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Consumer Products Marketing

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, consumer product safety, and FDA. 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 or Amy.Mudge@aporter.com.

Consumer Protection Enforcement[1]

FTC to Review Marketing and Promotion of Carbon Offsets

Companies and individuals are becoming increasingly conscious of their carbon footprint—a measure of carbon dioxide emissions, which are believed to contribute to global warming, attributable to their activities. In addition to reducing their carbon footprint by reducing emissions, companies and individuals can voluntarily purchase "carbon offsets" to compensate for their carbon dioxide emissions. Carbon offsetting involves investment in an activity to reduce carbon emissions (such as by planting trees that capture carbon from the atmosphere) by an amount equal to the carbon emissions sought to be offset (such as emissions associated with air travel).

Products or services with "carbon neutral" or "reduced carbon footprint" claims are proliferating. Consumers may be confused by such claims, which are subject to challenge when they are not substantiated.

More than three dozen firms currently sell carbon offsets in the U.S., and the worldwide voluntary offset market has a volume of more than $100 million. Some believe that by 2010 voluntary offsets may achieve reductions of several hundred million tons of carbon dioxide per year. While offsets are modest compared to the estimated 25 billion tons of greenhouse gases emitted into the atmosphere every year by human activity, they nevertheless represent a significant economic market.

On July 18, 2007, the House Select Committee on Energy Independence and Global Warming, chaired by Rep. Edward Markey (D-Mass.), held a hearing on the market for voluntary carbon offsets. The Committee's hearing addressed the problems and challenges facing this largely unregulated market. In particular, the hearing focused on whether offset purchasers are really getting what they pay for and whether the federal government should regulate the market. After the hearing, Rep. Markey sent a letter to Federal Trade Commission Chairman Deborah Platt Majoras urging the FTC to update its Guides for the Use of Environmental Marketing Claims, 16 C.F.R. 260, the so-called "Green Guides," to address claims made by carbon offset providers about their products.

In her response to Rep. Markey's letter, Chairman Majoras revealed that FTC staff has been monitoring the developing

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carbon offset market and plans to hold a public workshop in early January 2008 to "seek input on the consumer protection issues raised by carbon offset sales and the need for more direct FTC guidance than that already provided by the Green Guides and other advertising directives." Continuing the FTC's theme of industry self-regulation, Chairman Majoras said that staff will look at self-regulatory efforts already underway. The letter indicates that any changes to the Green Guides will likely not occur until 2008, which corresponds to the Green Guides' regularly scheduled review. Chairman Majoras emphasized that even absent specific guidance on marketing and promoting carbon offsets, the advertising of such products still must be truthful, not deceptive, and substantiated.

In the forthcoming edition of the ABA's Antitrust Source, Arnold & Porter attorneys Randy Shaheen, Amy Mudge, and Matthew Shultz will publish an article discussing consumer protection issues in the marketing and sales of carbon offsets. This article will discuss how the FTC may analyze and address the concerns raised at the Committee's hearing on carbon offsets and in Rep. Markey's letter when the FTC takes a look at the voluntary offset market and reviews the Green Guides.

A&P Victory on Behalf of Fast Food Restaurants

Arnold & Porter LLP's New York Office attorneys recently won an important victory on behalf of the New York State Restaurant Association ("NYSRA") challenging a regulation that would have required New York City restaurants to post calorie content of their dishes on menus if they already published such information elsewhere on a voluntary basis.

The NYSRA prevailed on the grounds that some of the provisions of the regulation were preempted by federal law. The NYSRA argued that the city health regulation was superseded by the Federal Nutrition Labeling and Education Act of 1990, which sets forth guidelines for restaurants that voluntarily post caloric information. The judge found that since federal law already regulates the voluntary disclosure of caloric information, the city could make regulations for mandatory disclosure of such information but could not make conflicting regulations for voluntary disclosure. The NYSRA also presented First Amendment arguments, but the judge did not address those arguments because he found the preemption arguments conclusive.

This case involves one of more than a dozen similar public health laws that have been recently enacted across the United States. New York City maintains that it is now considering other options to achieve its goal of getting nutrition labeling on the city's restaurant menus.

