Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

31 JUL 2017

FDA ADVISORY
No. 2017-221

TO: **THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS**

SUBJECT: **VOLUNTARY RECALL OF THE TERUMO INSULIN SYRINGE WITH NEEDLE WITH DVR NO. 4378 OF THIS PRODUCT SOLD ONLY AT INDONESIA.**

All are hereby advised by the Food and Drug Administration (FDA) about the voluntary recall of the following Terumo Insulin Syringe with Needle with DVR-4378 product code distributed by Terumo (Philippines) Corporation 124 East Main Ave., Laguna Technopark, Biñan, Laguna, Philippines:

Product Code:	**DVR – 4378**		
Description:	**Terumo Syringe With Needle, Insulin, 26G x ½"**		
Product Name:	**Product Code**	**Lot Numbers**	**Expiration Date**
Terumo Syringe with Needle Insulin, 26Gx1/2"	**SS+01N2613**	**160809D** **160914D** **161015D** **161129D** **161221D**	**2021-07** **2021-08** **2021-09** **2021-10-31** **2021-11-30**

The cited products are being voluntarily recalled by Terumo (Philippines) Corporation because of the customer reports from its main manufacturer in other country on potential effect of the device. In the report, This recall has been initiated due to issue. Instead of labelling a product with U-40/U-80, labelling of the products indicated U-100. Immediately, a recall notification letter was provided to sales territory in Indonesia and specific instruction was made regarding the product to be recalled.

The total quantity of products produced and supplied is 518,400 pieces Last April 10, Terumo Indonesia recalled a total of 516,600 pieces. 1,800 pieces are not intended to be used for insulin injection according to the customer in Indonesia, therefore, the customer requested and confirmed that it should not be recalled or pulled out. Recalled or pulled-out product will be destructed. Distributors, retailer, hospitals that have any of the stated medical device product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lots.

Any suspected adverse reaction experienced or any incident of the same cases from the use of the device but not limited to the lots stated above, should be reported immediately to FDA at telephone no. (02) 857-1900 loc. 8301 or email us at cdrrhr_prsdd@fda.gov.ph.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
Director General

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