



23 October 2013

FDA MEMORANDUM CIRCULAR

No. 2013-044

To : All Drug Establishments, and other concerned parties

From: *for us Saanabong*
KENNETH Y. HARTIGAN-GO, MD
Acting Director General

SUBJECT: **WARNING ON TOXIC ENANTIOMER LEVOMETHORPHAN-
CONTAMINATED API DEXTROMETHORPHAN MANUFACTURED BY
KONDUSKAR LABORATORIES PRIVATE LTD, INDIA**

The Food and Drug Administration received an International Drug Alert from the World Health Organization (WHO) involving contaminated Active Pharmaceutical Ingredient (API) Dextromethorphan, manufactured by Konduskar Laboratories Private Limited, India.

The API Dextromethorphan is contaminated with Levomethorphan, a toxic enantiomer. It has caused several adverse drug reactions, including death.

All drug manufacturers and distributors of Dextromethorphan products are strongly advised to exercise extreme caution by recalling or withdrawing products containing API Dextromethorphan that were sourced from Konduskar Laboratories Private Limited India, or by carefully testing the Dextromethorphan products for the presence of toxic Levomethorphan and if the products meet the specifications approved by the drug regulatory agencies.

For more details, kindly follow the WHO link: <http://www.who.int/medicines/publications/drugalerts/drugalertindex/en/index.html>. You may also contact WHO through rapidalert@who.int.

For information and strict compliance. For inquiries, kindly email us at info@fda.gov.ph.

