



## FDA News

**FOR IMMEDIATE RELEASE**

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### **FDA Warns Consumers Against Using Mommy's Bliss Nipple Cream**

*Product can be harmful to nursing infants*

The U.S. Food and Drug Administration is warning consumers not to use or purchase Mommy's Bliss Nipple Cream, marketed by MOM Enterprises, Inc., because the product contains potentially harmful ingredients that may cause respiratory distress or vomiting and diarrhea in infants. The product is promoted to nursing mothers to help soothe and heal dry or cracked nipples. Product labeling specifically states that there is no need for mothers to remove the cream prior to nursing. However, the ingredients contained in the product may be harmful to nursing infants.

Potentially harmful ingredients in Mommy's Bliss Nipple Cream are chlorphenesin and phenoxyethanol. Chlorphenesin relaxes skeletal muscle and can depress the central nervous system and cause respiratory depression (slow or shallow breathing) in infants. Phenoxyethanol is a preservative that is primarily used in cosmetics and medications. It also can depress the central nervous system and may cause vomiting and diarrhea, which can lead to dehydration in infants.

Mothers and caregivers should watch for a decrease in an infant's appetite. More serious signs would be difficulty in awakening the child, limpness of extremities or a decrease in an infant's strength of grip and a change in skin color. Please seek immediate medical attention if your child is showing these signs and symptoms.

"The FDA is particularly concerned that nursing infants are being unwittingly exposed by their mothers to this product with dangerous side effects," said Janet Woodcock, M.D., director, FDA's Center for Drug Evaluation and Research. "Additionally, these two ingredients may interact with one another to further compound and increase the risk of respiratory depression in nursing infants."

Though the FDA has not received any reports of injury to infants, the agency is alerting the public because of the potential harm this product can have on a child.

Chlorphenesin can also harm the mother by causing dermatitis, a skin condition that can worsen the drying and cracking of nipple skin.

MOM Enterprises, Inc. is based in San Rafael, Calif. The company has stated that it has discontinued marketing the nipple cream with the potentially harmful ingredients. The FDA is advising consumers to discontinue use of Mommy's Bliss Nipple Cream and to consult a health care professional if they experience problems or believe that their infant may have experienced problems due to this product. Nursing mothers with cracked, painful nipples, which is often a side effect of nursing, should speak with their health care professional or a certified lactation consultant if the problem is severe or for other treatment options.

Consumers are strongly encouraged to report adverse events related to this product or any FDA approved product to MedWatch, the agency's voluntary reporting program, by e-mail at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm), or by phone at 800-332-1088, or by fax to 800-332-0178. Consumers may also mail reports of adverse events to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20852-9787.

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