

F. No. 1-30 /CODEX (INFOSAN)/FSSAI/2010
Food Safety & Standards Authority of India
(Ministry of Health & Family Welfare)
FDA Bhawan, Kotla Road
New Delhi-11002

11th December, 2013

Subject: Outbreak of acute non-viral Hepatitis potentially with a range of OxyElite dietary supplement products.


An alert has been received from INFOSAN with regard to the Outbreak of acute non-viral Hepatitis potentially with a range of OxyElite dietary supplementary products. The ongoing incident of dietary supplement products in the OxyElite range leading to acute non-viral hepatitis have been identified in the USA, Ireland and New Zealand.

There have been 62 cases of acute non-viral hepatitis identified in the USA, 1 in Ireland and 2 in New Zealand up till 13 November 2013. The OxyElite products are used for a weight loss or muscle building dietary supplement.

The OxyElite products namely OxyElite Pro Super Thermo capsules; OxyElite Pro Ultra-Intense Thermo capsules; OxyElite Pro Super Thermo powder, and VERSA-1, OxyElite Powder Super T. Genic Caffeinated Beverage have been associated with severe liver disorders, including hepatitis and liver failure.

According to the FDA News Release, OxyElite Pro and another supplement called VERSA-1 were deemed to be adulterated. The products contained aegeline, a new dietary ingredient (i.e an ingredient not marketed in the United States before Oct 15, 1994) that lacks a history of use or other evidence of safety.

This information is being brought to the notice of all stakeholders and public at large.


(Ms. Vinod Kotwal)
Director (Codex)

INFOSAN documents (enclosed for information)

To:

- 1. All AOs, FSSAI.**
- 2. Custom Authorities**
- 3. All Food Safety Commissioner of State/UT's**
- 4. DGHS, Ministry of Health & Family Welfare,GOI**

Copy to:

- 1. PPS to CP**
- 2. PS to CEO**

Update - Outbreak of Acute Non-Viral Hepatitis Potentially Associated With a range of OxyElite Dietary Supplement Products

Alert details

The INFOSAN Secretariat has received updated information regarding the ongoing incident of dietary supplement products in the OxyELITE range leading to acute non-viral hepatitis.

As of 13 November 2013 there have been 62 cases of acute non-viral hepatitis identified in the USA, 1 in Ireland, and 2 in New Zealand (under investigation) with an unknown cause subsequent to the use of a weight loss or muscle building dietary supplement (OxyELITE product).

A recall of certain OxyELITE products is underway in the USA. The FDA is not aware of international shipments of the recalled product to foreign distributors or direct international consignees. The case in Ireland reported purchasing OxyELITE products online, however both cases in New Zealand purchased OxyELITE products from retail stores in New Zealand. The specific OxyELITE product consumed in New Zealand are not listed among products recalled by the USA company.

No causative agent or ingredient has yet been identified and investigations are still underway.

Given these developments, the INFOSAN Secretariat would like to emphasize our previous request to receive information about cases of acute non-viral hepatitis in other countries which could be linked to consumption of weight loss or muscle building dietary supplements. (Suggestion - insert information on the case definition for this event. Either draft or current and under review, would be helpful).

In addition, sharing any actions taken in response to this Alert would also be helpful as we try and summarize the international aspects of the event.

Please feel free to post directly on the INFOSAN Community Website by using the discussion function ("Discuss This" button on bottom of this page).

Below you will find additional details and links to public information provided from our INFOSAN colleagues in the USA, Ireland and New Zealand:

Information from US FDA:

