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SPECIAL FOCUS: FDA Issues Draft Guidance Document on New Dietary Ingredient in Dietary Supplement

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On July 1, 2011, the Food and Drug Administration (FDA) released a highly anticipated draft guidance document on the use of new dietary ingredients in dietary supplements. While the document does not create new requirements, once finalized, it will represent a significant step forward in FDA's efforts to fully implement the requirements of the 1994 Dietary Supplements Health & Education Act (DSHEA).

Under DSHEA, a new dietary ingredient (NDI) is an ingredient that was not marketed in the U.S. in or as a dietary supplement before October 15, 1994. If a dietary supplement contains an NDI, firms are required to notify FDA within 75 days of marketing it and

provide information demonstrating that it is reasonably expected to be safe. The one statutory exception to that rule is a notification is not required if the NDI "is present in the food supply as an article used for food in a form in which the food has not been chemically altered."

Despite the fact that there are over 55,000 dietary supplements on the market today, FDA has received only about 700 NDI notifications since 1994. One reason for that relatively low number is believed to be confusion about how to interpret the statutory provisions. For example, what information is needed to show that a product was marketed before 1994? What if the ingredient was manufactured in a different way? What does "has not been chemically altered" mean? Are separate notifications required for each supplement containing the same NDI?

The guidance represents FDA's attempt to provide the industry with its interpretation of these provisions and its expectations with respect to compliance. The guidance is organized in a "Question and Answer" format, and provides detailed information about what is and what is not an NDI, what NDIs require a notification, and what information should be in a notification. A few notable items include:

- FDA expects a notification for every finished dietary supplement product containing an NDI, even if the NDI itself is the subject of an NDI notification;
- FDA believes components of foods marketed before October 1994 are NDIs if they were not marketed in or as supplements;
- The use of many common manufacturing processes could cause a food ingredient to be considered "chemically altered," thereby requiring a notification; and
- There is no authoritative list of ingredients that were marketed in dietary supplements before October 1994. To demonstrate such marketing, FDA expects documentation such as actual business records, promotional materials, or press reports.

The complete text of the guidance document is available here.

You can submit comments on the draft guidance at any time; however, to ensure that they are considered before FDA begins working on the final version, it requests that comments be submitted within 90 days.

For any questions about preparing comments, contact Ivan Wasserman at (202) 585-6529 or iwasserman@manatt.com.

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NAD Rules on “Fair Trade” Seals, Personal Care Products

In a case of first impression, the National Advertising Division reviewed the use of the “fair trade” seal by TransFair, the licensor of the Fair Trade seal in the United States, as well as Avon Products “mark.” body product line use, a licensee of the seal.

Both cases were brought by challenger Dr. Bronner’s Magic Soaps, a maker of personal care items. In the TransFair case, the NAD analyzed whether the “Fair Trade” single-ingredient seal was identical to its whole-product seal. The NAD also reviewed whether TransFair and its licensees typically market an entire product line as Fair Trade Certified even though the products are required to contain only 2 to 5 percent fair trade ingredients in order to display one of the seals.

While the NAD said the single ingredient and whole-product seals are similar in appearance, it determined that there was little potential for consumers to view the two seals side by side and confuse them.

However, the NAD determined that authorized TransFair statements such as “By choosing this Fair Trade Certified product, you are directly supporting a better life for farming families through fair prices, direct trade, community development, and environmental stewardship,” and “Fair Trade Certification means our collection helps farmers around the globe help themselves by investing in their farms and communities, encouraging the development of business skills and mandating environmentally sustainable farming methods. After all, what’s fair is fair,” conveyed an inaccurate message regarding the degree to which licensed products are “Fair Trade” products.

TransFair’s statements should be modified to make it “clear to consumers that 1) the seal represents fair trade certification of ingredients, or that the product is using some

'Fair Trade Certified Ingredients'; and 2) personal care products need only contain 2-5 percent fair trade certified ingredients in order to bear one of the two composite product seals," the NAD said.

In the second case, the NAD turned to the use of TransFair seals on Avon's "mark." product line.

The NAD noted that Avon's use of the TransFair seals should be adjusted by its TransFair decision, but it also determined that Avon should modify its print and Internet advertisements. Avon included photos of farm workers and headings like "I [heart] making a DIFFERENCE" and "Help change the world with four of the best body care products on earth," for products targeted primarily to young women, the NAD noted.

"The print and Internet advertisements send a much stronger 'Fair Trade' ingredient content message than the mark. product packaging," the NAD said, recommending that Avon discontinue its use of photographs and headings that state the impact its products have on the fair trade movement.

