 18 milligrams to maintain the 20 percent or greater DV. On the flip side, the previous RDI for biotin was 300 micrograms, so 6 micrograms of biotin represented a 2 percent DV—not enough to make any sort of claim. The new RDI for biotin is 30 micrograms, so 6 micrograms now represent 20 percent of the DV and, suddenly, a product containing 6 micrograms is an “excellent source of biotin.” Again, even if the product formulations have not been altered, the FDA’s changes to the dietary supplement labeling regulations may require dietary supplement companies to alter their nutrient claims for better or worse.
Accepting change and moving forward

In the grand scheme of things, is it really a big deal if companies don't realize right away that the changes to the labeling regulations might also impact the ability to make certain claims? Of course, companies should always comply with the laws and regulations, but typically the FDA will grant some additional lag time before aggressively enforcing new regulations. However, we have another group of actors waiting for the revisions to the labeling regulations to become fully mandatory for all companies, so they can pursue legal action against non-compliant companies. Class action plaintiff lawyers love to bring actions over technical labeling requirements such as nutrient content claims. You can bet that these lawyers will have their calculators out and ready to check the math and make sure that nutrient content claims have been made based on the new RDIs and DRV's. Those nutraceutical companies that have not revised their claims accordingly should not be surprised when they receive a “Dear CEO" letter in the mail, threatening a class action lawsuit unless the manufacturer makes appropriate changes and compensates the alleged aggrieved plaintiffs or, more accurately, the alleged aggrieved plaintiffs' lawyers.

By January 1, 2021, all new labeling must be compliant with the revised provisions of 21 CFR 101.9 and 21 CFR 101.36. For dietary supplement companies, the time for embracing changes to the Supplement Facts panel and other labeling is now. The efforts companies make now to carefully examine, or have knowledgeable partners examine, all product packaging and labeling to ensure compliance with the federal labeling regulation revisions could go a long way toward avoiding unnecessary costs down the road.

References

2. www.fda.gov/media/97999/download
3. www.law.cornell.edu/cfr/text/21/101.9
5. www.law.cornell.edu/cfr/text/21/101.54

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