



06 JUN 2018

**FDA MEMO**  
No. 2018-011


**TO: ALL APPLICANTS, MARKETING AUTHORIZATION  
HOLDERS AND OTHER CONCERNED PARTIES**

**SUBJECT: REGULATION OF TOOTHBRUSH, SANITARY NAPKINS  
AND BABY DIAPERS**

The Center for Device Regulation, Radiation Health and Research would like to inform that toothbrush (except for electric toothbrush which is classified as medical device), sanitary napkins and baby diapers will remain as consumer products until further notice. However, sanitary napkins and panty liners with claims (e.g. health benefits and therapeutic) can be considered as medical device if proven with substantiated documented evidence. A thorough review and evaluation of the said products will be undertaken to qualify as a medical device.

All companies which are importing, distributing or manufacturing the above-mentioned consumer products are not required to secure License to Operate as Medical Device Importer/Distributor/Manufacturer. Furthermore, the FDA will not be issuing the Sales Promotion Permit (SPP) of these products. The issuance of the SPP of the above-mentioned consumer products will be covered by the Department of Trade and Industry (DTI).

For information and dissemination to all concerned is requested

  
**NELA CHARADE G. PUNO, RPh**  
Director General



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