Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 MAR 2016

FDA ADVISORY No. 2016-030

TO: **ALL HEALTHCARE PROFESSIONALS, THE GENERAL PUBLIC AND THE OFFICERS OF THE FIELD REGULATORY OPERATIONS OFFICE**

SUBJECT: **Product Recall of All Sterile Veterinary Drug Products Manufactured by Belman Laboratories from 10 August 2015 up to 15 December 2015**

All healthcare professionals and the general public are hereby warned by the Food and Drug Administration (FDA) that all sterile veterinary drug products manufactured by Belman Laboratories from 10 August 2015 up to 15 December 2015 are being recalled from the market.

Significant critical and major deficiencies in the manufacturing facility of the said establishment were noted by the Regional Field Inspectors. FDA has recommended recall of all sterile veterinary drug products manufactured from 10 August 2015 up to 15 December 2015 due to the non-compliance to the Pharmaceutical Inspection and Cooperation Scheme Good Manufacturing Practice (PIC/S GMP). This indicates that there is no assurance that the manufactured products are safe and of good quality. Thus, Belman Laboratories has been ordered to discontinue distributing and offering these products for sale to the consumers.

The affected products present safety risk and potential adverse health consequences. Therefore, distributors, retailers, veterinary hospitals, pharmacies or veterinary clinics that have the products manufactured by Belman Laboratories from 10 August 2015 up to 15 December 2015 are instructed to discontinue further distribution, sale and use. The public is likewise advised not to purchase or use these products on animals and may contact Belman Laboratories at telephone numbers (02) 634-0940 to 41 or (02) 712-0201 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the affected products in the market, appropriately seal discovered stocks of the same, and 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 observed from the use of the affected products should be reported immediately to FDA by visiting www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

By Authority of the Secretary of Health

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