Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

08 AUG 2015

FDA Advisory
No. 2015-063

SUBJECT: RECTIFICATION TO FDA ADVISORY NO. 2015-044 "RECALL OF SPECIFIC DRUG PRODUCTS OF MORISHITA-SEGGS PHARMACEUTICALS, INC. MANUFACTURED FROM JANUARY 2014 UP TO THE PRESENT"

The public is hereby warned by the Food and Drug Administration (FDA) that particular drug products manufactured by Morishita-Seggs Pharmaceuticals, Inc. from January 2014 up to the present are being recalled from the market. The drug products covered in this recall are as follows:

DRUG PRODUCT	BRAND NAME	REG. NO.
Phenylpropanolamine Hydrochloride + Paracetamol 12.5 mg/250 mg per 5 mL Syrup	**Nasathera**	DR-XY28845
Phenylpropanolamine HCl 12.5 mg/5 mL Syrup	**Nasathera P**	DR-XY30134
Phenylpropanolamine Hydrochloride 6.25 mg/mL Syrup (Oral Drops)		DR-XY30827
Phenylpropanolamine Hydrochloride/Chlorphenamine Maleate 12.5 mg/2 mg per 5 mL Syrup	**Nasathera CPM**	DR-XY36065
Paracetamol 250 mg/5 mL Syrup	**Dolexpel**	DR-XY20941
Paracetamol 500 mg Tablet		DR-XY2296
Ambroxol 15 mg/5 mL Syrup	**Sobromer**	DR-XY33373
Salbutamol (as Sulfate)/Guaifenesin 1 mg/50 mg per 5 mL Syrup	**Srilux Expectorant**	DR-XY34831

Critical and major findings of non-conformance to Pharmaceutical Inspectorate Cooperation Scheme-Good Manufacturing Practice (PIC/s-GMP) were noted upon inspection of the manufacturing facility of Morishita-Seggs Pharmaceuticals, Inc. which indicated that there was no assurance that the stated manufactured drug products with impacted lots manufactured from January 2014 up to the present are of good quality.

The affected drug products present safety risks and potential adverse health consequences. 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 January 2014 up to the present. All consumers are likewise advised not to purchase or use these products and to contact Morishita-Seggs Pharmaceuticals, Inc. at telephone number +632 532-0740 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 January 2014 up to the present), to seal the discovered stocks of the stated 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 manufactured lots from January 2014 up to the present of the stated 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.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

FDA Advisory No. 2015-044 dated 19 June 2015 is hereby rectified as follows: change of statement "contact Allied Pharmaceutical Laboratories, Inc." to "contact Morishita-Seggs Pharmaceuticals, Inc."

DTN: 20150619143655

[1]Pursuant to DPO 2015-1845