EMERGENCY STOP-SALE ORDER ON CAL-BAN PRODUCTS

TALLAHASSEE--The Florida Department of Health and Rehabilitative Services today issued an emergency order requiring Florida retailers to remove CAL-BAN products from their shelves and to stop selling the products immediately.

Following a four-month investigation conducted in cooperation with the Hillsborough County Sheriffs Office, HRS Secretary Gregory L. Coler authorized the emergency order based on increasing evidence of injury and medical complications reported by persons ingesting the product.

State Health officials have reviewed over 100 complaints from individuals taking the CAL-BAN product. At least 50 of those cases required some type of medical intervention, including surgery.

Conditions linked to the use of CAL-BAN products include esophageal obstruction, gastric obstruction, upper and lower intestinal obstruction, nausea, vomiting, headache, and dizziness.

The death of an Arkansas resident has been indirectly linked to CAL-BAN. That person died from a pulmonary embolism following surgery for the removal of an esophageal obstruction resulting from the ingestion of CAL-BAN.
The main ingredient in CAL-BAN is a food additive known as guar gum, which is widely used in food products as a filler. However, in most foods, guar gum is a small percentage of the product's composition and has no harmful effects.

CAL-BAN is advertised as a weight loss and diet aid. It is designed to swell after ingestion, creating a feeling of fullness and subsequent lack of appetite. The product has been advertised widely over television and in newspapers, tabloids, etc. throughout the United States.

One of three known manufacturers and the U.S. distributor of the product are located in Florida. The Hillsborough County Sheriff's Office last week arrested three owners of Health Care Products, Inc. of Lutz, Florida, distributors of CAL-BAN. The corporation's offices were also seized by local officials.

The stop-sale order for CAL-BAN products takes effect immediately. HRS State Health officials will be contacting local pharmacies and retail outlets to ensure compliance with the stop-sale order.
STATE OF FLORIDA
DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES

IN RE: REMOVAL OF ALL CAL-BAN PRODUCTS

EMERGENCY ORDER

The Florida Department of Health and Rehabilitative Services finds as follows:

Findings of Fact

1. Information gathered from an ongoing investigation has revealed that numerous injuries have occurred in Florida and other states as a result of the use of CAL-BAN products.

2. It can not be determined which of three facilities could have manufactured the product in question.

3. The use of this product has resulted in medical intervention for the following conditions:
   a. Esophageal obstruction
   b. Gastric obstruction
   c. Upper and lower intestinal obstruction
   d. Nausea and vomiting

Surgery was indicated for correction in several of the above cases.

Conclusion

1. Probable cause exists to believe that the use of the CAL-BAN products in the State of Florida may be dangerous and injurious to health.

2. Therefore, the Department or its authorized agents may issue and enforce a stop-sale, stop-use, hold order of the CAL-BAN products in the State of Florida.

3. Section 499.06(1), F.S., provides as follows:

   When a duly authorized agent to the department finds, or has probable cause to believe, that any drug, device or cosmetic is in violation of any provision of ss.499.001.081 or any rule adopted under such sections so as to be dangerous, unwholesome, or fraudulent within the meaning of ss.499.001-499.081, he may issue and enforce a stop-sale, stop-use, removal, or hold order, which order gives notice that such article or processing equipment is, or is suspected of being, in violation and has been detained or embargoed, and which order warns all persons not to remove, use, or dispose of such article or processing equipment by sale or
otherwise until permission for removal, use, or disposal is given by such agent or the court.

4. The CAL-BAN products in the State of Florida may be misbranded [Ch. 499.007 (9) F.S.]. Therefore, these products may be stop-saled by an agent of the State of Florida.

5. Section 120.59(3), F.S., provides as follows:

If any agency head finds that an immediate danger to the public health, safety, or welfare requires an immediate final order, it shall recite with particularity the facts underlying such findings in the final order, which shall be appealable or enjoinable from the date rendered.

6. The Department of Health and Rehabilitative Services specifically finds, based on the aforementioned facts, that an immediate danger to the public health, safety or welfare exists regarding the CAL-BAN products and an immediate final order is necessary.

WHEREFORE, it is ORDERED that

1. All sellers or distributors of the CAL-BAN products in the State of Florida are ordered to remove such products from sale or distribution.

2. All sellers or distributors of the CAL-BAN products in the State of Florida which do not remove such products from sale or distribution are subject to penalties as provided under Florida law and are subjecting the CAL-BAN products to seizure by an authorized agent of the Department of Health and Rehabilitative Services.

3. All authorized agents of the Department of Health and Rehabilitative Services are authorized and directed to enforce the terms of this Emergency Order.

4. Subject CAL-BAN products shall be held in quarantine and may be voluntarily destroyed or returned to the distributor.

DONE AND ordered this 18th day of July, 1990, in Tallahassee, Florida.

[Signature]

Gregory L. Coler, Secretary
Department of Health and Rehabilitative Services