

Consumer Products Marketing

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ARNOLD & PORTER LLP

Court decisions, new and pending laws, and regulations arise every day affecting companies that produce and market consumer products. Our Consumer Products Marketing newsletter summarizes notable policy and regulatory developments, as well as court decisions, in the areas of consumer protection, Lanham Act, trademark, privacy, and consumer product safety. Our aim is to keep you informed of these issues with a concise overview of selected developments. Attorneys in all practice areas listed are available to answer any questions you may have in regard to any of these issues. To reach the editor for any reason, contact Randal. Shaheen@aporter.com.

CONSUMER PROTECTION¹

FTC Issues its 28th Annual Report on Fair Debt Collection Practices Act

In April 2006, the FTC publicly released its 28th annual report to Congress on the Fair Debt Collection Practices Act (FDCPA). The FDCPA prohibits abusive, deceptive, and otherwise improper collection practices by third-party debt collectors. The report summarizes the FTC's administration and enforcement of the FDCPA during 2005 and its consumer and industry education initiatives. It also presents an overview of the types of consumer FDCPA complaints received by the FTC, noting a moderate decline in such complaints from 2004.

The FTC's report also made eight legislative recommendations. These recommendations were to: (1) make explicit the standard for clarity required for collectors' notices to consumers; (2) clarify that debt collectors may continue their collection activities during a 30-day period set aside for consumers to dispute their purported debts, unless a consumer, in writing,

disputes or requests verification of the debt; (3) exempt from the FDCPA's provisions attorneys who pursue debtors solely through litigation; (4) allow the FTC to issue model debt collection letters for optional use by debt collectors; (5) clarify that collectors may communicate with a customer only once after receiving a "cease communication" notice from the consumer; (6) expressly require collectors to take certain actions in response to a consumer's oral notification that the consumer disputes the purported debt; (7) require collectors to itemize their charges to consumers; and (8) encourage collectors to provide the name and address of the original creditor of the debt in their first communication with consumers. The FTC made these same recommendations in its previous annual report and reiterated its belief that these proposals would strengthen the FDCPA's consumer protections, and its clarity and effectiveness as a law enforcement tool. (A copy of the full report can be found at www.ftc.gov/os/2006/04/P0648042006FDCPAReport.pdf).

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The FTC Warns Against Media “Backsliding”

The FTC Chairman Deborah Platt Majoras predicted that the FTC might take action against the media, especially cable companies, that are “backsliding” in the agency’s “Red Flag” weight-loss media screening campaign, wherein the FTC asked advertising media not to run certain scientifically implausible diet claims. Since 2003, the most offensive “Red Flag” claims have dropped from 43 percent to five percent of weight-loss product ads, but Majoras says there have been indications of backsliding.

The FTC is planning to take a harder stance against media outlets that do not screen out scientifically implausible weight loss ads on their own initiative, including the identification of names of media companies that broadcast the misleading claims in press releases announcing FTC actions. In addition, companies that disseminate “Red Flag” claims may receive a formal letter from the FTC reminding them of the “Red Flag” campaign and demanding they take steps to stop such backsliding. Majoras’ speech can be found at www.ftc.gov/speeches/majoras/060503eraspeech.pdf.

In that same speech, Chairman Majoras told the Electronic Retailing Association (ERA) that the informational industry has made substantial progress towards an effective self-regulatory regime for electronic direct-response marketing. The ERA has implemented the Electronic Retailing Self-Regulating Program (ERSP), which is “designed to improve industry business practices and increase consumer confidence, while also allowing direct response professionals a forum to review claims independently of federal regulation.” Information on the ERSP can be found at www.retailing.org/new_site/govaffairs/self_reg.htm. The ERSP allows advocacy and consumer groups, direct response marketers, and other interested parties the

opportunity to refer suspect advertisements to the ERA, in an effort to remove offenders expeditiously from the airwaves. Since its founding in August 2004, the ERSP has reviewed 78 infomercials for unsubstantiated or false advertising claims; in 55 of those cases, participants have agreed to modify their advertisements. If companies refuse to participate in ERSP proceedings or do not comply with ERSP decisions, they will be referred to the FTC.

