

Use Caution With Ayurvedic Products



Associated Press

Lead, mercury, and arsenic have been found in some Ayurvedic products. Certain populations, including children, are particularly at risk for the toxic effects of heavy metals.

Ayurvedic medicine is a traditional system of healing arts that originated in India. It involves using products such as spices, herbs, vitamins, proteins, minerals, and metals (e.g., mercury, lead, iron, zinc). Some preparations combine herbs with minerals and metals. These products are commonly sold on the Internet or in stores and are represented as “Indian” or “South Asian.”

“Consumers should know that Ayurvedic products are generally not reviewed or approved by the Food and Drug Administration (FDA),” says Mike Levy, Director of the Division of New Drugs and Labeling Compliance in the Office of Compliance, part of FDA’s Center for Drug Evaluation and Research (CDER).

Most Ayurvedic products are marketed either for drug uses not approved by FDA or as dietary supplements. As such, consumers should understand that these products have not been approved by FDA before marketing.

“The bottom line,” Levy says, “is that consumers need to be on guard when purchasing any product using

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the Internet, especially medical products." This is an area that is challenging to regulate.

Concerns About Heavy Metals

The presence of metals in some Ayurvedic products makes them potentially harmful. A study published in the August 27, 2008, issue of the *Journal of the American Medical Association (JAMA)*, demonstrated that one-fifth of U.S.-manufactured and Indian-manufactured Ayurvedic products bought on the Internet contained detectable lead, mercury, or arsenic.

Researchers found 25 Web sites selling Ayurvedic products. After identifying 673 products, they randomly selected 230 for purchase. Of those, they received and analyzed 193 products. Nearly 21 percent were found to contain detectable levels of lead, mercury, or arsenic.

All metal-containing products exceeded one or more standards for acceptable daily metal intake. The researchers concluded that several Indian-manufactured products could result in lead and/or mercury ingestions 100 to 100,000 times greater than acceptable limits.

This study followed a previous study published in *JAMA* on December 15, 2004, which found that one out of five Ayurvedic "herbal medicine products" produced in South Asia and available in South Asian grocery stores in Boston contained

potentially harmful levels of lead, mercury, and/or arsenic.

A Priority for FDA

"This issue has been and will continue to be a priority for FDA," Levy says. The agency has had an import alert on certain Ayurvedic products in place since 2007. This import alert allows FDA personnel to prevent these products from entering the United States.

"Through this import alert, the agency is able to stop commercial import shipments of these products," Levy says, "but individual Internet purchases are harder to monitor."

In light of recent reports, FDA is re-evaluating its existing import alert and considering possible enforcement actions related to Ayurvedic products manufactured in the United States.

Advice for Consumers

- **Be aware that Ayurvedic products do not undergo FDA review.** In accordance with current law, FDA does not evaluate these products before they are marketed. This means their safety, quality, and effectiveness cannot be assured by FDA. Certain populations, including children, are particularly at risk for the toxic effects of heavy metals.
- **Use caution when buying medical products on the Internet.** FDA urges consumers to beware of unregulated Internet drug sellers.

Many of their products could pose direct or serious indirect health issues, or could contain toxic substances.

- **Tell your health care professional about all alternative products.** Some herbs, minerals, and metals can interact with each other and with conventional medications. [FDA](#)

This article appears on FDA's Consumer Health Information Web page (www.fda.gov/consumer), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html.

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