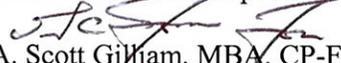




DATE: February 10, 2012

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: 
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Wholistic Herbs, Inc. Recall

SUGGESTED

ACTION: Unclassified Recall; Koff & Kold spray with herbal extract and Kold Sore spray with liquid sea water due to products intended for use in the eye that are non-sterile have the potential to cause eye infections, which may be sight threatening. Information provided in case of consumer inquiry.

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. "Koff & Kold" and "Kold Sore" were distributed throughout the Unites States to retail stores located in Texas, California, Washington, Virginia, New Jersey, New York, Maryland, Illinois, Georgia, Nevada, Arizona, North Carolina, South Carolina, and Florida. The products were also distributed through acupuncture clinics and the firm's website at www.naturalapothecary.com. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Wholistic Herbs, Inc. Recalls "Koff & Kold" and "Kold Sore" Because Of Possible Health Risk

Contact:
Ms. Sun Lee
214-691-3210

FOR IMMEDIATE RELEASE - , 2012 - Wholistic Herbs Inc. of Dallas, TX, is recalling **all quantities** of the following two, 1 fl. oz. spray products distributed from March 2009 through February 2012. Products intended for use in the eye that are non-sterile have the potential to cause eye infections, which may be sight threatening. Also, nasal solutions that are not sterile could lead to a respiratory infection.

- **Wholistic Herbs, Inc. "Koff & Kold" spray with herbal extract** as the product is not sterile and is intended to be sprayed into the nose and throat for treatment of colds, flu, cough, stuffy nose, and sinus infection.
- **Wholistic Herbs, Inc. "Kold Sore" spray with liquid sea mineral** as the product is not sterile and is intended to be sprayed into the eyes for the treatment of dry eye and pink eye. The product is also intended to be sprayed into the nose for sinus allergy by pollen, and onto the lips and genitals for the treatment of fever blisters, shingles and herpes simplex.

"Koff & Kold" and "Kold Sore" were distributed throughout the United States to retail stores located in Texas, California, Washington, Virginia, New Jersey, New York, Maryland, Illinois, Georgia, Nevada, Arizona, North Carolina, South Carolina, and Florida. The products were also distributed through acupuncture clinics and the firm's website at www.naturalapothecary.com.

"Koff & Kold" and "Kold Sore" are packaged in white plastic 1 fluid oz spray bottles which contain a product insert inside of the clear plastic lid. The product insert provides usage instructions to customers. The products are identified with a "USE BY" date on the bottom of the bottle. **All used by dates are being recalled.**

No illnesses have been reported to date.

The recall was the result of a routine FDA inspection which identified several labeling issues. These products are not tested properly as to assure their safety.

Consumers who have purchased "Koff & Kold" and "Kold Sore" are urged to discontinue use of the product and return the product to the place of purchase for a full refund. Consumers with questions may contact the company Monday through Friday 9:00am to 5:00pm CST at 214-691-3210.

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