The FTC takes such referrals seriously. Of the nine matters that ERSP referred to the FTC, three of the companies are currently under order, and two more are directly or indirectly involved in ongoing litigation.

LANHAM ACT²

Over \$16 Million in Damages Awarded In Product Disparagement Case

Consistent with a recent trend in which plaintiffs are obtaining significant money damages in Lanham Act false advertising cases, a Massachusetts federal jury awarded \$20.7 million to a maker of band instruments. The defendants issued an “alert” to the marketplace impugning the integrity of the plaintiff’s instruments (including flutes, trumpets, and clarinets) saying that the instruments “break and parts are NOT available.” Although the Court denied the defendants’ efforts to overturn the jury’s verdict, the court reduced the jury’s award from \$20.7 million to \$16.1 million on the basis that the \$5 million award for “future” damages to repel the “lingering effects” of the defendant’s false advertising was too high. The court considered the impact of its permanent injunction entered two years earlier, which barred the defendant from repeating the false claims. *First Act Inc. v. Brook Mays Music Co., Inc.*, No. 03-12020, 2006 WL 1134484 (D. Mass. Apr. 26, 2006).

¹ Arnold & Porter’s Antitrust & Trade Regulation Group has extensive experience in consumer protection matters before the Federal Trade Commission (FTC), state Attorneys General, and the National Advertising Division. Members of our group include Bob Pitofsky, former FTC Chairman and Director of the Bureau of Consumer Protection; Mike Sohn, former FTC General Counsel; Bill Baer, former FTC Bureau of Competition Director; Debbie Feinstein, former Assistant to the FTC Bureau of Competition Director and Attorney Advisor; Randy Shaheen and Amy Mudge who collectively have practiced in this area for over 25 years. In our EU offices, Tim Frazer and Susan Hinchliffe have advised clients on numerous non-US consumer protection matters.

² Arnold & Porter LLP attorneys have significant experience with Lanham Act deceptive advertising counseling and representing both plaintiffs and defendants in deceptive advertising litigation. The firm has represented companies and advertising agencies in diverse product areas (including some seminal cases in the pharmaceutical sector) and has handled both literal-falsehood cases and implied-falsehood cases, which require scientifically designed surveys. Attorneys in the firm with Lanham Act experience include Randy Miller, Chuck Ossola, Helene Madonick, Suzy Wilson, Randy Shaheen, and Roberta Horton.

Implied Falsehood Claims Will Fail Without Proof of Actual Deception

Border Collie Rescue v. Ryan, 418 F. Supp. 2d 1330 (D. Mass. 2006) involved competitors who trained dogs to “chase birds and waterfowl from airport runways so that they do not strike and damage aircraft.” Plaintiff accused the defendant of exaggerating its qualifications and experience in this field, claiming that the defendant’s statements were either literally false or, in the alternative, impliedly false. While alternative pleading is acceptable at the outset of the case, summary judgment is different. The Court categorized some of the statements as implied falsehood claims only. Unlike literal falsehood claims, implied falsehood claims carry a higher burden at summary judgment. The plaintiff may not merely rest on its pleading but must present “evidence of actual deception”—such as a survey showing that the relevant audience took away a false impression from the statements. Because the plaintiff failed to provide such proof, the implied claims were removed from the case. Other claims of “literal” falsehoods remained in the case, permitting these dogs to have their day in court.

