



FDA News

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FDA Completes Final Analysis of "Total Body Formula" and "Total Body Mega Formula" Products

Testing reveals high chromium levels in addition to selenium

The U.S. Food and Drug Administration's final analysis of certain flavors of "Total Body Formula" and "Total Body Mega Formula" has detected hazardous amounts of chromium.

On April 9, 2008, the FDA reported the dietary supplement products contained hazardous amounts of selenium in samples of "Total Body Formula" in Tropical Orange and Peach Nectar flavors and "Total Body Mega Formula" in the Orange/Tangerine flavor. (<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01818.html>) Further FDA analysis of the products found high levels of chromium as well. The samples contained up to 3,426 micrograms of chromium for the recommended serving (17 times the recommended intake). The recommended chromium intake for an adult ranges from 35 to 45 micrograms per day.

Excessive consumption of chromium can cause fatigue, muscle cramps, hyperactivity, hypoglycemia, renal failure and liver toxicity. Excessive chromium intake also can interfere with certain medications.

The new FDA finding comes as the U.S. Centers for Disease Control and Prevention (CDC) reports that the number of confirmed cases of adverse reactions in consumers using the products has climbed to at least 201 individuals in Alabama, Florida, Georgia, Kentucky, Michigan, New Jersey, North Carolina, Tennessee, Texas and Virginia.

Consumers were first cautioned March 27, 2008 not to purchase and to discontinue the use of "Total Body Formula" in Tropical Orange and Peach Nectar flavors and "Total Body Mega Formula" in the Orange/Tangerine flavor after receiving reports of adverse reactions. (<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01812.html>).

The FDA continues to investigate how excessive amounts of selenium and chromium got into the products.

The sole distributor of the "Total Body Formula" and "Total Body Mega Formula" products has voluntarily recalled the affected products.

Consumers who have been taking the products and have experienced adverse reactions should consult their health care professional. Consumers and health care professionals are encouraged to report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/how.htm.

More information about selenium and chromium and toxic effects of excessive intake is available from the CDC and the Agency for Toxic Substances and Disease Registry at: <http://www.atsdr.cdc.gov/>.

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