Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

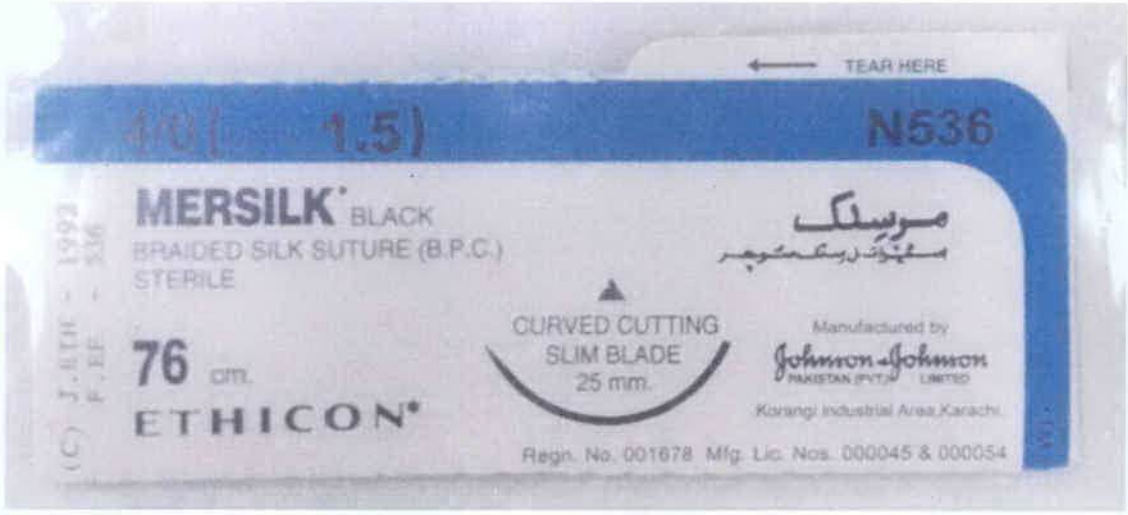
14 FEB 2018

FDA ADVISORY
No. 2018-046

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS, ESTABLISHMENTS and GENERAL CONSUMING PUBLIC**

SUBJECT: **Public Health Warning Against the Use of Unregistered Medical Device (Mersilk Black Braided Silk Suture N536)**

The Food and Drug Administration (FDA) hereby advises all concerned healthcare professionals, establishments and general consuming public against the purchase and use of **MERSILK BLACK BRAIDED SILK SUTURE N536** manufactured by Johnson & Johnson Pakistan PVT Limited, Korangi Industrial Area, Karachi whose picture appears below:



FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical device product has not gone through the registration process of the agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Pursuant to the provisions of Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", **the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is adulterated, unregistered or misbranded are prohibited.**

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The abovementioned product did not undergo the evaluation process of the FDA. Thus, the agency cannot guarantee its quality and safety.

Furthermore, FDA, in coordination with the Market Authorization Holder (MAH), Johnson & Johnson Philippines, Inc., has verified that the above-stated medical device product is counterfeit.

In this regard, the public is hereby advised not to purchase the above-mentioned violative product and to be vigilant against the medical device products that are not registered with the FDA.

Distributors, retailers, hospitals and all healthcare professionals/users are advised to discontinue further distribution, sale and use of the said medical device product.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that the product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please email us at cdrrhr_prsdd@fda.gov.ph or call the Product Research and Development Division - Center for Device Regulation, Radiation Health and Research of the FDA at telephone no. (02) 857-1900 loc. 8301.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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