Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

11 FEB 2020

FDA ADVISORY
No. 2020-156

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

SUBJECT: **Public Health Warning Against the Purchase and Use of Counterfeit Medical Device "Cos-Med Inset Adult without Needle"**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the purchase and use of the counterfeit Cos-Med Inset Adult without Needle. Please see particulars/details of the original vs. the counterfeit product as provided below:

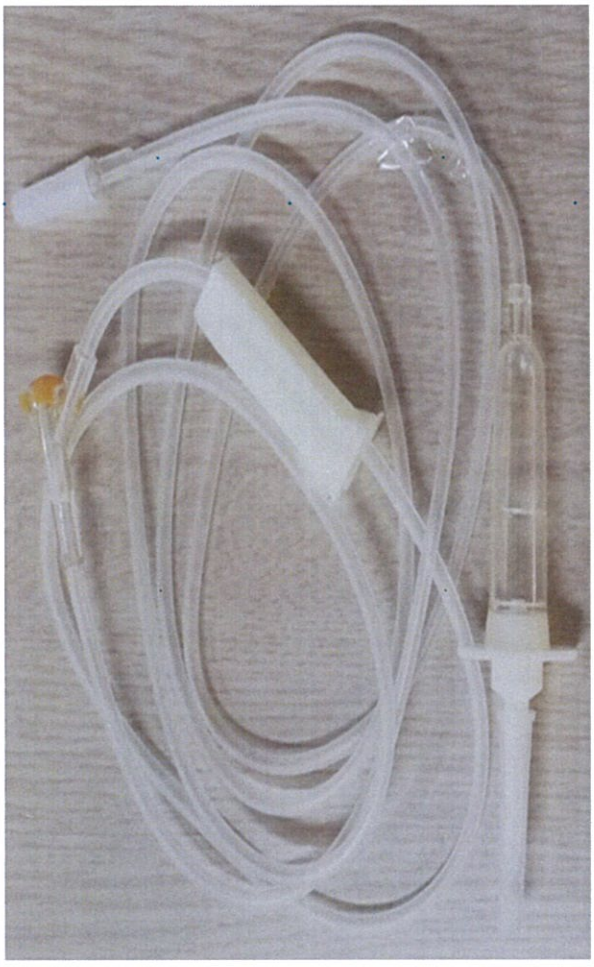
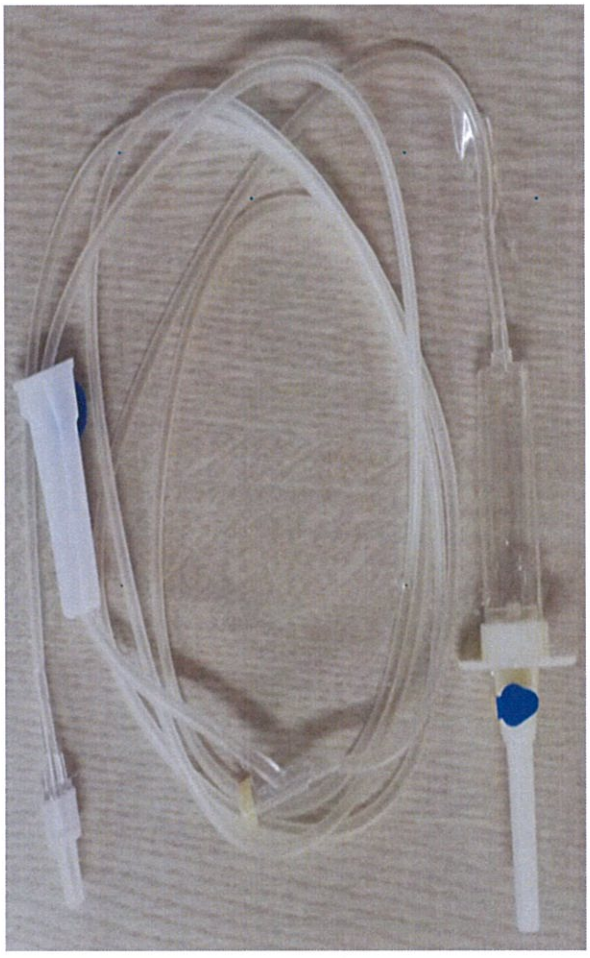
ORIGINAL	COUNTERFEIT
	