Five Years Not Too Long to Bring a Lanham Act Suit

Solvay Pharmaceuticals sued Global Pharmaceuticals under the Lanham Act for falsely advertising its enzyme supplement as the “generic equivalent” of the plaintiff’s product. Global defended by asserting the equitable doctrine of laches, i.e., that the plaintiff unreasonably delayed in bringing suit, and the defendant was prejudiced by the delay. Solvay became aware of a potential claim in 1998 but did not bring suit until 2003—five years later. Solvay explained that it needed several years to complete scientific testing to confirm that the defendant’s product was not an “equivalent” to its product. The court rejected Global’s laches defense and allowed Solvay’s case to continue. The court noted that the result would have been different if the plaintiff simply sat on its hands. Solvay overcame the laches defense only because it was able to demonstrate continuous and diligent efforts during the years leading to the lawsuit. *Solvay Pharmaceuticals v. Global Pharmaceuticals*, 419 F. Supp. 2d 1133 (D. Minn. 2006).

TRADEMARK³

District Courts Reach Different Conclusions Concerning the Purchase of Search Engine Keywords and Whether They Amount to “Use in Commerce” Under the Lanham Act

Recently, the United States District Court for the District of Minnesota and the United States District Court for the Southern District of New York reached different conclusions concerning the purchase of search engine keywords and whether they amount to “use in commerce” under the Lanham Act. In *Edina Realty v. The MLSOnline.com*, No. 04-4371, 2006 WL 737064 (D. Minn. May 11, 2006), the plaintiff and the defendant were competing real estate brokerage firms. The plaintiff owned rights to the trademark “Edina Realty.” The defendant purchased sponsored links from Google and Yahoo that were triggered by keyword Internet searches for the words “Edina Realty.” The United States District Court for the District of Minnesota held that this was a use of the “Edina Realty” trademark and was a “use in commerce” under the Lanham Act and thus amounted to trademark infringement. The court found that while the purchase of search terms is not a conventional “use in commerce,” the defendant nevertheless used the Edina Realty trademark commercially when it purchased the search terms.

The United States District Court for the Southern District of New York, however, reached the opposite conclusion in *Merck & Co. v. Mediplan Health Consulting Inc.*, No. 05 Civ. 3650, 2006 WL 1418616 (S.D.N.Y. 2006). In *Merck*, the defendants purchased sponsored links that were triggered by keyword Internet searches for the word “Zocor.” In this case, the Southern District of New York Court found that there was nothing improper about the defendants’ purchase of sponsored links tied to searches for “Zocor.” The Southern District of New York Court found that the defendants did not actually “place” the trademark “Zocor” on goods, displays, or other associated documents, nor did they use the trademark to indicate source or sponsorship. The court found that, instead, the trademarks were used “only in the sense that a computer user’s search of the keyword ‘Zocor’ [would] trigger the display of the sponsored links to the defendant’s websites.” The

³ Arnold & Porter has extensive experience in all areas of trademark and domain name law, including emerging issues in the areas of federal dilution law and nominative fair use over the Internet. Members of the group include, in our DC offices: Chuck Ossola, Roberta Horton, and Anna Manville; and in our LA office: Suzy Wilson, Ron Johnston, and Jim Blackburn.

court reasoned that the use of the keyword “Zocor” was an internal use akin to a drug store placing its generic products next to similar national brands to capitalize on the latter’s name recognition and thus does not constitute trademark use or trademark infringement.

Domain Registrar Target of U.S. Federal Cybersquatting Lawsuit by Neiman Marcus and Bergdorf Goodman

High-end retailers Neiman Marcus and Bergdorf Goodman filed a lawsuit against Dotster, one of the largest domain name registrars, alleging that it abused its status as a registrar by searching for hundreds of domain names that resemble the names of retailers and then only registering for the ones that were misspelled inadvertently by customers. For example, the domain name NeimuMarcus.com featured advertisements for Neiman Marcus rivals, such as Bloomingdales and JCrew, so that consumers looking for Neiman Marcus but misspelled it were directed to Neiman Marcus competitors. One day after the suit was filed, that website and dozens more were taken offline.

