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Developments in Food and Dietary Supplement Enforcement

By Mark Mansour and Emily Strunk

Food and dietary supplements continued to be a particular focus of FDA regulation and enforcement in 2015. Based on Warning Letters and other data, enforcement in these areas is largely targeting product safety and accurate labeling. Over the course of the year, FDA issued a large volume of Warning Letters, for violations primarily related to manufacturing standards and marketing claims, and secured a handful of injunctions against manufacturers. In November, a multi-agency crackdown on outlier dietary supplement manufactures announced civil and criminal charges against more than 100 supplement firms. Meanwhile, consumer-driven litigation continues to serve as a de facto enforcement mechanism in areas where FDA has refused to clarify regulations.

In 2015, FDA also issued the most important final rules implementing the Food Safety Modernization Act (FSMA), which FDA will begin enforcing next fall when the first of several rolling compliance deadlines will come to pass. In a surprising move, FDA also requested comments on whether and how the agency should define "natural," a term that FDA has not traditionally enforced, but has great potential for enforcement action given its widespread and inconsistent use.

All of these events have resulted in greater attention to these issues within the industry, trade associations, and the media. To understand the agency's enforcement priorities, we will review recent trends in food and dietary supplement enforcement, then examine current major initiatives, and look forward at how enforcement is likely to develop over the next several years.

Recent Trends in Food and Dietary Supplement Enforcement

Dietary Supplements

FDA continues to aggressively target dietary supplement companies, focusing primarily on marketing claims and illegal ingredients. In April and November of 2015, FDA carried out three Warning Letter initiatives against a total of 24 dietary supplement manufacturers for products that contained one of three targeted ingredients[1] that FDA considers illegal because they do not qualify as a "dietary ingredient" under the 1994 Dietary Supplement Health and Education Act (DSHEA). Other Warning Letters to dietary supplement firms were for (1) marketing products with claims that rendered the product a drug under the Federal Food Drug and Cosmetic Act (FDCA) because the products claimed to cure, mitigate, treat, or prevent disease; (2) making therapeutic claims in promotional materials and on the company website; or (3) violating current good manufacturing practice (CGMP) regulations, mostly related to identity, purity, strength, and composition of the finished batch.

In addition to Warning Letters, FDA successfully pursued at least five injunctions that resulted in either a court-ordered injunction against or a consent decree with several smaller dietary supplement manufacturers. These injunctions were for the most egregious violations. For example, one company made unsubstantiated claims that its product could treat serious diseases such as Alzheimer's, autism, and fibromyalgia. FDA warned the company of the violations in 2010, but the firm failed to remedy the violations for several years before FDA began seeking injunctive relief.

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The year culminated with two major game changers in dietary supplement regulation: a multi-agency crackdown on certain firms and a new FDA office to enhance oversight of dietary supplements. On November 17, 2015, seven federal agencies, spearheaded by the U.S. Department of Justice (DOJ), collectively announced that a federal crackdown on unsafe or illegally marketed supplements had resulted in civil injunctions and criminal actions against 117 firms manufacturing or marketing dietary supplements or tainted products purporting to be dietary supplements.[2] Although DOJ led the charge, FDA, the Federal Trade Commission (FTC), the U.S. Postal Inspection Service, the Internal Revenue Service, the Department of Defense, and the U.S. Anti-Doping Agency were all involved. Although FDA and FTC often issue joint Warning Letters, and FDA also works with DOJ on a regular basis, the participation of the four other agencies was unprecedented and extraordinary. The press conference highlighted enforcement action against USPlabs, detailing the 11-count indictment charging the dietary supplement company, its executives, and its collaborators with a variety of offenses related to the sale of its products, including falsifying documents, mislabeling and manipulating marketing materials, and making misrepresentations to promote its products.