Figure 1. Photo of the Original and the Counterfeit Cos-Med Inset Adult without Needle

Product Details	ORIGINAL	COUNTERFEIT
Spike	airvented without airvent cap, with clear spike cap	airvented with blue airvent cap, short, opaque spike cap, different spike model
Chamber	bottom is slightly rounded	bottom is squared
Roller and Clamp Case	both ABS natural	both PVC white
Tubing	non-dehp PVC, slightly cloudy (opaque)	clear, smaller inner diameter (id) and od than original
Y-site	with finger grip guard, brownish	no finger grip guard, beige in color, shorter
Connector	luer slip connector	luer lock connector

Table 1. Comparison of the Original and the Counterfeit Cos-Med Inset Adult without Needle

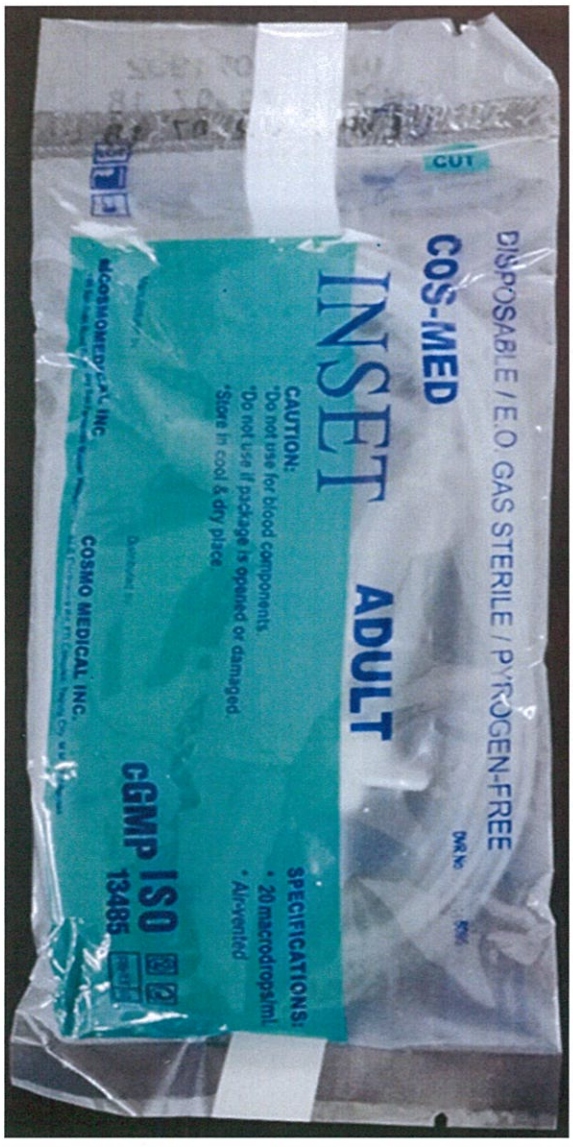
ORIGINAL	COUNTERFEIT
	

Figure 2. Front Photo of the Original and the Counterfeit Polybag of Cos-Med Inset Adult without Needle

