



## FDA NEWS RELEASE

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**Media Inquiries:** Tamara Ward, 301-796-7567; [Tamara.Ward@fda.hhs.gov](mailto:Tamara.Ward@fda.hhs.gov)

**Consumer Inquiries:** 888-INFO-FDA

### **FDA: Minnesota companies agree to halt sale of amino-acid products with unapproved claims**

*Websites touted products as cure or treatment for diseases*

The U.S. Food and Drug Administration announced today that two Minnesota companies have agreed to halt distribution of amino-acid products marketed to treat a number of diseases, until requirements of the Federal Food, Drug, and Cosmetic Act are met.

West Duluth Distribution Co., a corporation doing business as CHK Nutrition, and NeuroResearch Clinics Inc., both of Duluth, Minn., and their owners or principals, signed a consent decree of permanent injunction, which was entered by the U.S. District Court for the District of Minnesota on September 13.

The complaint for permanent injunction alleges that the companies violated the Federal Food, Drug and Cosmetic Act. As alleged in the complaint, CHK Nutrition's amino-acid products are marketed with claims that they may cure, mitigate, or treat diseases. The products are not the subject of approved new drug applications nor do they qualify for exemption from the premarket approval process as investigational new drugs. Therefore, the amino-acid products are unapproved new drugs within the meaning of the Act.

The consent decree prohibits the defendants from distributing any of their amino-acid products into interstate commerce unless and until they remove the drug claims from their websites. The defendants also agreed to hire an expert to review the claims they make for their products and certify that they have omitted all violative claims. Under the decree, FDA can order the defendants to stop distributing their amino-acid products if they fail to comply with the Act or the terms of the decree.

"By ensuring that CHK Nutrition and NeuroResearch can't distribute these unapproved products, FDA is helping to prevent health risks for consumers that might take these drugs or delay other important treatments," said Dara A. Corrigan, the FDA's associate commissioner for regulatory affairs. "Until these companies meet FDA requirements, they will no longer be able to process or distribute their products."

The FDA conducted an inspection of CHK Nutrition and NeuroResearch Clinics in July 2010. During that inspection, an FDA investigator observed evidence of the coordination

of the sale of CHK Nutrition's products with claims that such products are effective treatments for "neurotransmitter diseases."

In September 2010, the FDA reviewed CHK Nutrition's website and observed a link to NeuroResearch Clinics' website containing extensive discussions about "amino-acid therapy" for the treatment of Parkinson's disease, Alzheimer's disease, depression, obsessive-compulsive disorder, attention-deficit hyperactivity disorder, fibromyalgia, and others.

Despite FDA warnings to stop making unapproved drug claims, CHK Nutrition and NeuroResearch Clinics did not do so. The FDA conducted a follow-up review of the companies' websites in February 2011 and found an ongoing connection between the sale of CHK Nutrition's products and claims that they can be used to treat diseases. The FDA believes that, unless restrained by a court, the companies would continue to violate the law.

For more information:

[Dietary Supplements](#)

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.