

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



FDA ADVISORY No. 2017-327

2 9 DFC 2017

TO

THE GENERAL PUBLIC

SUBJECT:

CREATION OF A TASK FORCE THAT WILL REVIEW,

SUBMIT RECOMMENDATIONS AND TAKE APPROPRIATE ACTIONS RELATING TO THE DENGUE TETRAVALENT VACCINE (LIVE, ATTENUATED), REGISTERED DENGVAXIA, AND THE TRANSMITTAL OF APPLICATIONS, LETTERS, REQUESTS, CORRESPONDENCE AND OTHER RELEVANT DOCUMENTS ONLY TO THE TASK FORCE SO

CREATED.

In view of the recent clinical findings released by Sanofi Pasteur Inc. (SPI) on the possible effects of the Dengue Tetravalent Vaccine (Live, Attenuated), registered as Dengvaxia, (to those inoculated without prior history of dengue), the FDA created a Task Force (TF) on 3 December 2017, through FDA Personnel Order No. 2017-1019, to: conduct a comprehensive review of all the records relating to the approval of the said vaccine; submit appropriate recommendations; and take appropriate actions, having in mind its fundamental mandate to protect and promote the right to health of the people.

The TF was given the authority retrieve and retain custody of ALL files involving the said vaccine, pending the said review, issuance of recommendations, and the taking of appropriate actions, among others authorities.

The public is thus advised that all applications, requests, letters, correspondence and other documents related to Dengvaxia should be directly forwarded to the FDA Action Center (FDAC), Attention: Atty. Kevin Jardine S. Lozano, TF Dengvaxia, Secretary. Any and all documents transmitted to or by offices, other than the TF on Dengvaxia, shall not be considered official.

> HARADE G. PUNO, RPh Director-General/ Undersecretary





