

Cardio Renew FDA Compliance

The FDA & Dietary Supplements

It is important to note that the U.S. Food & Drug Administration (FDA) regulates dietary supplements under different guidelines than those governing foods and prescription and over-the-counter drugs.

The Dietary Supplement Health and Education Act of 1994 states that the manufacturer of a dietary supplement is responsible for ensuring that their product is safe prior to marketing it; manufacturers generally do not need to register their products with the FDA or receive FDA approval before producing or selling their products. Manufacturers must also ensure that all product label information is truthful and not misleading.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act") included a provision classifying dietary supplements as "food" under section 1.227. This classification is also included in the Food, Drug, and Cosmetics Act (FDCA). The provision included in the Bioterrorism Act mandates that dietary supplement companies that manufacture or warehouse supplement products must be FDA-registered.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act") included a provision classifying dietary supplements as "food" under section 1.227. This classification is also included in the Food, Drug, and Cosmetics Act (FDCA). The provision included in the Bioterrorism Act mandates that dietary supplement companies that manufacture or warehouse supplement products must be FDA-registered.

The FDA is responsible for taking action against any unsafe dietary supplement after it reaches the market. Other FDA responsibilities include product information, such as labeling, packaging inserts, claims, and accompanying literature.

Cardio Renew's FDA Compliance

The FDA has completed an evaluation of Cardio Renew, which classified our product as a dietary supplement. We were found to be in compliance with all applicable FDA rules and regulations, including, but not limited to, those named above. This is claim few of our competitors can make, and Cardio Renew is proud to hold this distinction.

Visit [here](#) to read more about our close out letter from the FDA.

Regrettably, the FDA does not permit Cardio Renew (or any company) to discuss or expound on any specific health benefits that EDTA chelation may offer.

* source: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108938.htm>