Lanham Act[2]

Denigrating "Angus" Burgers

Jack In The Box unleashed an aggressive (and humorous) television advertising campaign suggesting that its "Sirloin" burgers are superior to the "Angus" meat used by competitors Carl's Jr. and Hardees. The ad campaign allegedly implied that

[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, Suzy Wilson, Randy Shaheen, and Roberta Horton.

the competitor's meat "comes from the rear-end and/or anus of beef cattle by creating phonetic and aural confusion between the words 'Angus' and 'anus.'" The ads did not make this claim expressly, but allegedly implied it. For example, one ad portrayed a fictional defendant employee asking the CEO if he could "point to the Angus area of the cow," and the CEO looks at the rear of the cow and replies, "I'd rather not."

Although Angus is a breed of cattle and not a particular cut of beef, a district court nevertheless denied plaintiff CKE Restaurants' motion for preliminary injunction because the survey offered by plaintiff used inappropriate leading and suggestive questions that rendered the survey useless. Because the survey was rejected, Plaintiff failed to furnish sufficient evidence of the implied message and therefore could not sustain its burden for a preliminary injunction. The case once again demonstrates that a plaintiff claiming an implied falsehood must, in most instances, even at the preliminary injunction phase, present a well-designed survey. *CKE Rest. v. Jack In The Box*, 494 F. Supp. 2d 1139 (C.D. Cal. July 2, 2007).

DirecTV Jessica Simpson/William Shatner Commercial—Injunction Affirmed by Second Circuit

In an important decision, the Second Circuit affirmed in part an injunction entered by the Southern District of New York in a case in which DirecTV claimed superior HD picture quality compared to cable. In the case, memorable television commercials featuring Jessica Simpson (as "Daisy Duke") and William Shatner's "Captain Kirk" made claims that DirecTV's HD "picture quality…beats cable" and "settling for cable would be illogical." DirecTV replaced these claims with a more innocuous "can't be beat" claim after the dispute began. In affirming the injunction in part, the Second Circuit adopted the "necessary implication" doctrine, *i.e.*, that an advertising claim can be "literally false"—even though it does not contain an expressly false assertion—as long as the words or images considered in context necessarily imply a false claim. For example, the phrase "settling for cable would be illogical," when viewed in context with the repeated references to HD picture quality, necessarily implied a false claim of superiority.

In addition to adopting the necessary implication doctrine, the Second Circuit issued two other rulings of note. First, the court held that "puffery" "encompasses visual depictions that, while factually inaccurate, are so grossly exaggerated that no reasonable consumer would rely on them in navigating the marketplace." In so holding, the court reversed a portion of the injunction that applied to an Internet ad comparing two television picture screens with the competitor service portrayed by a completely distorted image that was "unwatchable." The court held that no reasonable consumer would be fooled into thinking that cable television picture quality was this poor. Second, the court held that irreparable harm may be presumed if the plaintiff can demonstrate a likelihood of success as to a comparative advertisement. *Time Warner Cable, Inc. v. DirecTV*, 2007 WL 2263932 (2d Cir. Aug. 9, 2007).

Recent Filing: Are "Pulsating Bubbles" from New Pricey Toothbrush "Magic"?

Procter & Gamble recently filed a false advertising lawsuit in the U.S. District Court for the Southern District of New York against Ultreo, Inc., alleging false advertising. P&G challenged Ultreo's claim that its $169 "Ultrasound Toothbrush" creates "pulsating bubbles" which work like "magic" to "remove plaque bacteria found in the mouth." The challenged advertisements are principally targeted to dental professionals. P&G alleged that Ultreo has offered only in vitro studies to substantiate its claim, but these studies cannot be replicated in actual consumer use. In particular, P&G alleges that it conducted its own clinical studies with consumers that proved that the "bubbles" are not effective. The case was filed on September 27, 2007. *Procter & Gamble v. Ultreo, Inc.*, Civil Action No. 07-CIV- 8379 (S.D.N.Y. 2007).