This lawsuit involves a new concept because Dotster is not just an average cybersquatter, but it is a registrar that uses its special status with the Internet Corporation for Assigned Names and Numbers (ICANN) to secure misspelled domains, temporarily monitors how many people visit these sites, and then to pay for the ones that could be profitable in terms of advertising. This seems to be the first dispute with a registrar that has led to a lawsuit, but cases involving alleged registrar malfeasance may become more common. The current lawsuit charges Dotster with violating federal laws against trademark infringement and dilution, federal cybersquatting laws, and Washington state consumer protection laws against deceptive acts and practices. Plaintiffs’ request for injunctive relief seeks the transfer of domain names and asks that Dotstar be shut down to avoid future acts as a registrar typosquatter.

Canadian High Court Rejects Mattel’s Request for an Order Barring a Quebec Restaurant from Calling Itself “Barbie”

The Supreme Court of Canada rejected Mattel’s request for an order barring a Quebec restaurant from calling itself Barbie. The Barbie restaurant has been in operation since 1992 and most of its food is made on the “barbie-Q,” hence the name. Mattel, the world’s largest toymaker and the maker of the Barbie doll, claimed that some marks such as Barbie were so famous that the average consumer would be led to infer the existence of a trade connection between Mattel and the restaurant.

However, the court found that there was no chance that consumers could confuse the toy Barbie with the restaurant Barbie. The court stated that Barbie’s fame is “to be tied to dolls and doll accessories and that the respondent’s applied-for mark, used in connection with very different products and services, was not likely to be confusing with any of the appellant’s Barbie marks.” The court reasoned that “care must be taken not to create a zone of exclusivity and protection that overshoots the purpose of trademark law.” The court ultimately held that famous trademarks cannot be extended to areas without connection to the product. A complete copy of the decision can be found at scc.lexum.umontreal.ca/en/2006/2006scc22/2006scc22.html.

PRIVACY⁴

Protecting Against Identity Theft: Agencies Issue Notice of Proposed Rulemaking Regarding Identity Theft Guidelines and Regulations

As required by sections 114 and 115 of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act), the Board of the Federal Deposit Insurance Corporation (FDIC) and other federal banking regulators have met and considered a proposal regarding identity theft guidelines and regulations for the banking industry.

⁴ Arnold & Porter’s Privacy Team provides legal and strategic counsel to help clients meet their privacy obligations in a demanding, evolving, and competitive marketplace. Our attorneys have held significant senior government positions, including Jeff Smith, former General Counsel of the CIA; Bob Pitofsky, former Chairman of the FTC; Ron Lee, former General Counsel of the National Security Agency; Rick Firestone, Chief of the Common Carrier Bureau of the FCC; and Brian McCormally, former director of the Enforcement and Compliance Division of the Office of Comptroller of Currency. Others with extensive experience in this area include Nancy Perkins and Scott Feira in our DC office; Gregory Fant in our LA office; and Sarah Kirk in our London office.

Section 114 of the FACT Act requires the agencies to issue guidelines addressing identity theft for use by both financial institutions and creditors. The Act requires the agencies to identify patterns, practices, and specific forms of activity that indicate the possible existence of identity theft. The Act also requires the bank regulators to consider requiring financial institutions and creditors to follow reasonable policies and procedures that provide for notice to a consumer when a transaction occurs with an inactive account. The federal banking agencies are proposing to implement section 114 through: (1) regulations requiring financial institutions and creditors to adopt and implement an Identity Theft Protection Program ("Program") designed to address the risk of identity theft to customers and (2) a special rule for debit and credit card issuers requiring them to assess the validity of change of address requests (collectively, referred to as the "Red Flag Regulations"). Under the proposed Red Flag Regulations, the Program must contain reasonable policies and procedures to address the institution's risk of identity theft, including consideration of any relevant red flags from the proposed Red Flag Guidelines, which are set forth in an appendix to the regulations. The proposed Red Flag Regulations also bar a credit or debit card issuer that receives notification of a change of address for an account, and within a short period of time afterwards receives a request for an additional or replacement card for the same account from honoring the request unless it first assesses the validity of the change of address request. The card issuer must make this assessment by notifying the cardholder of the request or by using other means to assess the validity of the change of address, in accordance with the policies and procedures established by the card issuer pursuant to the Red Flag Regulations.

