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US FDA Orders Drug Recalls From Indian Firms

July 27, 2025

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Three major Indian pharmaceutical companies, Sun Pharma, Lupin, and Dr. Reddy's Laboratories, are voluntarily recalling medications from the United States market following concerns raised by the U.S. Food and Drug Administration (FDA). The recalls were triggered by product mix-ups and manufacturing issues, as outlined in the agency's latest enforcement report.

Sun Pharmaceutical Industries, headquartered in Mumbai and with operations in Princeton, New Jersey, is recalling 5,448 bottles of a generic version of Tizanidine hydrochloride tablets (2 mg). The medication, which is used to manage muscle spasms, was found to contain foreign tablets that did not match the label contents. The recall was classified as Class II, which indicates that the use of the product may cause temporary or medically reversible adverse health effects.

Lupin Pharmaceuticals, another Mumbai-based firm with U.S. offices in Naples, Florida, is recalling 58,968 bottles of Lisinopril and Hydrochlorothiazide tablets (USP 20mg/12.5mg), a drug combination used to treat high blood pressure. The affected batch was produced at the company's Nagpur facility in India and has also been flagged under a Class II recall. The FDA report cited the presence of foreign Divalproex Sodium tablets, which are used for different medical conditions, found within bottles labeled as omeprazole capsules.

Dr. Reddy's Laboratories has also initiated a product recall from the U.S. market, although the specific quantity and medication involved were not disclosed in the public FDA report at the time of writing. All three companies have confirmed the recalls are precautionary and that no serious adverse events have been reported.

The FDA classifies Class II recalls as situations where the use of a product could result in temporary health problems or where the probability of serious adverse health consequences is remote.

These recalls highlight ongoing quality assurance challenges for international pharmaceutical firms operating in the U.S. market. The FDA continues to monitor imported medications rigorously to ensure safety and compliance with American pharmaceutical standards.

All recalled batches are being removed from distribution channels, and healthcare providers and consumers are being advised to return affected products if identified.