Trademark[3]

Citation of Wikipedia Entries in Trademark Cases

A recent precedential Trademark Trial and Appeal Board ("TTAB") decision held that the TTAB would "consider

evidence taken from Wikipedia so long as the non-offering party has an opportunity to rebut that evidence by submitting other evidence that may call into question the accuracy of the particular Wikipedia information." *In re IP Carrier Consulting Group*, TTAB, Serial No. 78542726 (June 18, 2007). The TTAB recognized that "[t]here are inherent problems regarding the reliability of Wikipedia entries because Wikipedia is a collaborative website that permits anyone to edit the entries." *Id*. On the other hand, the TTAB considered that "Internet evidence is generally admissible and may be considered for purposes of evaluating a trademark." *Id*. The TTAB also cited the Southern District of New York's determination that "the information provided there [Wikipedia] is not so inherently unreliable as to render inadmissible any opinion that references it . . . ." *Id*. (quoting *Alfa Corp. v. OAO Alfa Bank*, 475 F. Supp. 2d 357, 362 (S.D.N.Y. 2007). The Wikipedia evidence in that case was used by the court in its determination of the definition of "IP." *Id*. The court used this information to discern whether the disputed marks "ipPICS" and "ipPIPE" were merely descriptive and therefore invalid trademarks. *Id*. The court went on to explain that "[t]he better practice with respect to Wikipedia evidence is to corroborate the information with other reliable sources, including Wikipedia's sources." *Id*.

Despite concerns about the reliability of Wikipedia and other online evidence, the US Patent and Trademark Office has previously stood firm in its determination "that questions of descriptiveness, misdescriptiveness, geographic descriptiveness, scandalousness, and other grounds for refusal under the Trademark Act are to be determined on the totality of the evidence of record" and that the TTAB "will ultimately determine what weight, if any, to bestow upon all of the evidence of record from whatever source it has been acquired." Letter from Lynne G. Beresford, Commissioner for Trademarks, United States Patent and Trademark Office, to Paul W. Reidl, President, International Trademark Association (Aug. 7, 2006), *available at* http://www.shapeblog.com/PTO%20Wikipedia%20Response%2008-07-06.pdf.

It appears that, despite the often questionable origins of Wikipedia evidence, it is here to stay in trademark cases. In light of the Patent and Trademark Office's decision to admit Wikipedia evidence, any person with a matter before the Patent and Trademark Office or a party to a trademark action in federal court should consider the evidence available on Wikipedia and be prepared to respond to it—either with contrary evidence to refute the entry or supporting corroborating evidence.

Privacy[4]

House and FTC Weigh Measures to Limit Use of Social Security Numbers

On July 16, the leaders of the Social Security Subcommittee of the House Ways and Means Committee introduced legislation designed to provide further protection for the privacy of Social Security numbers ("SSNs"). The bill, titled the Social Security Number and Privacy and Identity Theft Prevention Act of 2007 (H.R. 3046), would amend the Social Security Act to prevent private parties from selling or purchasing SSNs except in limited circumstances, such as for purposes of law enforcement (including child support

[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.

[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.

collection), national security, or public health protection. In addition, the bill would place new restrictions on the sale, use, or display of SSNs by the government. According to the bill's principal sponsor, Social Security Subcommittee Chairman Michael R. McNulty (D-NY): "It is time to place some common-sense limits on the use of Social Security numbers by government and businesses in order to reduce their easy availability and ensure the privacy of this sensitive information."

The proposed bill has triggered widespread concern in the financial services industry. In a letter to the House Ways and Means Committee, the Financial Services Coordinating Council (representing the American Bankers Association, the American Council of Life Insurers, and other industry associations) urged Congress to recognize that SSNs play a "critically important" role in the operation of financial institutions. The FSSC criticized the bill for imposing "inconsistent and in some cases duplicative requirements" that fail properly to take account of existing laws such as the Gramm-Leach-Bliley Act ("GLBA") and the Fair Credit Reporting Act. According to the industry, the restrictions in the bill would impair the ability of financial institutions "to combat fraud, identity theft, money laundering, and terrorist financing."

