

April 10, 2015

IMPORTANT NOTICE:

This is an important FDA Notice for state, local, tribal, and territorial public health officials.

Bo Ying Compound, a powdered product marketed for treatment of various ailments in infants and children, may contain excessive levels of lead. The product is labeled in Chinese and English and is marketed in retail outlets and online. The label says the product should be given to infants and children for influenza, fever, sneezing and nasal discharge. The FDA is asking public health officials nationwide to warn parents and caregivers not to use Bo Ying Compound, due to the potential risk of lead poisoning.

The Maryland Department of Health and Mental Hygiene analyzed samples of this product being sold in two stores in Montgomery County, Maryland, and found lead levels between 1.224-3.385 parts per million (ppm). In 2014, the New York City Department of Health and Mental Hygiene received a report of lead poisoning in an 18-month-old child who was given Bo Ying Compound. The New York City Department of Health and Mental Hygiene analyzed samples of this product collected in New York City and found lead levels between 2.5-16 parts per million (ppm).

Exposure to lead can cause serious damage to the central nervous system, the kidneys, and the immune system. In children, chronic exposure to lead, even at low levels, is associated with impaired cognitive function, including reduced IQ, behavioral difficulties, and other problems.

FDA is asking local health departments for assistance in disseminating consumer warnings to retail outlets that serve Asian communities or are otherwise thought to carry this product. Specifically, public health officials should advise all consumers to discontinue use and

discard the product. In addition, parents and caregivers who may have given Bo Ying Compound to their children should consult a health care provider for evaluations and possible blood lead testing.

Health care professionals and consumers are encouraged to report to FDA any adverse events potentially related to "Bo Ying compound" manufactured by Eu Yan Sang (Hong Kong) Ltd. or to any other alternative medicines to FDA's MedWatch Adverse Event Reporting program by:

- Completing and submitting the report online at <u>MedWatch Online Voluntary</u> <u>Reporting Form</u>
- Downloading and completing the form, then submitting it via fax at 1-800-FDA-0178

If you have any questions, please contact: Huascar Batista, Senior Advisor:

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This message is being broadcast by ORA's Division of Communications. Thank you,

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