



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

November 29, 2022

Advisory No. 30

Advisory on Shelf Life Extension of COVID-19 Vaccines

This Advisory is issued to provide guidance to all Regional/Local Vaccination Operation Centers (R/LVOCs), Implementing Units, Vaccination Sites regarding the updated shelf life status of certain batches of Pfizer Adult (Purple Cap) vaccines.

The Food and Drug Administration (FDA) has issued the Amended Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccines dated 10 October 2022 which reflects its 15-month shelf-life extension, as long as approved storage conditions between -90°C to -60°C are maintained. The updated shelf life for the Pfizer-BioNTech (Comirnaty) COVID-19 mRNA vaccines 30 micrograms suspension for injection, purple cap can be accessed in the link below.

The monitoring sheet with the complete batch and lot numbers, printed expiration dates and the latest extension of shelf life may be viewed through this link: <https://bit.ly/SCMSC19VaccineMonitoring>. Kindly check the monitoring sheet regularly and cascade to the implementing units as needed. A digital or print copy of the most updated monitoring sheet must be available in all vaccination sites at all times. These may be used as reference of vaccination teams and vaccinees to clarify the shelf life extension of the vaccine batches being administered in their site.

Furthermore, this is to reiterate the Advisory No. 20 dated 27 September 2022 with subject "*Shelf Life Extension of COVID-19 Vaccines*" stating that the shelf life of vaccines are extended as COVID-19 manufacturers update their data and evidence on the stability of their products. The local Emergency Use Authorization (EUA) holders submit their request for amendment to the Philippine Food and Drug Administration (FDA) and extensions are processed per batch and per brand after the completion of the updated stability studies.

For any issues and concerns related to this Advisory, you may email c19vaccineopen@doh.gov.ph.

This Advisory is effective immediately, and for wide dissemination and compliance.

Date:
2022.11.29
19:14:01 +0800

NESTOR F. SANTIAGO, JR., MD, MPH, MHA, CESO II
Undersecretary of Health
Public Health Operation Center

Drugs In American Life The Reference Shelf

Peipei Pang



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Specification of Drug Substances and Drug Products is a fully comprehensive reference on Specification Setting for Pharmaceuticals There have been several recent developments in the ICH Guidelines which were not captured in previous editions notably the new guideline on Development of Analytical Procedure and the revisions to the validation guidelines and the specification guidelines This edition contains chapters discussing the unique requirements for the universal critical quality attributes as well as the specific tests required to characterize and control different types of products ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug antibody conjugates and mRNA based products This substantially expanded revision of the 2nd edition will serve as practical comprehensive reference for scientists managers educators and consultants involved in the development and regulation of pharmaceutical products Presents critical assessment potential impact and application of the recent revisions to ICH guidelines on method validation Q2 as well as the latest guideline on Analytical Method Development Q14 and the special regional requirements in non ICH regions Addresses comprehensive treatment of the development and validation of analytical methodologies used in the analysis control and specification of a variety of different types of dosage forms ranging from traditional oral solid dosage forms to proteins nRNA based drugs vaccines and gene therapy This book will also address drug device combination products such as digital drug delivery systems transdermal systems and inhalation products Presents detailed treatment of latest statistical approaches including new approaches to the treatment of validation data method specification setting and shelf life prediction based on stability data **Books in Series** , 1985 Vols for 1980 issued

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