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भारत सरकार

Business Standard, Delhi
Monday 28th September 2015, Page: 3
Width: 8.36 cms, Height: 11.05 cms, a4, Ref: pmin.2015-09-28.21.21

Apotex recalls India arm's medicine in US

PRESS TRUST OF INDIA
New Delhi, 27 September

Canada-based Apotex is recalling 117,644 bottles of Cevimeline Hydrochloride Capsules in the US that were made by the firm's Indian arm Apotex Research.

The company is recalling the drug due to "failed stability specifications", as per the US Food and Drug Administration (USFDA) website.

Cevimeline Hydrochloride Capsules are used for treatment of symptoms of dry mouth in patients with Sjogren's Syndrome.

The recall of the product in 30 mg strength in 100 and 500 count bottles, was initiated by the company on August 17.

It has been classified as a 'Class-II recall' which FDA defined as "a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote".

The company could not be immediately contacted for its comments. Sjogren's syndrome is a chronic autoimmune disease in which the body's white blood cells destroy the exocrine glands, specifically the salivary and lacrimal glands, that produce saliva and tears respectively.

Earlier this year, Apotex had recalled 91,962 bottles of Losartan potassium tablets in the US made by Bengaluru-based Apotex Research.

Regulatory