



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



FDA ADVISORY  
No. **2017-180**

20 JUN 2017

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

**SUBJECT: Public Health Advisory on the Use of the Following Medical Devices:**

1. Powdered Surgeon's Gloves
2. Powdered Patient Examination Gloves
3. Absorbable Powder for Lubricating a Surgeon's Glove

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The Food and Drug Administration of the Philippines (FDA) hereby informs the public that the US Food and Drug Administration has recently issued Medical Device Bans with Document Number 2016-30382 regarding the risks posed by powdered gloves.

*FDA Philippines shall implement the gradual switching to powder-free gloves and eventually phase out powdered gloves, and shall be completed by the end of 2018.*

Based on US FDA Advisory, "The Food and Drug Administration (FDA or Agency) has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling." This rule took effect on 18 January 2017. (Attached is a copy of the U.S. FDA Advisory)

In order to ensure safety, the Food and Drug Administration of the Philippines shall adopt the use of powder free medical gloves.

This advisory shall cover the importation, distribution, manufacture, storage, distribution, and use of (1) powdered surgeon's gloves; (2) powdered patient examination gloves; and (3) absorbable powder for lubricating a surgeon's glove. However, this ban does not apply to (1) powdered radiographic protection gloves; (2) powder used in the manufacturing process of non-powdered gloves; and (3) powder intended for use in or on other medical devices, such as condoms.

This advisory shall take effect on 01 January 2019, therefore, all CDRRHR applications for product certification and/or other authorization for powdered gloves shall not be allowed. All valid CPRs issued prior to December 31, 2018 shall be revoked/terminated/cancelled as this pose potential danger to clinician and patient and/or consuming public.



All healthcare professionals and the general public are hereby informed of the gradual phasing out of powdered gloves and it's eventually phase out by end of 2018 in Philippine Market.

The FDA hereby warn the public that any importation/selling/manufacturing/distribution or offering for sale of the abovementioned medical devices after 31 December 2018 shall be considered as a direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.

For more information and inquiries or to report continuous sale or distributions of banned medical device, kindly e-mail us via [cdrrhr\\_prsdd@fda.gov.ph](mailto:cdrrhr_prsdd@fda.gov.ph) or you may call the telephone numbers **(02) 857-1900 local 8301**.

Dissemination of the information to all concerned is requested.

  
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Director General



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