On December 21, 2015, FDA announced a new Office of Dietary Supplement Programs (ODSP), separating the program from nutritional labeling to enhance the agency's ability to regulate dietary supplements. In an agency press release,[3] FDA highlighted enforcement activities as a main driver of the office. Specifically, FDA emphasized that ODSP will enforce GMPs, work with FDA's Center for Drug Evaluation and Research (CDER) to remove products that potentially contain harmful pharmaceutical ingredients, and take action to remove products that are dangerous to consumers, make egregious claims, or involve potential economic fraud.

Food

Rigorous enforcement of food manufacturing standards continued throughout 2015. Consistent with current agency programs to combat antibiotic resistance and for safe seafood, FDA issued the vast majority of food-related Warning Letters to dairies and seafood processors. One of the goals of FDA's initiative to combat antibiotic resistance, which is part of the White House's National Action Plan for Combating Antibiotic-Resistant Bacteria, is to eliminate the use of antibiotics for growth promotion in food animals. FDA cited more than 74 dairies for violations involving antibiotic use in animals (e.g., illegal drug residues) and at least one dairy was the subject of a consent decree resulting from illegal levels of drug residues. In summer 2015, FDA finalized the Veterinary Feed Directive rule, which requires veterinarians to supervise antibiotic use in animals intended for food to ensure antibiotics are only used when necessary for animal health.[4] In spite of increased enforcement in this area, FDA published a report[5] in December, 2015 finding that sales and distribution of antibiotics for food-producing animals actually increased from 2013 to 2014, which may lead the agency to redouble efforts in this area as FDA attempts to meet federal antibiotic resistance imitative goals. Shortly after FDA published the report, it announced a consent decree against a Vermont dairy farm for illegally administering drugs to cattle.

Second only to dairies, seafood processors also received a significant number of Warning Letters for failures to comply with the fish and fishery products Hazard Analysis Critical Control Point (HACCP) regulations. The agency additionally issued Warning Letters throughout the year for CGMP violations specific to low-acid canned food and bottled water.

Truthful and accurate labels also continue to be an FDA priority. In 2015, the agency issued Warning Letters to food companies for undeclared allergens, improper nutrient content or health claims, and failures to declare ingredients or correctly format nutritional information.

Current Initiatives in Food and Dietary Supplement Enforcement

In November 2015, FDA called for comments on whether and how the agency should define "natural,"[6] one of the largest looming questions for food marketers and at issue in food advertising litigation. Because "natural" products have so much appeal to consumers, food companies are interested in producing and marketing natural products. However, FDA has only hinted at how the agency might define the term, and rarely enforces against its use—usually only for added color or an obviously synthetic ingredient. Some companies have defaulted to the U.S. Department of Agriculture (USDA) definition of

"minimally processed," which is an imperfect solution because USDA's authority does not extend to FDA-regulated foods. To fill the regulatory gap, consumers, through organizations and class-action suits, have used the court system to attempt to enshrine their own definition of natural. In an attempt to decide cases in a manner consistent with the law, courts have sought guidance from FDA, which has repeatedly declined requests to define the term. In addition to court requests, three citizen petitions have asked FDA to define "natural," and this appears to be one impetus for the recent request for comments from stakeholders. Even if FDA decides to issue a formal definition of "natural," it is unlikely to be a swift process and enforcement of an FDA-sanctioned definition is probably years away at best. However, the agency's interest in the subject is consistent with prioritizing enforcement against what it perceives as misleading marketing claims. We can only expect to see more of this in the future.

Related to FDA's failure to define controversial food label terms, courts are increasingly being asked to decide whether certain terms are appropriate on the label, particularly regarding use of the terms "natural" and "evaporated cane juice" (ECJ). Although many courts have issued stays hoping FDA will soon clarify the definitions of these terms, any decisions in these cases will essentially amount to de facto enforcement because food companies will need to consider those outcomes in their compliance efforts. Despite requests from courts, FDA had previously declined to define "natural," referring judges to nonbinding policy language in various agency materials. Now that FDA has opened a docket for comments on this issue, food companies defending their use of the term will likely seek stays on their cases pending an FDA determination. However, because FDA has not promised any action on the issue, it remains to be seen whether courts will grant such motions. On the issue of ECJ, in June 2015, a Federal Judge in California asked FDA to "inform the Court whether a final determination regarding ECJ is feasible within agency priorities and resources."[7] FDA responded that it would issue a final guidance by the end of 2016.[8] Food companies defending their use of the term ECJ have largely been successful in staying cases pending FDA's promised action. In either case, any further definition of "natural" or "ECJ" by FDA will probably have a significant impact on pending suits as judges should defer to the agency definition.