Noting that print and Internet advertising provide sufficient space to fully educate consumers about the fair trade content of its products and their impact on enhancing fair trade practices, the NAD said that Avon should "provide consumers with *all* of the information regarding the products' impact on fair trade so that consumers can make an informed purchase decision."

To read the NAD's press release about the decisions, click here.

Why it matters: The NAD said the issues in the case were a matter of first impression, but noted that in recent years it has "observed a dramatic rise in environmental and social impact advertising claims in the marketplace. Because customers cannot easily verify for themselves whether social impact claims, such as 'Fair Trade Certified,' are truthful or meaningful, purchasers often rely on advertising, including certification marks, to determine what public interest benefits the products offer. As a result, advertising self-regulation plays an important role in helping to ensure the truth and accuracy of such claims."

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$2.5M Settlement in Flash Cookies Lawsuit

A $2.5 million settlement in a class action lawsuit against Quantcast and Clearspring over the alleged use of Flash cookies has received final approval from a U.S. District Court judge.

Multiple suits were filed in 2009 by plaintiffs who claimed that Quantcast and Clearspring, in conjunction with other defendants, stored information about consumers on Flash cookies that were harder to find and delete than HTTP cookies.

The suits, which were consolidated, alleged that the defendants violated the federal Computer Fraud and Abuse Act and Electronic Communications Privacy Act and California's privacy law.

A mediation prompted the settlement, which will result in the payment of roughly $2 million to advocacy groups and educational institutions devoted to consumer privacy concerns.

The remainder of the settlement will be divided between the plaintiffs' attorneys and incentive awards for the 18 named plaintiffs.

U.S. District Court Judge George H. Wu noted that only one person filed an objection to the settlement, which was voluntarily withdrawn prior to the court's fairness hearing.

Why it matters: Privacy suits remain a hot area of class action litigation, although the terms of the settlement were similar to other recent suits alleging privacy violations, such as the litigation over Google's Buzz social networking feature, where the main recipients of cash awards were privacy organizations and educational institutions.

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Suit Filed Over Organic Personal Care Products

The Center for Environmental Health filed suit against 26 cosmetics companies – including Kiss My Face Corp. and Hain Celestial Group – alleging that the defendants illegally marketed their products as "organic" in violation of California's Organic Products Act of 2003.

The Act requires that products labeled as "organic" must contain at least 70 percent organic ingredients; products with less than 70 percent organic ingredients may use the term "organic" only on their ingredient lists. The suit, filed in California state court, alleges that some of the defendants' products have few, and in some cases, no organic ingredients, while other products contain chemicals linked to potential health risks that include cancer, among other diseases.

The Oakland, California-based nonprofit organization claims that the defendants prominently placed the word "organic" on their products' front labels while listing ingredients in a "substantially smaller font" on the back label, with an asterisk next to the organic ingredients.

Hold Up Styling Mousse by Kiss My Face, for example, has the word "organic" on its front label, but of 16 ingredients listed on the back label, only one is certified organic, according to the complaint. That ingredient – camellia sinensis – is the 12th most predominant ingredient and, as such, falls far below the 70 percent required under the California law.

According to the complaint, other products manufactured by the defendants contain no organic ingredients, and worse, some contain ingredients that are actually harmful to consumers' health.

Kids Hair Softening System, made by Organics by Africa's Best, contains BHA and cocamide DEA, "chemicals that have been classified as cancer-causing by government agencies," as well as triethanolamine, which has caused asthma in exposed workers, according to the complaint.

The suit seeks relief to permanently enjoin the defendants from violating the California organic labeling law, as well as attorneys' fees and the costs of suit.

To read the complaint in *Center for Environmental Health v. Advantage Research Laboratories, Inc.*, click here.

Why it matters: As evidenced by the CEH lawsuit as well as the NAD decisions above, marketers making "organic" claims on personal care products face increasing challenges by competitors, consumer groups, and class action attorneys. The Center for Environmental Health noted that it had joined in a false labeling-based class action lawsuit brought in May by a California resident against Hain-Celestial, one of the largest makers of organic products in the United States.

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FDA Releases Images for Cigarette Packaging

The Food and Drug Administration released nine new images that must appear on all cigarette packaging and advertisements. They include graphic pictures of a body post-autopsy, diseased lungs lying next to healthy lungs, and a man blowing smoke out of a tracheotomy hole.

"These labels are frank, honest and powerful depictions of the health risks of smoking and they will help encourage smokers to quit, and prevent children from smoking," U.S. Secretary of Health and Human Services Kathleen Sebelius said in a statement when the images were released.

