FDA News Release

Federal judge approves consent decree with California dietary supplement maker

Health One Pharmaceuticals, Inc., failed to follow FDA manufacturing practice regulations

For Immediate Release

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Release

A California dietary supplement manufacturer was ordered by a federal court to stop selling its products until the company comes into compliance with the U.S. Food and Drug Administration's dietary supplement manufacturing regulations and other requirements listed in the consent decree.

U.S. District Judge Beverly Reid O'Connell of the Central District of California signed a consent decree of permanent injunction against Health One Pharmaceuticals, Inc., of City of Industry, California, and Richard S. Yeh, the firm's president and owner on January 15, 2015.

Health One Pharmaceuticals, Inc., is a private label and contract manufacturer of dietary supplements.

As part of the decree, Health One Pharmaceuticals and Richard S. Yeh represented to the court that they have already ceased manufacturing and distributing all articles of food, drugs and dietary supplements.

The decree requires Health One Pharmaceuticals, under FDA supervision, to recall and destroy all dietary supplements that were manufactured, prepared, packed, labeled, held or distributed between September 1, 2011, and January 15, 2015.

"When a company puts consumers at risk, the FDA will take action to protect public health," said Melinda K. Plaisier, FDA associate commissioner for regulatory affairs. "Our goal is to ensure that consumers have access to dietary supplements that meet federal standards for safety and quality."

FDA issued Health One Pharmaceuticals a warning letter on March 28, 2012, that outlined serious violations of FDA's current good manufacturing practice (cGMP) requirements. The violations included failure to perform tests to verify the identity of dietary ingredients used to manufacture the supplements; failure to establish appropriate manufacturing controls; and failure to maintain, clean and sanitize equipment.

Despite assurances from Health One Pharmaceuticals that it was correcting the violations noted in the warning letter, follow up inspections showed that the company failed to correct all of the manufacturing violations. Failure to follow cGMP requirements made the firm's products adulterated under the Federal Food, Drug, and Cosmetic Act.

According to the complaint filed with the court, certain dietary supplements manufactured by Health One Pharmaceuticals also were not properly labeled because the labels did not list the common or usual names of all product ingredients.

In order to resume operations, Health One Pharmaceuticals needs to receive permission from the FDA and hire an independent expert to assess whether the firm is in compliance with cGMP requirements. Audit reports documenting compliance with FDA manufacturing regulations then need to be filed with the agency biannually for at least five years.

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, products that give off electronic radiation, and for regulating tobacco products.