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Personal Care Products Council
Speaker: Linda Goldstein
Vancouver, British Columbia
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FDA Provides Advice on Presenting Drug Risks

The Food and Drug Administration has released draft guidelines that advise drug and medical device manufacturers on how to comply with agency rules governing the presentation of risk information in ads and other marketing material aimed at consumers and health care professionals.

The proposed guidelines, which were put up on the FDA's Web site on May 12, are not mandatory. The 24-page document does, however, provide useful advice on ways in which drug makers can steer clear of violating its rules. The proposal even details how fonts, contrast, and white space in print materials can best present risk information.

The agency pointed out that the absence or downplay of risk information is the most frequent violation it cites, accounting for dozens of warning letters each year.

The guidelines offer numerous examples to illustrate its points. For instance, the FDA guidelines recommend that a product requiring monthly blood tests for possible liver damage should state as much in clear language, instead of using language such as the need for "certain monitoring." The agency also wrote that it considers the "net impression" of a direct-to-consumer ad or material given to health care professionals to ascertain the accuracy of the risk and effectiveness information provided. It pointed out that material can be misleading even if individual claims or presentations are not. For

example, music played during a description of a drug's side effects could be considered misleading if it is inappropriately upbeat. Similarly, "discordant" images of patients benefiting from the medicine while the risk information is detailed could also mislead consumers, the agency said.

Why it matters: According to the FDA, the guidelines are in response to an industry request for advice on complying with agency rules on the presentation of risk and effectiveness information. Interested parties have 90 days to comment on the proposed guidelines, after which the FDA will issue a final version.

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Battle Mounts Over ICANN Control

With the expiration of the United States' control of the Internet Corporation for Assigned Names and Numbers (ICANN) just months away, battle lines are being drawn over who will control the Internet going forward.

ICANN, which was created in 1998 as a mechanism for assigning URLs to more than 1.5 billion users worldwide, has traditionally operated under an agreement with the U.S. Commerce Department, and the United States is the only organization that has any control or authority within ICANN. That agreement is set to expire on September 30, and the European Union is seizing the opportunity to urge the United States to abdicate its control and permit the rest of the world to participate.

EU Commissioner Vivian Reding said that although she believes the U.S. so far has exercised control over ICANN "in a reasonable manner," she hopes the Obama Administration will continue with the plan of the Clinton Administration to privatize ICANN. "I trust that President Obama will have the courage, the wisdom and the respect for the global nature of the Internet to pave the way in September for a new, more accountable, more transparent, more democratic and more multilateral form of Internet governance," Reding wrote on her Web site.

Reding wants judicial review of ICANN-related disputes to be conducted in an international tribunal in lieu of the system of private arbitral bodies that operate under the Uniform Domain-Name Dispute-Resolution Policy. She pressed for a forum in which all governments could debate Internet governance, albeit outside the United Nations, which she said cannot move fast enough on urgent matters and security issues.

On the other side of the debate, a number of trade groups, including the American Advertising Federation, have written to the Commerce Department urging its continued involvement in ICANN. Without the Department's oversight, the groups warn that there will be no way to hold

June 18-19
ABA Antitrust Section's Consumer Protection Conference
Topic:
Use, Misuse, and Disregard of Evidence of Actual Confusion in Federal and State Regulatory Proceedings
Speaker: Christopher Cole
Georgetown University Law Center
Washington, D.C.
for more information

June 25-26, 2009
Food and Drug Law Institute
Introduction to Drug Law and Regulation:
A Program on Understanding How the Government Regulates the Drug Industry
Speaker: Ivan Wasserman
for more information

Newsletter Editors

Jeffrey S. Edelstein
Partner
jedelstein@manatt.com
212.790.4533

Linda A. Goldstein
Partner
lgoldstein@manatt.com
212.790.4544

ICANN accountable for governance decisions that might adversely affect the business community or other users and stakeholders in the Internet.

As just one example of the potential danger, the groups cite ICANN's proposed plan to create thousands of new generic Top Level Domains (gTLD). If the plan goes forward as proposed, it could impose a huge financial burden on companies by forcing them to register brands and trademarks defensively to protect against cybersquatters and copyright pirates.

Why it matters: Eleven years ago, when the Internet was in its infancy, nobody predicted it would be as ubiquitous as it is today. The matter of its oversight is obviously of importance to any number of governments, companies, individuals, and other groups. It is impossible to predict how this issue will play itself out, but we will keep you apprised of developments as they occur.

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FTC's Negative Option Rule Up for Comment

The Federal Trade Commission has announced that it is seeking public comment on its Rule Concerning the Use of Prenotification Negative Option Plans, 16 C.F.R. Part 425, as part of a systematic review of agency rules and guides. The Rule regulates one type of negative option marketing, in which consumers are sent periodic announcements that merchandise will be delivered unless they decline the items within a set time.

The notice asks standard rule-review questions, including whether there is a continuing need for the Negative Option Rule, its benefits and costs, and what modifications, if any, should be made to account for changes in technology or economic conditions. The agency also requests input on whether it should expand the rule to include other forms of negative option marketing. Public comments are due by July 27, 2009.

