Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

01 FEB 2016

FDA ADVISORY NO. 2016 002

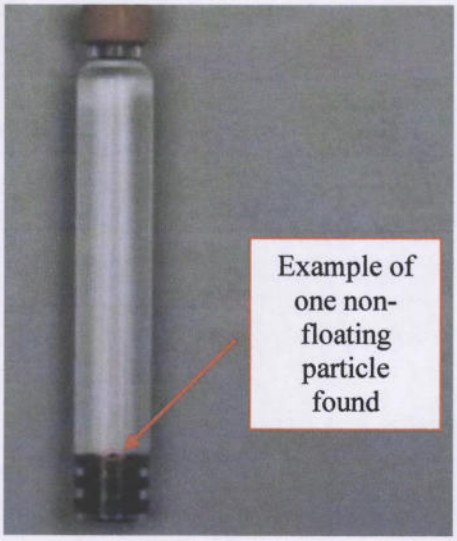
SUBJECT: Product Recall of Specific Batches of Lixisenatide (Lyxumia) Solution for Injection (S.C.)

The public is hereby warned by the Food and Drug Administration (FDA) that specific batches of Lixisenatide (Lyxumia) Solution for Injection (S.C.) products are being recalled from the market due to a quality event resulting in a defect wherein metal or silicon agglomerates are either lodged between the cartridge stopper and the inner surface of the cartridge or attached to the inner surface of the stopper. This is from the notification of the Marketing Authorization Holder (MAH), Sanofi-Aventis Philippines, Inc. The details of the concerned drug products manufactured by Sanofi-Aventis Deutschland GmbH in Germany are the following:

PRODUCT NAME (1)	**LIXISENATIDE (LYXUMIA) 20 mcg/0.2 mL SOLUTION FOR INJECTION (S.C.)**	
REGISTRATION NUMBER	**BR-1042**	
BATCH NUMBER / EXPIRY DATE	**5F203A / JANUARY 2017**	**5F226A / APRIL 2017**
	5F219A / JANUARY 2017	**5F231A / APRIL 2017**

PRODUCT NAME (2)	**LIXISENATIDE (LYXUMIA) TREATMENT INITIATION PACK CONTAINING SOLUTION FOR INJECTION (S.C.) OF: 1 GREEN PRE-FILLED PEN OF 10 mcg/0.2 mL 1 PURPLE PRE-FILLED PEN OF 20 mcg/0.2 mL**
REGISTRATION NUMBER	**BR-1043**
BATCH NUMBER / EXPIRY DATE	**5F202A / SEPTEMBER 2016**

PRODUCT NAME (3)	**LIXISENATIDE (LYXUMIA) 10 mcg/0.2 mL SOLUTION FOR INJECTION (S.C.)**
REGISTRATION NUMBER	**BR-1044**
BATCH NUMBER / EXPIRY DATE	**5F165A / DECEMBER 2016**
	5F177A / DECEMBER 2016
	5F184A / MARCH 2017



The stated drug products are indicated for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.

Therefore, distributors, hospitals, retailers, pharmacies or clinics that have the affected batches of the drug products are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batches and may contact Sanofi-Aventis Philippines, Inc. at telephone number +632 859-5730 or mobile no. +63 998 9625699 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 product batches in the market, appropriately seal discovered stocks of the affected batches of the product, and instruct the concerned establishment to return the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA Representative.

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

MARIA LOURDES C. SANTIAGO, MSc, MM
Officer-in-Charge, Director General
Food and Drug Administration

DTN: 20151110161729