It is yet unclear if or how these industry concerns will be addressed. However, financial services providers and others who use SSNs are almost certainly going to face some new restrictions on how they handle this sensitive information. The connection between SSNs and identity theft has prompted the Administration, as well as Members of Congress, to take action aimed at private sector abuse of SSNs, including identity theft and fraud. In April 2007, the President's Identity Theft Task Force (formed in 2006 to address the issue) released a report, *Combating Identity Theft, a Strategic Plan*. The Task Force report acknowledges that the use of SSNs is "an integral part" of our financial system and "essential . . . in granting credit and detecting fraud." But, because of the risk of identity theft created by the use of SSNs, the report urges "federal agencies . . . such as DOJ, FTC, [and] SSA . . . to gather information from stakeholders . . . [and] then make recommendations to the President as to whether additional specific steps should be taken with respect to the use of SSNs."

In response to the Task Force report, the FTC issued a call for comments on the ways in which SSNs are used by members of the private sector. The comments submitted to the FTC, which were due on September 5, included a letter from the Financial Services Roundtable ("FSR"), an industry group that represents 100 of the largest integrated financial services companies, describing SSNs as the "only unique, permanent, universal individual identifier" available to businesses. With respect to the existing regulations that apply to the financial services industry, the FSR argued that existing laws such as the GLBA should be extended to other industries in order to ensure a "uniform, national standard across all industries."

There is widespread interest among consumers in the adoption of some means of enhanced protection for the privacy and security of SSNs. Consumers Union ("CU")—publisher of *Consumer Reports*—recently provided comments to the FTC stating that SSN regulations are a "policy measure that consumers would overwhelmingly support." CU's letter contains the results of a survey showing that a startling nine of out ten consumers are concerned about identify theft. According to the survey data, 95% of consumers strongly agree that companies should not be allowed to sell consumers' SSNs, while 99% agree that companies that hold SSNs should be required to protect them. Further, more than 90% of the survey respondents agree that when security of SSNs has been compromised, a company or government agency should provide consumers with a remedy to prevent ID theft, such as the ability to freeze spending on credit cards. With this level of consensus of among consumers, the recent activity at the FTC and the House of Representatives may well lead to a new legal framework governing the use of SSNs.

Consumer Product Safety Commission[5]

Lessons Learned: Reducing Safety and Liability Risks from Consumer Products

In light of the large numbers of consumer product recalls this year, most of which involved imports from China, many companies are wondering what steps they can take to help ensure that their products are safe. At the outset, however, it is important to understand that the key lesson from recent recalls is not that there is a China problem. Rather, recent recalls demonstrate the need to take care at each stage of a product's life cycle, as discussed below, no matter the product's origin.

1. Start with a robust design that addresses potential hazards: It's a given that a product will be designed to meet applicable mandatory industry standards. However, it is also important to attempt to design around potential hazards that are not subject to standards. Understanding why competitors have recalled their products is a good first step to avoid repeating the mistakes of others. For example, now that the potential hazard from toys with imbedded magnets is appreciated, companies can design around this issue to help ensure that the magnets do not come out through reasonably foreseeable use.
2. Proper instructions and warnings don't happen by accident: It can take considerable time and effort to develop proper instructions and warnings. Therefore, allow time in the product development process to craft instructions and warnings, and consider reassessing them after a product is on the market based on feedback concerning how the product is used in practice.
3. Choose vendors with care: Price is only one part of the picture. In some cases a company may benefit by reducing the number of vendors with whom it does business to a core of key suppliers to help ensure proper training and monitoring, as necessary. In addition, it is important to closely scrutinize and control the use of sub-contractors.
4. Adopt and follow manufacturing and change control procedures as well as procedures for production testing: Problems may arise if vendors substitute parts or components without proper documentation and testing, or if a properly designed product is not manufactured according to specifications. It is a safe bet that none of the companies that have recalled toys with lead paint specified such paint for their products, and that the companies would have rejected the products had the use of lead paint been known. Similarly, problems can arise if a vendor runs out of specified parts during production and substitutes parts that are inadequate for the job. While not every problem can be caught, proper change controls and production testing can reduce the risk that sub-standard or violative products will be distributed to consumers.
5. Choose labs (and samples) with care: Not all laboratories are created equal. Choose a qualified lab that has experience with the applicable standards. In addition, ensure that the samples being tested are representative of production units.
6. Collect, monitor, and assess post-market data from available sources: Incident reports—whether received from a company's own customers, from a vendor who has sold the same product to other companies, from CPSC or from other sources—as well as other sources of safety information, should be reviewed on an ongoing basis to identify potential problems. This is important to reduce the risk of injury from consumer products, and to comply with the duty to notify CPSC "immediately" of information that "reasonably supports the conclusion"

