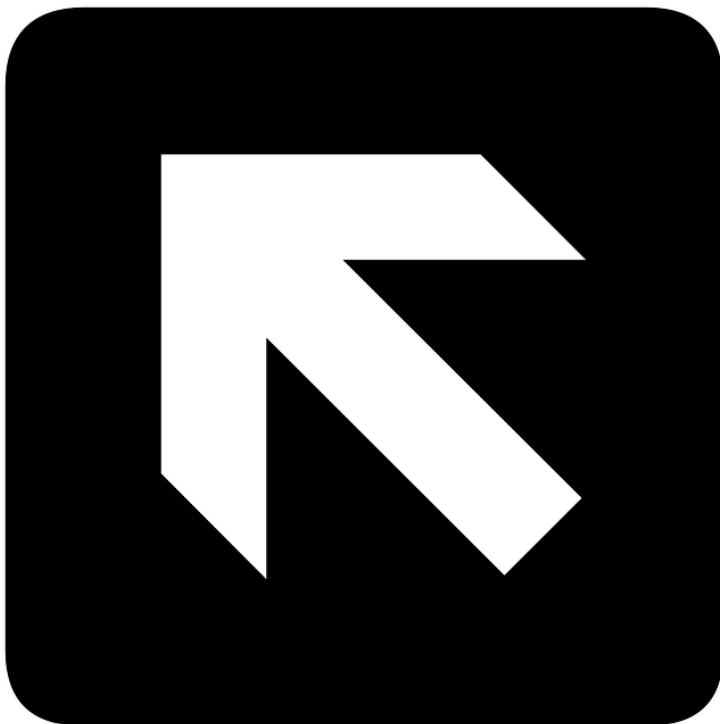


Sun unit recalls Cephalexin capsules from US

August 18, 2014 | Regulatory | By BioSpectrum Bureau



Singapore: A unit of Sun Pharma from India, Caraco Pharma has initiated the process of recalling multiple lots of its Cephalexin capsules from the US market.

The US Food & Drug Administration had notified that the company had voluntarily recalled 3,40,553 units of 500 mg and 1,13,677 units of 250 mg bottles after it wrote a letter to the regulator in June under 'Class-II' classification.

Reports explained that as per the US FDA, Class II recall is a one 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.

Citing the reason for the recall, the US FDA said on its website, "These products are being recalled because they were manufactured with active pharmaceutical ingredients (APIs) that were not manufactured with good manufacturing practices."

The company said that Cephalexin, used to treat some bacterial infections, is an antibiotic that belongs to the family of medications known as cephalosporins.

Further, reports explained that the recalled drug bottles were manufactured by Sun Pharma in India and distributed by Caraco in the US.

Some reports also pointed out that Caraco Pharmaceutical had recently initiated a recall of some lots of Venlafaxine Hydrochloride extended-release tablets from the US market for not meeting the drug release dissolution specifications under 'Class-II' classification.