Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

22 May 2014

FDA Advisory
No2014-039

SUBJECT: RECALL OF STERILE DRUG PRODUCTS (OPHTHALMIC, OTIC AND PARENTERAL) MANUFACTURED BY ASHFORD PHARMACEUTICAL LABORATORIES, INC. FROM SEPTEMBER 2012 UP TO THE PRESENT

The public is hereby warned by the Food and Drug Administration (FDA) that all sterile drug products manufactured by Ashford Pharmaceutical Laboratories, Inc. from September 2012 up to the present are being recalled from the market.

Critical and major deficiencies in the manufacturing facility for sterile products of the said establishment were noted by the Regional Field Inspectors. FDA has recommended the recall of all sterile drug products (ophthalmic, otic and parenteral) due to poor compliance to Pharmaceutical Inspectorate Cooperation Scheme – Good Manufacturing Practice (PIC/s-GMP), which indicates that there is no assurance that the manufactured products are of good quality.

The affected products present a safety risk and potential adverse health consequences. Therefore, Ashford Pharmaceutical Laboratories, Inc. has been ordered to discontinue manufacturing, distributing and offering these products for sale to the consumers. All consumers are advised not to purchase or use the affected products.

If you happen to buy sterile drug products that are subjects of product recall, consumers may report to FDA via report@fda.gov.ph.

For more information and inquiries, please e-mail us at info@fda.gov.ph. Any suspected adverse reaction experienced from the aforementioned product should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the ADR Report tab, proceed and fill-out all of the required fields.

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