Monday, November 26, 2018

The Dietary Supplement Health and Education Act of 1993 (DSHEA) was intended to provide a framework for FDA to regulate dietary supplements. DSHEA established a new category of permitted claims for dietary supplements called “statements of nutritional support.” Claims of mitigating or treating a disease, however, are “drug claims” and are not permitted on products marketed as dietary supplements. As reported on this blog, FDA has recently stepped up enforcement action against kratom dietary supplements with label claims indicating they are drugs, as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (namely, opioid use withdrawal in the case of the kratom products).

Last week FDA posted warning letters issued to two companies for the illegal marketing of products labeled as dietary supplements that contain tianeptine, a chemical compound that companies claim treats opioid use disorder (OUD), pain and anxiety, and other conditions. As was the case with kratom, FDA actions against products containing tianeptine follow reports of serious adverse events associated with the use of the dietary supplement products.

In a November 20, 2018 press release, FDA Commissioner Scott Gottlieb characterized the action against tianeptine as part of a broader effort to protect consumers from products illegally marketed as dietary supplements and he promised an upcoming announcement of a new FDA enforcement policy. Further, Dr. Gottlieb indicated that FDA is re-examining its resources and authorities related to products marketed as dietary supplements.

FDA’s actions against opioid-related dietary supplements harkens back to its release on November 9, 2004 of a “strategy for dietary supplements (discussed here) that followed enforcement action against products containing androstenedione. FDA’s 2004 strategy has three prime components: (1) monitoring and evaluating product and ingredient safety; (2) assuring product quality; and (3) monitoring and evaluating product labeling. Since FDA is faced with statutory limits on its authority to regulate dietary supplements, the major effect of FDA’s revamped strategy is likely to be the devotion of more resources to enforcement efforts. At the very least, product manufacturers can expect FDA to increase its scrutiny of claims made for dietary supplements and to be more aggressive in pursuing enforcement action against products that do not meet the current standards.

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