

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



23 MAY 2019

FDA ADVISORY No. 2019-122

TO: ALL CONCERNED MARKETING AUTHORIZATION

HOLDERS (MAH)

SUBJECT: LIST OF VAT-EXEMPT DIABETES, HIGH

CHOLESTEROL AND HYPERTENSION DRUGS

Pursuant to the Republic Act (RA) No. 8424, otherwise known as 'National Internal Revenue Code of 1997'as amended by RA No. 10963 otherwise known as the TRAIN Law, the sale of drugs prescribed for diabetes, high cholesterol and hypertension shall be exempt from Value Added Tax (VAT) beginning 1 January 2019.

On 3 January 2019, the Bureau of Internal Revenue (BIR) published the full text of the implementing guidelines on the said exemption by virtue of Joint Administrative Order (JAO) No. 2-2019 effective on 1 January 2019.

Item V.C of the JAO, provides that the Food and Drug Administration (FDA) should have the responsibility, among others: (1) to identify drugs which are specifically prescribed for the treatment and/or prevention of diabetes, high-cholesterol and hypertension to be included in the "List of VAT-exempt diabetes, high-cholesterol and hypertension" and (2) Regularly update such list when drugs are registered or de-registered.

Since the effectivity of the JAO, the FDA submitted a list of registered drugs for diabetes, high-cholesterol and hypertension for VAT exemption to BIR. However, this Office has received reports from the industry that a number of drug products indicated for the same conditions were not included in the list.

In view thereof, all concerned Marketing Authorization Holders (MAH) are required to submit a letter to this Office through the FDA Action Center (FDAC) indicating all drug products for VAT-exemption which were not included in the previous list within fourteen (14) calendar days from the date of issuance of this Advisory for proper evaluation of the Center for Drug Regulation and Research (CDRR).



Thereafter, the FDA shall issue an Addendum to the list of VAT-exempt drug products previously issued to reflect those which were not included.

For strict compliance.

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