

State of Montana DPHHS HAN ADVISORY

Distributed via the DPHHS Health Alert Network (HAN) System
Tuesday, April 15, 2008 9:40 AM

DPHHS Health Alert Hotline 1-800-701-5769

DPHHS Contact Information:

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DPHHS Recommendations:

DPHHS does not recommend you forward this CDC Advisory. This is for your information only.

The products associated with this recall may have been distributed within Montana via direct and Internet sales. Local Health Departments should be aware of the possibility of persons consuming these products presenting to local health care providers that match the case definition detailed below in the CDC Alert.

Please contact Howard Reid, R.S., at the Montana DPHHS Food and Drug Program if there are questions.

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The goal of Montana's Health Alert Network is to transmit information to local public health authorities as quickly as possible, and assign a suitable priority to the message that is sensitive to the impact of a health-related event providing information relative to the public health and safety of Montanans. For questions or comments relative to Montana's HAN system you may contact the DPHHS HAN Coordinator, Gerry Wheat at <mailto:gwheat@mt.gov>

Categories of Health Alert messages:

- Health Alert:** conveys the highest level of importance; warrants immediate action or attention.
- Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.
- Health Update:** provides updated information regarding an incident or situation; unlikely to require immediate action.

You have received this message based upon the information contained within our emergency notification data base. If you have a different or additional e-mail or fax address that you would like us to use please notify us as soon as possible by e-mail at hhshan@mt.gov <mailto:hhshan@mt.gov>

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This is an official

CDC Health Advisory

Distributed via Health Alert Network

April 14, 2008, 18:50 EDT (06:50 PM EDT)

CDCHAN-00274-08-04-14-ADV-N

CDC Alert on Adverse Effects Associated with Consuming “Total Body Formula” and “Total Body Mega Formula”

The Centers for Disease Control and Prevention is working collaboratively with state health departments, the American Association of Poison Control Centers, and the U.S. Food and Drug Administration (FDA) on reports of adverse health effects following consumption of the dietary supplement “Total Body Formula,” and “Total Body Mega Formula” manufactured in the USA exclusively for Total Body Essential Nutrition, Inc. This dietary supplement has been found by FDA to contain hazardous levels of selenium (up to 200 times the label value) and chromium (up to 17 times the label value).

An FDA press release on April 9, 2008 detailed information regarding the level of selenium in the product (<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01818.html>). FDA is advising consumers to stop using “Total Body Formula” in flavors Tropical Orange and Peach Nectar and “Total Body Mega Formula” in the Orange/Tangerine flavor and discard them by placing them in a trash receptacle outside of the home. “Total Body Formula” products are sold in eight-ounce and 32-ounce plastic bottles. “Total Body Mega Formula” is sold in 32-ounce plastic bottles. Products with the following lot numbers should be discarded: Total Body Tropical Orange with lot numbers 4016801, 4024801 and 4031801; Total Body Peach Nectar with lot numbers 4016802 and 4031802; and Total Body Mega Orange/Tangerine with lot number 4031803.

As of April 11, 2008, 91 adverse reactions have been reported from Florida, Georgia, Kentucky, Pennsylvania, Tennessee, and Virginia health departments. The American Association of Poison Control Centers and the FDA report additional exposures in other states.

Total Body Essential Nutrition, Inc reportedly distributed this product to 16 states (Alabama, California, Florida, Georgia, Kentucky, Louisiana, Michigan, Missouri, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, and Virginia), and also sells its products over the Internet.

Clinical description of selenium toxicity

Excessive intake of selenium is known to cause the following symptoms: significant hair loss, muscle cramps, diarrhea, joint pain, fatigue, loss of finger nails and blistering skin.

Clinical description of chromium toxicity

Excessive intake of chromium may result in the following symptoms: renal failure, elevated hepatic enzymes, thrombocytopenia, hemolysis, changes in thought processes, gastrointestinal disorders, chest pain, erythema/flushing/rash, dizziness, headache, agitation, and rhabdomyolysis.

Case definition

Individuals presenting with two or more of the following symptoms that occurred within two weeks of ingesting a dietary supplement manufactured in the USA exclusively for Total Body Essential Nutrition, Inc: hair loss, muscle or joint pains, fingernail discoloration or changes, headache, foul breath, weakness, gastrointestinal symptoms (such as nausea, vomiting, diarrhea or abdominal pain), rash, oliguria/anuria or abnormal renal function tests, jaundice or abnormal liver function tests, anemia or hematological changes.

CDC requests that consumers and clinicians who encounter patients with symptoms consistent with selenium and/or chromium poisoning report these cases to their local poison control center (PCC) at 1-800-222-1222. Medical personnel are available at PCCs to provide specific medical management advice and will make appropriate referral to state and local health authorities.

Health care professionals and consumers are also encouraged to report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/how.htm.

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##This Message was distributed to State and Local Health Officers, Epidemiologists, State Laboratory Directors, PHEP Coordinators, HAN Coordinators and Public Information Officers as well as Public Health Associations and Clinician organizations##

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You have received this message based upon information contained within our emergency notification database.

If you have a different or additional e-mail or fax address that you would like to be used, please contact the

Health Alert Network program at your State Health Department.

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