Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

23 June 2015

FDA Advisory No. 2015 046

SUBJECT: RECALL OF ALL DRUG PRODUCTS MANUFACTURED BY DOCTORS PHARMACEUTICALS, INC. FROM MARCH 2014 UP TO THE PRESENT

The public is hereby warned by the Food and Drug Administration (FDA) that all drug products manufactured from March 2014 up to the present by Doctors Pharmaceuticals, Inc. are being recalled from the market.

Critical and major findings of non-conformance to Pharmaceutical Inspectorate Cooperation Scheme-Good Manufacturing Practice (PIC/s-GMP) were noted during inspection of the said manufacturing facility which indicated that there is no assurance that the manufactured drug products are of good quality.

The affected drug products present safety risks and potential adverse health consequences. Therefore, Doctors Pharmaceuticals, Inc. has been ordered to discontinue their manufacturing operations. All distributors, retailers, hospitals, pharmacies, or clinics are instructed to discontinue further distribution, sale and use of the affected drug products which were manufactured from March 2014 up to the present. All consumers are likewise advised not to purchase or use these products and to contact Doctors Pharmaceuticals, Inc. at telephone number (02) 839-0819 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

All Field Regulatory Operations Office (FROO) Officers are ordered to monitor the availability of these products in the market (i.e. manufactured from March 2014 up to the present), to seal discovered stocks of the impacted drug products, and to instruct the concerned establishment to give back the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of the affected drug products should be reported immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

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Secretary of Health
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[1]Pursuant to DPO 2015-1845