FDA NEWS RELEASE

Federal Judge Enters Consent Decrees Against Utah-Based Dietary Supplement Distributor and Manufacturer of Balance of Nature Products

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Español (https://www.fda.gov/news-events/press-announcements/un-juez-federal-dicta-decretos-de-consentimiento-contra-el-distribuidor-de-suplementos-nutricionales)

Yesterday, the U.S. Food and Drug Administration announced that a dietary supplement distributor, manufacturer, and two executives have been ordered by a federal court to stop producing and selling their products until they come into compliance with federal regulations and requirements under the Federal Food, Drug, and Cosmetic Act.

The U.S. District Court for the District of Utah, Central Division has entered two consent decrees of permanent injunction against Evig LLC, of St. George Utah, and the company's CEO, Douglas Lex Howard, as well as Premium Production LLC, of St. George, Utah, and its Manager, Ryan Petersen.

Balance of Nature products are marketed as dietary supplements, with labeling that rendered them unapproved new drugs and misbranded drugs. The FDA has not approved Balance of Nature products for any use, despite the company's claims that its products could be used to diagnose, cure, mitigate, treat, or prevent diseases such as cancer, heart disease, cirrhosis, diabetes, asthma, and COVID-19. In addition, Evig LLC violated current good manufacturing practice (CGMP) requirements, which rendered its products adulterated dietary supplements. Evig distributes Balance of Nature dietary supplement products through Amazon, Walmart, and its own online store at www.balanceofnature.com.

Premium Production LLC and Mr. Petersen manufactured Balance of Nature products in violation of multiple CGMP requirements, such as failing to establish ingredient and finished products specifications for identity, purity, strength, and composition, which rendered them adulterated dietary supplements.

"This FDA action ensures that dietary supplements distributed to American consumers are appropriately labeled, lawfully manufactured, and prevents products that potentially put people's health at risk with unproven claims to cure, treat or prevent a serious illness," said Michael C. Rogers, the FDA's Acting Associate Commissioner for Regulatory Affairs. "We previously warned Evig LLC and Premium Production LLC, but they have demonstrated repeated violations of manufacturing requirements, and the public cannot have confidence that their products are what they purport to be. The FDA will continue to protect the U.S. public health by taking appropriate actions when companies violate the law."

In 2019, the FDA issued warning letters to Evig LLC (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/evig-llc-dba-balance-nature-580888-08202019) and Premium Production LLC (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/premium-production-llc-579705-07292019) after facility inspections identified CGMP violations at both companies' facilities. The warning letter to Evig LLC also informed the company that a review of its Balance of Nature website revealed that its products as labeled were unapproved new and misbranded drugs because they were intended to cure, mitigate, treat, or prevent disease. Following the 2019 warning letters, FDA inspections showed that the firms failed to address the deviations and come into compliance with the FDA's requirements. Based on the firms' continued violations, the FDA pursued injunctions against the firms.

"Products intended to treat or cure diseases require FDA approval," said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division. "Dietary supplement makers also must abide by federal health and safety requirements. The Department will continue to work closely with FDA to stop the distribution of unapproved, adulterated, and misbranded dietary supplements."

The consent decrees prohibit Evig LLC and Premium Production LLC from distributing or manufacturing products until they are in compliance with CGMP and labeling regulations. Under the consent decrees, both firms must hire CGMP experts, submit documents demonstrating compliance, and receive the FDA's approval to resume operations. In addition, Evig LLC must hire a labeling expert to ensure their products are no longer considered new and/or misbranded drugs.

The U.S. Department of Justice filed the complaints on behalf of the FDA.

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, radiation-emitting electronic products, and for regulating tobacco products.

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