

FDA PRESS RELEASE

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FDA: Don't buy drugs marketed as antimicrobial dietary supplements

Fast Facts

The FDA is warning consumers not to use products marketed as dietary supplements that also claim to be antimicrobial (antibiotic, antifungal or antiviral) drugs. These illegal products are falsely promoted with claims to treat illnesses such as upper respiratory infections, sinusitis, pneumonia, bronchitis and the common cold.

The FDA has learned that several companies are distributing and promoting products labeled as dietary supplements for antimicrobial uses. These products may or may not contain antimicrobials, and their use could delay treatment for serious illnesses.

The FDA has determined that many of these products mimic the labeling of drugs available in Mexico, and that they are marketed specifically to the Hispanic community.

Consumers should stop using these products immediately and contact their health care providers.

What is the Problem?

The FDA has determined that several companies are marketing products that look like antimicrobial products available in Mexico. Consumers using the products may believe they will receive the beneficial health effects of an antimicrobial drug. These products may or may not contain antimicrobials, and their use could delay treatment for serious illnesses. These products are not FDA approved to treat, cure or prevent any medical conditions.

What are the Symptoms of Illness/Injury?

Consumers may be using these products under the belief that they contain antimicrobials. Doing so may cause worsening of existing illness and delayed treatment. An antimicrobial is a substance that kills or inhibits the growth of pathogens such as bacteria, viruses and fungi.

The FDA is aware of at least four cases in Texas in which children received emergency care due to worsening illnesses after being given products that the parents may have believed contained antimicrobials. These products were packaged to resemble antimicrobial drugs that are readily available in Mexico. It was determined the children had been given a product, Amoxilina, which the parents may have believed was the antimicrobial Amoxicillin. Giving the product to the children delayed legitimate medical treatment.

## Who is at Risk?

All consumers are at risk. Although package labels are printed in English and Spanish, the packaging mimics antimicrobials readily available in Mexico and possibly familiar to Hispanic consumers.

## What Do Consumers and Health Care Providers Need To Do?

Consumers who have been using these types of products should consult their health care providers immediately. Consumers should be skeptical of any product that claims to be a dietary supplement and claims to treat, prevent or cure disease or contain an antimicrobial.

Health care professionals and consumers are encouraged to report serious adverse events (side effects) or product quality problems with the use of these products to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, fax or phone.

Online : <https://www.accessdata.fda.gov/scripts/medwatch>.

Regular Mail: Use FDA postage paid form 3500 and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

Fax: 800-FDA-0178

Phone: 800-FDA-1088

## What Does the Product Look Like?

Various companies market these products. The FDA is aware of several products listed below, but this list may not be complete.

Product Name	Distributor	UPC #	Status
Amoxicilina Capsules 500 Mg (30 Caps)	Multi-Mex	619114010081	Voluntarily recalled 05/06/2011
Amoxicilina Suspension (3.4 Oz)	Multi-Mex	619114010074	Voluntarily recalled 05/06/2011
Pentreximil Plus 500 Mg (30 Caps)	Multi-Mex	619114010012	Voluntarily recalled 05/06/2011
Pentreximil Plus Syrup 3.4 Oz	Multi-Mex	619114010050	Voluntarily recalled 05/06/2011
Pentrexyl Forte Natural, 30-capsule box containing capsules in blister packs	Phoenix Import & Distribution	8 93843 00129 3	Voluntarily recalled 05/12/11

## Where is it Distributed?

The products have been distributed in Colorado, Delaware, Texas, Florida, California, Georgia, and potentially other markets. The products are marketed toward Hispanic consumers. They may be sold at various retailers, including small independent stores that cater to the Hispanic community.

*The information in this press release reflects the FDA's best efforts to communicate what it has learned from the manufacturer and the state and local public health agencies involved in the investigation. The agency will update this page as more information becomes available.*

*For more information:*

Drug Claims Prompt Health Alert:

<http://www.dshs.state.tx.us/news/releases/20110429.shtm>

Multi-Mex Recall Notice:

<http://www.fda.gov/Safety/Recalls/ucm254605.htm>

Phoenix Recall Notice:

<http://www.fda.gov/Safety/Recalls/ucm255324.htm>

Beware of Fraudulent "Dietary Supplements":

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm246744.htm>

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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