Section 315 of the FACT Act requires that, when providing consumer reports to requesting users, nationwide consumer reporting agencies (CRAs) must provide a notice to the user of the existence of a discrepancy if the address provided by the user in its request "substantially differs" from the address the CRA has in the consumer's file. The proposed interagency regulations require each user of consumer reports,

and each person requesting consumer reports, to develop and implement reasonable policies and procedures for verifying the identity of the consumer for whom it has obtained a consumer report whenever it receives a notice of address discrepancy. The proposal also contains an illustrative list of measures that a user may employ to reasonably confirm the accuracy of the consumer's address.

CONSUMER PRODUCT SAFETY COMMISSION⁵

On May 26, 2006, the U.S. Consumer Product Safety Commission (CPSC) published for comment in the Federal Register proposed revisions to CPSC's interpretive rules that attempt to clarify when companies must notify the agency of a potential safety hazard or conduct a recall. 71 Fed. Reg. 30350 (May 26, 2006) Failure to comply with CPSC's mandatory requirements can subject companies to civil penalties of up to \$1.825 million.

The proposal would make three changes. *First*, the proposed rule would add four factors to the current non-exhaustive list of criteria CPSC considers in deciding whether a product "defect" exists. The new factors are: "the obviousness of such risk," "the adequacy of warnings and instructions to mitigate such risk," "the role of consumer misuse of the product," and "the foreseeability of such misuse." *Second*, the proposed rule provides that, in making a "substantial product hazard" assessment, CPSC "recognizes that the risk of injury from a product may decline over time as the number of products being used by consumers decreases." This reduced risk could, in turn, weigh against the need for a recall. *Third*, the proposed rule makes explicit that CPSC considers compliance or noncompliance with mandatory or voluntary standards in determining the need for a recall. However, the proposed rule also states that even compliance with a mandatory standard "may not, of itself, relieve a firm from the need to report to the Commission."

⁵ Arnold & Porter has several attorneys with broad experience on matters involving the U.S. Consumer Product Safety Commission, including two former General Counsels of the agency—Eric Rubel and Jeff Bromme—and Blake Biles, formerly with the Environmental Protection Agency. We take a proactive approach to product safety issues, helping clients establish and audit internal controls. We represent clients in CPSC enforcement actions, as well as in private litigation that can result from CPSC matters.

Although the proposed rule seeks to further advise industry on “how to comply with the requirements of section 15(b),” the provision of the Consumer Product Safety Act that requires notification to the CPSC of a reasonable belief that a product fails to comply with a CPSC rule applicable voluntary safety standard, the proposal seems to provide little relief from the subjectivity inherent in the reporting requirements. Companies already use the “new” factors when arguing to the CPSC staff, and the staff already considers these factors when it deems appropriate. Questions concerning the relevance of particular factors and the weight they should be given typically require the exercise of judgment and are not readily susceptible to being resolved through a regulation. Thus, it is unlikely that the proposed amendments would result in any significant change in the staff’s approach to section 15(b) reporting or recall issues, as the additions do not limit CPSC’s enforcement discretion in any way.

The most promising aspect of the Federal Register notice is a statement that the Commission may adopt a new interpretive regulation on civil penalties. Currently, there is little guidance on how the staff decides when to seek civil penalties or the amount of such penalties. Although CPSC may look to statutory criteria on civil penalty amounts, those criteria are vague. Additional guidance in this area is overdue.

Comments to CPSC’s proposed revisions to its interpretative rules were due by June 26, 2006. We will provide updates on developments in this area in future issues of the *Consumer Products Marketing Newsletter*.

Breaking News: Hal Stratton Announces Resignation as CPSC Chairman

As this issue of the newsletter was going to press, CPSC Chairman Hal Stratton announced his resignation, effective July 15, 2006. There has not yet been word as to who President Bush will nominate to replace Stratton as Chairman, although Commissioner Nancy Nord, a Republican who has been at CPSC since 2005, seems to be a likely possibility. CPSC can

operate for six months with only two commissioners, and would then no longer have a quorum needed for matters that require a commission vote.