The new labels, which represent the biggest change to cigarette labeling in 25 years, are required under the Family Smoking Prevention and Tobacco Control Act.

Starting in September 2012, the new labels – which also include a hotline number for smokers who want to stop – will be required on every cigarette advertisement and pack of cigarettes.

At least 50 percent of cigarette packaging must be covered by a warning label on which one color image is displayed with a written warning, such as "Cigarettes are addictive" or "Smoking can kill you." The warnings also must cover at least 20 percent of cigarette advertisements.

The FDA said it selected the images from 36 that were based on study results, scientific literature, and 1,700 comments from consumers, retailers, tobacco companies, health professionals, academics, state and local public health agencies, medical organizations, and public health advocates.

To see the nine images selected by the FDA, click here.

Why it matters: The tobacco companies are not accepting the labeling changes without a fight. A coalition of the companies – including R.J. Reynolds and Lorillard – filed a lawsuit challenging the Tobacco Control Act, which established the new labeling requirements. Last year a federal court judge ruled that the companies could be required to use the labels, but also held that a separate limitation on marketing materials to black text on a white background was unconstitutional. The decision is currently on appeal before the 6th Circuit. The Association of National Advertisers, which joined in the lawsuit, said it is considering an additional challenge to the FDA's new images. "We are still discussing whether we go directly with a lawsuit or whether we will enter a friend-of-the-court filing," Dan Jaffe, the executive vice president of the ANA for government relations, told *Advertising Age*. "We will certainly join with others in opposing this proposal" because "the government on its own. . .can't put words in the mouths of advertisers."

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U.S. Supreme Court Tackles Use of Prescriber Data

In a closely watched case concerning use of prescriber data and privacy, the U.S. Supreme Court ruled that the state of Vermont violated the First Amendment when it passed a law requiring the consent of drug prescribers before their nonpublic, identifying information could be sold.

Vermont passed the law in 2007, arguing that it was necessary to safeguard medical privacy and decrease the likelihood that drug marketing would lead to prescription decisions not in the best interests of patients or the state. It expressed concern with the practice of "detailing," where pharmaceutical salespersons purchase information from pharmacies about what medications doctors have prescribed. The Prescription

Confidentiality Law prohibited entities from selling, licensing, or exchanging for value prescriber-identifiable information for use in marketing or promoting a prescription drug, absent consent by a prescriber.

A group of Vermont companies that compile prescriber data and an association of pharmaceutical manufacturers brought suit, claiming that the law was unconstitutional because it violated their First Amendment rights.

The U.S. Supreme Court agreed, ruling that the law, because it imposed content and speaker-based burdens on speech, was subject to heightened judicial scrutiny. And the state's reasoning failed to withstand such scrutiny, Justice Anthony Kennedy wrote in a 6-3 opinion.

Although Vermont argued the law was an attempt to advance privacy interests, it contained multiple exceptions for entities other than marketers, like those conducting health research, the Court noted.

"The explicit structure of the statute allows the information to be studied and used by all but a narrow class of disfavored speakers. Given the information's widespread availability and many permissible uses, the State's asserted interest in physical confidentiality does not justify the burden that [the Act] places on protected expression," the justices wrote.

Further, the state could not regulate certain speech that it disapproved of, the Court said. "The capacity of technology to find and publish personal information, including records required by the government, presents serious and unresolved issues with respect to personal privacy and the dignity it seeks to secure. In considering how to protect those interests, however, the State cannot engage in content-based discrimination to advance its own side of a debate," the Court said.

If the law had established that information couldn't be sold except in more narrow circumstances, Vermont might have had a stronger case, the Court said. "The State has burdened a form of protected expression that it found too persuasive. At the same time, the State has left unburdened those speakers whose messages are in accord with its own views. This the State cannot do," the justices determined.

Justice Stephen Breyer authored a dissenting opinion, joined by Justices Ruth Bader Ginsburg and Elena Kagan.

To read the Court's decision in *Sorrell v. IMS Health,* click here.

Why it matters: The Court noted that it granted certiorari to resolve a split in the federal appellate courts. By affirming the 2nd Circuit decision below and finding Vermont's law unconstitutional, the Court also made clear that a 1st Circuit case – which had reached an opposite result, upholding similar legislation in Maine and New Hampshire – places an impermissible burden on Constitutionally-protected expression. Indeed, while the decision focused primarily on the Vermont law at issue, the justices also addressed both privacy issues and the regulation of commercial speech more generally. For example, the Court noted that "the State may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements that contain impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers."

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