[5] Arnold & Porter has several attorneys with broad experience on matters involving the US 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.

that a product contains a defect that "could present a substantial product hazard." The risk of civil penalties if CPSC challenges decisions about whether and, if so, when to notify the Commission under this subjective standard is very real. Further, the maximum civil penalty is now $1.825 million, although under pending legislation this may jump to as much as $100 million and include criminal penalties for late reporting.

7. Understand who bears the risk of a recall or product liability claims: CPSC and plaintiffs in a product liability action may seek to hold responsible any party in the chain of distribution. However, a company should consider whether existing and future contracts allocate such risks appropriately among business partners and customers through indemnification provisions and suppliers' insurance agreements.
8. Obtain insurance from a company that will stand behind the policy: It is far more common for companies to have product liability insurance than recall insurance. Companies should carefully consider the level of risk for which they can afford to be self-insured. In addition, it is important to obtain insurance—whether directly or when it is obtained for a company by one of its suppliers—through a carrier that is likely to remain solvent when claims arise.
9. Consider conducting a product safety assessment: A self-assessment can help ensure that a company's policies and practices are adequate and being followed.

While not all problems can be avoided and there is no "one size fits all" approach to product safety, keeping the above points in mind can help reduce risks to consumers, a company's reputation and the bottom line.

Food & Drug Administration[6]

Third Circuit Finds FDA Preemption of Claims Under State Law

The Third Circuit has held that false advertising claims targeting prescription drug marketing that were brought under state consumer protection laws are preempted by federal law.

In *Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc.*, 499 F.3d 239 (3d Cir. 2007), the court dismissed a consumer class action brought under state consumer protection laws on the grounds that the FDA has exclusive authority to regulate pharmaceutical advertising. This decision is the most expansive interpretation of FDA preemption of state laws in the area of pharmaceutical advertising to date, and the only decision on this issue thus far by a Court of Appeals.

Plaintiffs in *Pennsylvania Employees* alleged that Zeneca's advertising for Nexium was unlawful advertising under the Delaware Consumer Fraud Act, 6 Del. Code. Ann. § 2513, and deceptive under the consumer protection laws of the fifty states. Specifically, Plaintiffs challenged Zeneca's claims that Nexium was more effective in treating acid reflux and heartburn that its predecessor Prilosec, which had gone off patent in 2001. Clinical trials had demonstrated 40 mg of Nexium to be more effective that 20mg of Prilosec, but plaintiffs argued that no trial had been done with comparable dosages, and that few consumers would require a 40 mg dosage of Nexium. Defendants responded that the state consumer protection laws at issue were preempted by the FDA's regulation of pharmaceutical advertising.

The *Pennsylvania Employees* court found the claims to be preempted. Considering the "degree of discretion inherent in the [FDA] regulations" the court found that the FDA "envisioned itself occupying an ongoing and extensive role in the supervision of prescription drug advertising." The court found "[a]n even stronger" case for preemption" in cases where "FDA-approved labeling is the basis" for the false advertising claims, because of the "essential affinity"

[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; Greg Levine; and Kathy Means (a Senior Health Care Policy Advisor).

between advertising and labeling that is evident in the FDA regulations. The *Pennsylvania Employees* court therefore concluded that "the high level of specificity in federal law and regulations with respect to prescription drug advertising is irreconcilable with general state laws that purport to govern all types of advertising."