FDA⁶

The Use of “All-Natural” Claims Come Under Attack

Firms considering claims that their products are “all natural” should proceed with caution. The Center for Science in the Public Interest (CSPI) announced plans to file a suit against Cadbury Schweppes, claiming that their new marketing campaign for 7Up is misleading. 7Up TV ads now say that 7Up “*tastes better than ever because we stripped out all the artificial stuff*,” and go on to show cans of 7Up being picked from fruit trees or harvested from the ground as an indication that they are “all-natural.” The suit to be filed by CSPI will seek to prevent Cadbury Schweppes from describing any product containing high fructose corn syrup as “natural,” as well as requesting restitution, corrective advertising, and attorneys fees. Information on CSPI’s upcoming lawsuit can be found at www.cspinet.org/new/200605111.html.

CSPI argues that the “all natural” claim is misleading because 7Up contains high fructose corn syrup, which is not a naturally occurring ingredient. The problem stems from the fact that the Food and Drug Administration (FDA) does not provide a detailed definition of the term “natural.” Under the FDA’s current policy, as set forth in the preamble to the FDA’s 1993 food labeling regulation, a food can be considered “natural” if nothing artificial or synthetic has been added to it that would not normally be expected to be found in that food. For more information on the FDA policy, see 58 Fed Reg. 2302, at 2407 (Jan. 6, 1993). Recently, the Sugar Association filed a petition with the FDA requesting they establish a clear definition for the use of the term “natural” on food and drink labels. Their petition claims that the current lack of a formal definition has resulted in misleading claims and consumer confusion.

⁶ Arnold & Porter’s Food, Drug and Medical Devices Group has represented a variety of companies in responding to inquiries from FDA and other agencies about advertising claims and other marketing activities, as well as worked on complaints to FDA and others regarding apparently violative conduct by competitors. Members of the group in our DC office include Bill Vodra, Arthur Levine, and Don Beers, each of whom previously were prominent lawyers at FDA; Dara Corrigan, former Acting Inspector General at HHS; Dan Kracov; Helene Madonick; Greg Levine; and Kathy Means (a Senior Health Care Policy Advisor)

Studies indicate that the term “all natural” is the most popular new product category for food and drinks. In 2004, the Natural Marketing Institute reported that 63 percent of consumers prefer food and drinks that are marked as “natural.” Other research shows that the natural soda market has grown by almost 15 percent between 2004 and 2005. In 1993 the FTC said “because of the widespread use of this term, and evidence that consumers regard the many uses of this term as non informative, the agency would consider establishing a definition.” However, the FDA never formally defined the term “natural.” In the meantime, food and drink companies should tread carefully in this area given the risk of private litigation such as the CSPI’s threatened suit against Cadbury Schweppes.

Class Action Consumer Fraud Lawsuit Filed Against Prominent Sunscreen Manufacturers

A class action consumer fraud lawsuit was filed March 30, 2006 in the Los Angeles County Superior Court claiming that companies misled consumers regarding their products’ ability to protect skin from the sun’s rays. The suit names as defendants five manufacturers of popular sunscreens: Schering-Plough (manufacturer of Coppertone), Johnson & Johnson (Neutrogena), Chattem (Bullfrog), Playtex (Banana Boat), and Tanning Research Labs (Hawaiian Tropic).

The suit alleges that sunscreen manufacturers “misrepresented material information in the marketing, labeling, advertising and sale of consumer protection products.” For example, the defendants’ labels state that their products protect the skin from both UVA and UVB rays, but plaintiffs claim that “defendants knew or should have known their skin protection products ... only protect the skin against harmful UVA rays with shorter wave lengths, while skin remains exposed to harmful UVA rays with longer wavelengths that penetrate deeper into the skin’s layers.” The FDA is working to publish guidelines to measure a sunscreen’s effectiveness against UVA rays, which may impact this claim.

