Generic Name:
Porcine thyroid API
Trade Name:
No trade name
Company:
Sichuan Friendly Pharmaceutical Co.
Notes:

FDA is alerting active pharmaceutical ingredient (API) repackagers and distributors, finished drug manufacturers, and compounders that Sichuan Friendly Pharmaceutical Co. Limited, China, is recalling certain lots of porcine thyroid API because of inconsistent quality of the API. FDA recommends that manufacturers and compounders not use Sichuan Friendly?s porcine thyroid API received since August 2015.

This thyroid API comes from porcine (pig) thyroid glands and is used to make a non-FDA approved drug product, composed of levothyroxine and liothyronine, to treat hypothyroidism.

FDA laboratory testing confirmed the Sichuan Friendly API has inconsistent levels of the active ingredients ? levothyroxine and liothyronine ? and should not be used to manufacture or compound drugs for patient use. Risks associated with over- or under- treatment of hypothyroidism could result in permanent or life-threatening adverse health consequences.

FDA placed Sichuan Friendly on import alert 66-40 on March 22, 2018, based on current good manufacturing practice (CGMP) deviations observed during an FDA inspection.

However, FDA confirmed Sichuan Friendly?s thyroid API remains in the U.S. supply chain. Sichuan Friendly API may be repackaged and/or relabeled before it is further distributed, and not all of the repackaged/relabeled API identifies Sichuan Friendly as the original API manufacturer. Therefore, manufacturers and compounders who make levothyroxine and liothyronine drug products should contact their API supplier to verify the actual manufacturer of the thyroid API they received before using it. Sichuan Friendly?s products may be labeled as ?Thyroid Powder? or ?Thyroid Powder USP.?

In addition, manufacturers and compounders who have received API made by Sichuan Friendly should quarantine the API and associated drug products. If manufacturers and compounders have API or drug products made from Sichuan Friendly API, FDA requests these companies contact FDA?s regional offices.

FDA recommends patients talk to their health professional before they stop taking their combination levothyroxine and liothyronine thyroid medicine. FDA also recommends that patients discuss FDA-approved hypothyroidism treatment options with their doctors, as combination levothyroxine and liothyronine products are not FDA approved.

Medication Monitor Categories:
Alerts and Recalls

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