The Negative Option Rule requires companies to include clear and conspicuous information on their plans in all enrollment materials. Terms and conditions for a plan must also be clearly and conspicuously disclosed in any oral sales presentation for a plan.

Specifically, companies must disclose:

- whether there's a minimum purchase obligation;
- how and when a consumer can cancel his or her membership;
- how many announcements and rejection forms consumers will be sent each year, and how often;

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- how to reject merchandise;
- the deadline for returning the rejection form to avoid shipment of the merchandise; and
- whether billing charges include postage and handling.

Why it matters: Changes to the Negative Option Rule could potentially affect all companies and marketers that offer automatic renewal plans in which consumers receive products or services unless they cancel the plan. Potentially affected parties should take a moment to review the rule and consider whether to submit comments.

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Alcohol Brands Cautiously Launch Twitter Campaigns

In a bid to embrace the latest in new media, Anheuser-Busch has launched a Twitter-based campaign for its beer brand Michelob.

Twitter is a free social networking service that allows users to send and read other users' text-based posts known as tweets. It is estimated to have 4 million to 5 million users. Michelob's tweets focus on beer styles, food pairings, and other beer-themed thoughts.

Industry guidelines require alcohol marketers to limit ad messages to venues in which at least 70% of the audience is of legal drinking age. Michelob is considered an older-skewing brand, but as a cautionary measure, it sends all new potential followers of its tweets a direct-message inquiry asking if they are of legal drinking age.

Age verification of online users has caused problems for Anheuser-Busch before. The Bud.tv site, which cost the company millions of dollars, was protected by an aggressive firewall that checked viewers' age claims against state ID databases. Activists and state attorneys general nevertheless continued to pressure Anheuser-Busch to do more to keep underage users out of the site, and the venture ultimately failed.

Beam Global's top-shelf Tres Generaciones line extension of its Sauza tequila brand has created a Twitter persona for deceased tequila patriarch Don Cenobio Sauza. A Beam spokesperson said Twitter works well with Beam's word-of-mouth-driven approach to brand marketing. He added that Twitter gives the company demographics information that indicates that more than 75% of the people following its tweets are of legal drinking age.

Why it matters: Twitter – as with any new medium – presents opportunities for marketers. However, as with most Internet-based social networks, the anonymity of Twitter users makes it challenging to determine the

demographics of its users. This creates challenges on several levels, especially for marketers who must ascertain the age makeup of their audience.

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Court to Examine Grounds for Taster's Choice Case

Seven years ago California resident Russell Christoff was startled to see himself staring back at him from a jar of Taster's Choice sitting on a shelf in a RiteAid store. The then 16-year-old photo of Christoff had been taken at a long-forgotten shoot in Canada many years prior.

Christoff sued Nestlé USA Inc., the maker of Taster's Choice, in California state court in Los Angeles, arguing that the company owed him millions of dollars for using his image without his consent. In 2005 a jury awarded Christoff more than $15.6 million. Victory for the then-teacher was sweet but short-lived. Two years later, in 2007, L.A.'s Second District Court of Appeal threw out the award, on the grounds that Christoff's suit was governed by the state's single-publication rule, limiting damages to one cause of action even if the offending statement or photo was published thousands of times.

The case, *Christoff v. Nestlé USA Inc.*, is now on appeal before the California Supreme Court. The argument was heard on June 3rd. The dispute centers on the relationship between the single-publication rule and the right of publicity, both of which appear in the California Civil Code. The question rests on whether the right of publicity, which involves misappropriation of the likenesses of public figures, falls under the auspices of the single-publication rule, which typically has been applied toward libelous comments in print publications.

The case has stirred intense interest in the entertainment and media industries. Several major news organizations and the Motion Picture Association of America have submitted amicus briefs supporting Nestlé, while the Screen Actors Guild and the American Federation of Television and Radio Artists are backing Christoff.

In his original complaint filed in 2003, Christoff claimed that he had never given permission for the photos from the 1986 shoot to be used outside Canada. But in 1997 Nestlé USA got his photo from Nestlé Canada and decided to use it on Taster's Choice labels – as well as in newspaper coupons, bus ads, magazines, and on the Internet – distributed in 22 countries around the world. Christoff argued that under the right of publicity, Nestlé owed him millions of dollars in damages for its more than $500 million in sales of jars bearing his mug. Nestlé USA countered that it mistakenly believed it had authorization to use Christoff's image and that, in

any event, the statute of limitations had lapsed.

In February 2005 a jury awarded Christoff more than $15.6 million in damages and about $580,000 in attorneys fees. In reversing the verdict, the Second District found that the state legislature considered the right of publicity to be a form of invasion of privacy, which is governed by the single-publication rule. "Just as in a defamation case, the litigation would have become unwieldy and potentially endless with every coffee can, print, television and electronic advertisement generating a separate cause of action. . . . This is exactly the scenario the SPR was designed to avoid," the court wrote.

Why it matters: The case has potentially important ramifications for virtually any dispute involving California's right of publicity. California is a key forum for disputes of this kind, given the number of celebrities, actors, and other public figures that reside there, as well as its status as the seat of the U.S. entertainment and media industries. If the California Supreme Court finds that the single-publication rule applies to right of publicity cases, it could severely curtail the amount of damages available in such cases.

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