



U.S. Food and Drug Administration

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FDA News

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FDA Warns Consumers about "Total Body Formula" and "Total Body Mega Formula"

Distributor recalls dietary supplement products after reports of adverse reactions

The U.S. Food and Drug Administration is advising consumers not to purchase or consume Total Body Formula in the flavors of Tropical Orange and Peach Nectar, or Total Body Mega Formula in the Orange/Tangerine flavor. The liquid dietary supplement products may cause severe adverse reactions, including significant hair loss, muscle cramps, diarrhea, joint pain and fatigue.

The Total Body Formula products are sold in eight-ounce and 32-ounce plastic bottles. The Total Body Mega Formula is sold in 32-ounce plastic bottles. Both products are distributed by Total Body Essential Nutrition of Atlanta. The company is the sole distributor of the products and has voluntarily recalled Total Body Formula in the flavors of Tropical Orange and Peach Nectar and Total Body Mega Formula in Orange/Tangerine flavor.

The Florida Department of Health recently provided reports to the FDA on 23 individuals who experienced serious reactions to these products seven to 10 days after ingestion. In all cases, the reactions included significant hair loss, muscle cramps, diarrhea, joint pain and fatigue. The FDA subsequently learned and is investigating a report that some individuals in Tennessee using the same products have experienced similar reactions.

FDA laboratories are analyzing samples of the products to identify the cause of the reactions, including the possibility that the products contain excessive amounts of selenium, which is known to cause symptoms such as those described in the adverse events reported to the agency. Selenium, a trace mineral, is needed only in small amounts for good health.

The products have been distributed in Alabama, California, Florida, Georgia, Kentucky, Louisiana, Michigan, Missouri, New Jersey, North Carolina, Ohio, Pennsylvania, Tennessee, Texas and Virginia.

The FDA is advising consumers in all states to avoid using the products immediately and to discard the products by placing them in a trash receptacle outside of the home.

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

The FDA is working with the Florida Department of Health in its investigation.

For more information, consumers can call the FDA's toll-free Food Safety Hotline at 1-888-SAFEFOOD.

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