The suit also alleges that the sunscreen manufacturers deceptively advertise that their products provide waterproof and/or sweat-proof protection, knowing that sun protection in

their formulas will diminish over a short period of time or after exposure to water. This is problematic, the suit claims, because the public falsely believes that it can spend more time in the sun without risk because they are using sunscreen products made by the defendants.

EU⁷

The EU Moves Closer to Adopting Legislation Regulating the Use of Health and Nutrition Claims In Europe

On May 16, the European Parliament voted on a series of amendments to the Council’s revised draft of the proposed EU Regulation on nutrition and health claims for food. This was the second parliamentary vote on the proposal, which has been through several rounds of significant amendments by both the Parliament and the Council since it was first put forward by the European Commission in July 2003.

However, the amendments introduced by the Parliament were such that it is now expected that the draft will get political agreement from the Council, which will likely adopt the Regulation before the autumn. The Regulation will enter into force shortly after its adoption (and publication in the Official Journal). Its first provisions will begin to apply six months from entry into force.

The proposed Regulation aims to harmonize national rules within Europe on nutrition and health claims for food. It will apply to any food or drink product produced for human consumption to be sold on the EU/Member States’ market, but it will not apply to fresh food such as fruit and vegetables.

Nutrition claims: The Regulation lays down strict conditions for the use of nutrition claims, such as “low fat,” “high fiber” or “reduced sugar.” For example, “low fat” food may contain no more than 3g of fat per 100g and “high fiber” food must contain at least 6g of fiber per 100g. Additionally, a nutrition claim can only be used for a particular food if it meets the relevant nutritional profile. Nutritional profiles will be established by the Commission and Member States based

⁷ The practice areas of our London and Brussels offices, Arnold & Porter (UK) LLP, and Arnold & Porter (Brussels) LLP, include competition and EU law, litigation, telecommunications, information technology, intellectual property, corporate, biotechnology, pharmaceutical regulatory, product liability, and health care. The offices’ clients include multinationals and European concerns ranging from start-ups to *Fortune 500* firms.

on the scientific opinion of the European Food Safety Authority (EFSA), within 24 months of the Regulation entering into force. However, producers will still be allowed to make a claim if a single nutrient exceeds the nutrient profile provided that the food is labeled to be high in that particular nutrient.

Health claims: The Commission will draw up a positive list of well-established “functional” health claims (i.e., a claim that refers to the role of a nutrient or other substance in growth, development, and the functions of the body, including psychological and behavioral functions), which may be used on any food so long as they are proven to apply to the food in question and the food complies with the relevant nutrient profile. The Commission will establish this list on the basis of claims submitted by Member States that were already approved at a national level within three years of the Regulation entering into force. Any claims submitted for the list after this three-year period will have to be examined by EFSA and approved by the Commission and Member States. The EFSA will use a simplified approval process if a producer wishes to make a functional health claim that is not on the list. However, the approval process will be more complex if the new claim is based on new scientific evidence, and all claims of disease risk reduction claims health benefits for children will require a specific authorization by the Commission, following scientific assessment and verification of the claim by EFSA.

Prohibited claims: References to general, nonspecific benefits of a nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim. Moreover, claims relating to the rate or amount of weight loss are prohibited, as are claims that refer to recommendations of individual doctors or health professionals.

Trademarks: The Regulation will apply to any trademark that can be construed as a health or nutritional claim. Existing brand names suggesting health benefits (such as promises of weight loss) that do not meet the requirements of the Regulation must be phased out and removed from the market within 15 years of the entry into force of the Regulation. No new trademarks or brand names that imply health or nutritional benefits will be allowed to be put on the EU market, unless the claims implied can be substantiated in line with the provisions of the Regulation. Certain generic descriptors, such as “digestives,” may however apply for derogation from this rule.

Alcohol: Food and beverages containing more than 1.2% alcohol will not be allowed to make health or nutritional claims under the Regulation, unless the claim refers to a reduction in alcohol or energy content (calories). This accords with the EU and Member States’ campaign to reduce or eliminate health problems associated with overconsumption of alcohol.