Future Outlook in Food and Dietary Supplement Enforcement

FDA food and dietary supplement enforcement trends will likely continue to focus on safe ingredients and truthful marketing, with a particular emphasis on any terms that FDA comes to define in the coming years; potential examples include "natural" and "evaporated cane juice."

In the last half of 2015, FDA finalized the most significant FSMA rules, historically changing the regulatory landscape of safety for foods produced and grown domestically, as well as those imported from abroad. Compliance deadlines are staggered over the next several years, with the earliest deadline in September 2016 for food producers subject to the first deadline in the preventive controls rule.[9] While the rules officially establish higher standards for food safety with a focus on prevention, many food companies have been operating at equivalent, or in many cases at higher, standards. As compliance becomes required, we expect FDA to more carefully inspect firms for specific violations of the FSMA regulations and, if major violations are found, to enforce swiftly. As was the case when its mandatory recall authority became effective, FDA will likely want to demonstrate that it expects industry to take compliance seriously. This will almost certainly impose the greatest burden on medium- and small-sized companies, as well as their international suppliers.

Finally, the recent multiagency crackdown on bad actors in the dietary supplement industry is not likely a final culmination of agency efforts, but rather intended to be a message to industry that this is only the beginning. The federal government is sending a message that chronic and blatant noncompliance will not be tolerated, particularly when it involves illegal or unsafe substances in products being marketed as dietary supplements. We can expect these agencies to continue to collaborate to remove such products from the marketplace and hold responsible the people and companies selling them.

All of the above will be accompanied by a concurrent emphasis by FTC on marketing and advertising claims. Social media attention is likely to increase, as is the growing interest in testimonials, celebrity speeches, and other new media. While enforcement by both agencies shifts from time to time, we can expect FDA's resources to

be directed toward FSMA and food and dietary supplement safety enforcement, with as much attention on labeling and claims as resources permit.

1. BMPEA in Dietary Supplements, April 27, 2015, http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm443790.htm; DBMA in Dietary Supplements, April 28, 2015, http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm444719.htm; Picamilon in Dietary Supplements, December 2, 2015, http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm472881.htm.
2. DOJ Press Release, Justice Department and Federal Partners Announce Enforcement Actions of Dietary Supplement Cases, http://www.justice.gov/opa/pr/justice-department-and-federal-partners-announce-enforcement-actions-dietary-supplement-cases.
3. FDA Constituent Update, FDA Creates the Office of Dietary Supplement Programs and Announces New Nutrition Office Leadership, http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm478303.htm.
4. FDA Press Release, FDA Regulation to Help Ensure Judicious Use of Antibiotics in Food-Producing Animals, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm448446.htm.
5. FDA Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals (December 2015), http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM476258.pdf.
6. Use of the Term 'Natural' in the Labeling of Human Food Products; Request for Information and Comments, 80 FR 69905-01(Nov. 12, 2015); https://www.federalregister.gov/articles/2015/11/12/2015-28779/use-of-the-term-natural-in-the-labeling-of-human-food-products-request-for-information-and-comments.
7. J. Chen Order Re. FDA Action and Referral to Comm'r, Swearingen v. Late July Snacks, No. C-13-4324 (N.D. Cal. May 5, 2015).
8. HHS Letter, Swearingen v. Late July Snacks, No. C-13-4324 (N.D. Cal. July 16, 2015).
9. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 80(228) FR 74255 (Nov. 27, 2015); https://www.federalregister.gov/articles/2015/11/27/2015-28158/foreign-supplier-verification-programs-for-importers-of-food-for-humans-and-animals. For compliance dates, see FDA Fact Sheet, FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm.