Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

0 3 MAY 2018

FDA ADVISORY
No. 2018-160

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

SUBJECT: **VOLUNTARY RECALL OF THE BD VACUTAINER® PLUS SST TUBE WITH HEMOGARD CLOSURE WITH PRODUCT REGISTRATION DVR NO. 3713**

Metro Drug Inc., the importer/distributor of BD Vacutainer® Plus SST Tube with Hemogard Closure with the product registration number DVR-3713. has informed the Food and Drug Administration of the voluntary recall of the said product, specifically described as follows:

Product Name	BD Vacutainer® Plus SST Tube with Hemogard Closure
Specifications	13x75mm x 3.5ml
Catalog Code	367983
Lot No.	7135828 and 7125692
Intended Use	For the collection of venous blood
Packaging/Selling Unit	Shelf pack of 100 tubes/Case of 10 shelf packs
Registration No.	DVR-3713

Product Name	BD Vacutainer® Plus SST Tube with Hemogard Closure
Specification	13x100mm 5.0ml
Catalog No.	367986
Lot No.	7146901
Intended Use	For the collection of venous blood
Packaging/Selling	Shelf pack of 100 tubes/Case of 10 shelf packs
Registration No.	DVR-3713

Figure 1. Stopper creep-out/pull-out/pop-off in centrifuge

Said items are being voluntarily recalled due to reports of BD has confirmed that a limited number of tubes associated with the above lots of BD portion of the lots BD Vacutainer® Plus SST Tubes which are currently in the market may exhibit stopper creeper-out/pull-out/pop-off, where the stopper dissociates from the tube. An example of stopper creep-out/pull-out/pop-off is demonstrated in Figure above. BD has received reports of this issue occurring during collection and processing (including centrifugation, transportation and testing). Stopper creep-out/pull-out/ pop –off can result in potential user exposure to blood resulting from an un-stoppered tube, which may result in exposure to blood borne pathogens. Lot and Ref numbers that are critical in determining the identity of the product for traceability. In the report to the FDA , Metro Drug Inc. disclosed that the affected lots were not distributed in the Philippine market as per their distribution list record.

At any rate, distributors, retailers and hospitals that have any lot of the stated medical device product are instructed to discontinue their further distribution, sale, and use. Furthermore, other distributors of said product shall coordinate with the FDA for the conduct of product recall. 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, R.Ph
Director General

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