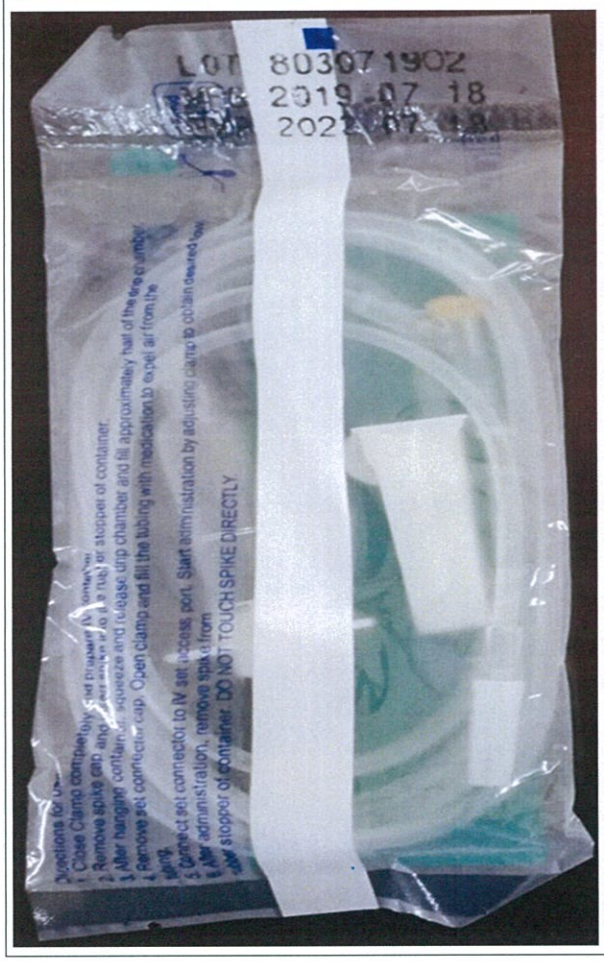
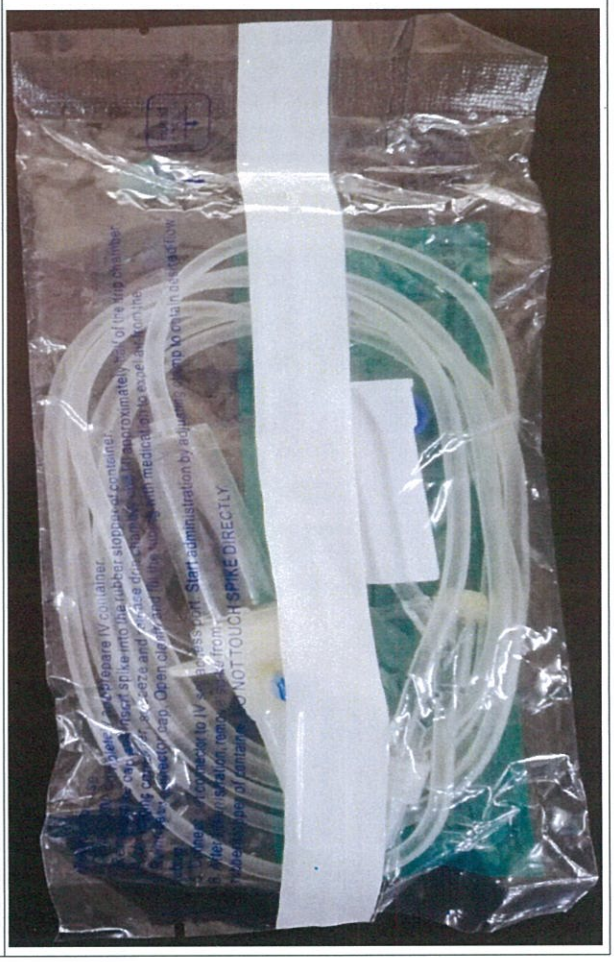
ORIGINAL	COUNTERFEIT
	

Figure 3. Back Photo of the Original and Counterfeit Polybag of Cos-Med Inset Adult without Needle