The ramifications of *Pennsylvania Employees* are difficult to predict. Most immediately, the decision suggests that the Third Circuit may also find preemption in *Collacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006), a case currently on appeal that raises the issue of whether claims that the antidepressant Zoloft should have been labeled with additional warnings are preempted by FDA regulations. More broadly, the decision marks the first decision by a Court of Appeals to agree with the FDA's position that "under existing preemption principles, FDA approval of labeling . . . preempts conflicting or contrary State law." *See* 71 Fed. Reg. 3922 (Jan. 24, 2006). However, *Pennsylvania Employees* also raises the specter of a circuit split, because numerous district courts have recently considered the same issue and found no FDA preemption. *See, e.g., Sarli v. Myland Bertek Pharm., Inc.*, 2007 WL 2111577 (M.D.N.C. July 19, 2007); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230 (E.D.N.Y. June 11, 2007); *McNellis v. Pfizer, Inc.*, 2006 WL 2819046 (D.N.J. Sept. 29, 2006). Moreover, the law may only become murkier, as the recently passed Food and Drug Administration Amendments Act of 2007 contained a provision stating that drugmakers have a "duty" to update the labeling of products previously approved by the FDA. The potential effect of this provision on preemption cases, if any, is unclear. Thus *Pennsylvania Employees*, while a point in favor of preemption, is likely to be only the beginning of a larger debate about FDA preemption of claims under state advertising laws.

FDA Proposes Sunscreen Labeling System

On August 27, 2007, the FDA issued a long-awaited proposed rule to establish standards for the testing and labeling of over-the-counter ("OTC") ultraviolet A ("UVA") and ultraviolet B ("UVB") sunscreen products. Under the proposed rule, sunscreen manufacturers will be required to mark sunscreen packaging with between one star (lowest protection) and four stars (highest protection) to denote the products' effectiveness in blocking UVA exposure. This UVA labeling requirement will be in addition to the traditional sun protection factor ("SPF") rating system, which measures a sunscreen's ability to block UVB rays. To clarify the difference between the two rating systems, the proposed rule specifies that the phrase "UVA" be included next to the new star-based rating, while the term "UVB" will appear near the SPF rating.

The proposed rule also imposes additional labeling requirements. For example, sunscreen products that contain no protection against UVA rays will be required to carry the label "No UVA Protection" on the front of the bottle. Moreover, the required Drug Facts box on each package must contain the statement, "UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage." A bottle of sunscreen and the drug fact box manufactured and labeled pursuant to the new regulation will look like this:

Drug Facts

Active ingredients	**Purpose**
Avobenzone 3% Homosalate 10% Octinoxate 7.5%	Sunscreen

Uses
- high UVB sunburn/UVA protection
- for skin highly sensitive to sunburn
- retains SPF after 80 minutes of activity in the water

Warnings
For external use only

UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if skin rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions
- apply liberally before sun exposure
- apply and reapply as directed to avoid lowering protection
- reapply after 80 minutes of swimming or sweating and after towel drying. Otherwise, reapply at least every 2 hours.
- children under 6 months: ask a doctor

Inactive ingredients alphabetical listing of ingredients

Questions or comments? call toll free **1-800-XXX-XXXX**

The proposed rule is the latest step in a prolonged rulemaking. FDA began the sunscreen rulemaking in 1978 and issued a tentative final monograph in 1993. In the Food and Drug Modernization Act of 1997, Congress ordered FDA to issue

regulations within eighteen months for OTC sunscreen products for the treatment or prevention of sunburn. In May 1999, FDA published a final monograph governing sunscreen ingredients and labeling requirements for protection from UVB rays. In response to comments from industry and consumer groups, however, FDA stayed the implementation of the rule indefinitely until it could issue standards for protection from UVA rays. The stay has remained in effect and will only expire when the FDA publishes final regulations governing UVA and UVB protection in sunscreen. Even then, however, the final regulations will not become effective until eighteen months after publication in the Federal Register.

The proposed rule also calls for comments about the safety and effectiveness of sunscreen ingredients that utilize nanotechnology. This call for comments comes on the heels of a similar call for comments, issued in February of 2007, on the usage of nanotechnology in insect repellents that contain sunscreen ingredients. Both of these notices followed the filing of a citizen petition in May 2006 requesting that FDA re-examine the use of nanoscale materials in sunscreens. Although a recent report from FDA's Nanotechnology Task Force suggests that the agency is not, as a general matter, planning any near-term regulatory actions with respect to nanotechnology products, sunscreens clearly are a focus of the agency's current information-gathering activities in this emerging field.