

15 November 2012

DOH-FDA Advisory
No. 2012-013

SUBJECT: VOLUNTARY RECALL ORDER OF CALCHEWS

Pascual Laboratories notified this office that it recalled its product CALCHEWS Chocolate Flavor with LN: 382BWA & 382BWB ED: 8/2014.

Staphylococcus aureus and Salmonella infections is a bacterial infection with broad ranges of illness, from no symptoms to severe illness. The most common clinical presentation is acute gastroenteritis characterized by headache, diarrhea, abdominal pain, nausea, fever of 38°C to 39°C and sometime vomiting..

Pascual Laboratories conducted an investigation to determine the cause of the contamination and has stopped distribution of the same pending completion of the investigation.

In view of the foregoing, this office hereby enjoins those concerned of their strict compliance to the following:

- Consumers who have purchased said products are advised not to consume the affected CALCHEWS and to return the same to Pascual Consumer Healthcare Corporation located at 10/F ETON Cyberpod 1, Centris Bldg., Edsa corner Quezon Avenue, Quezon City. Consumers may contact Chiko Lara, Corporate Communication Manager at 0917 727 1710 or Mr. James F. Yaranon Pharmacovigilance Officer at 0917 727 1304 and email address jfyaranon@pascuallab-pharma.com.
- Persons who think they may have become ill from taking the affected calcchews are advised to consult their health care providers.
- Concerned FDROs are instructed to immediately identify the affected establishments and conduct outright monitoring, and if possible, assess and coordinate with affected establishments to prevent distribution of products, the quality or safety of which have been compromised.

The FDA shall continuously monitor products in the market to ensure the safe supply of products.



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Acting Director IV