Polybag Details	ORIGINAL	COUNTERFEIT
Polybag	slightly opaque, LDPE, mid portion of white ribbon packing is not laminated to allow ethylene oxide gas penetration	clear (see-thru), crisp plastic, looks-like PP, white ribbon packing at the back of polybag is completely sealed
Label	- Blank Lot No., Mfg date and Expiry Date Icons are preprinted on the left of the polybag. This information is printed at the left portion at the back of polybag to accommodate the big font sizes of the printer. - Dates are separated by spaces and uses bold, big, black fonts	- Lot No., Mfg date and Expiry Date are pre-printed on the left of the polybag. But Lot No is not in accordance with the system used by Cosmomedical. - Dates are separated by dashes, preprinted in small, blue font.
Others	ISO 13485 and GMP are in the label without the Co. logo of the ISO issuer	Co. logo of the ISO issuer is in the label

Table 2. Comparison of the Original and Counterfeit Polybag of Cos-Med Inset Adult without Needle

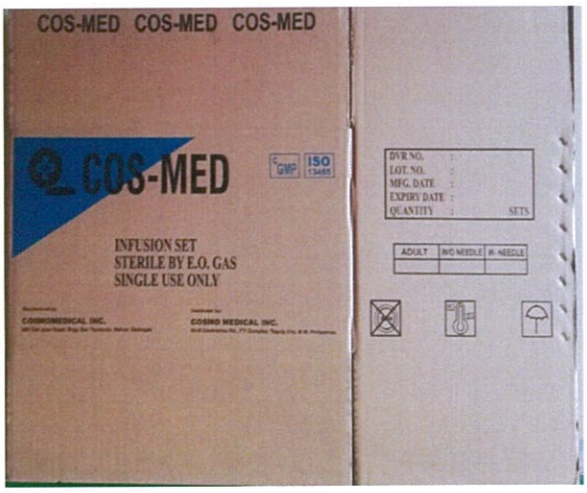
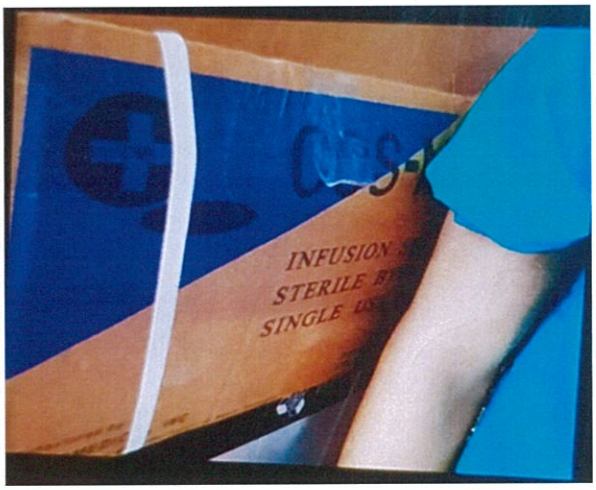
ORIGINAL	COUNTERFEIT
	

Figure 4. Photos of the Original and Counterfeit Carton Box of Cos-Med Inset Adult without Needle

ORIGINAL	COUNTERFEIT
Corrugated box is sturdy	Corrugated box is soft and easily crumble
Light brown color of carton box with dark blue triangular marker on the left, topmost part on the front and back panels	Dark brown color of carton box with big dark blue triangular marker on the left, topmost part on the front and back panels
Font colors are more pronounced and style is bold	Font colors are light and style is narrow

Table 3. Comparison of the Original and Counterfeit Carton Box of Cos-Med Inset Adult without Needle

The Market Authorization Holder (MAH), Cosmo Medical, Inc., reported to the FDA that the aforementioned medical device is counterfeit.

Counterfeit product has not go through the required safety assessment and the FDA verification process. This product pose potential health hazards to the consuming public since its safety and purity cannot be guaranteed.

In light of the foregoing, the public is advised not to purchase the aforementioned violative product.

All concerned establishments are warned not to distribute, the said counterfeit medical device.

All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that this violative product is not sold or made available in the market or their areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this counterfeit product.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at **cdrrhr@fda.gov.ph**, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health
Officer-in-Charge, Director General

DTN: 20190913151641