FDA ADVISORY
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TO: **ALL PROFESSIONAL HEALTH SOCIETIES, CHIEFS OF HOSPITALS AND MEDICAL CENTERS, HEALTHCARE PROFESSIONALS AND ACADEMICIANS**

SUBJECT: **Call for Nomination as member of the Human Drug Registration Advisory Committee (HDRAC)**

Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", the FDA is responsible for the issuance of appropriate authorizations, such as a Certificate of Product Registration (CPR), following compliance with the standards of the quality, safety and efficacy of drug products for human use. Prior to registration or issuance of a marketing authorization of a given drug product, the FDA, through the Licensing and Registration Division (LRD) under the Center for Drug Regulation and Research (CDRR), shall conduct the review of dossiers containing data and information of drug products.

To ensure the effective review of drug product dossiers, the FDA should have an access to an advisory committee that will support in the decision-making process in the registration of drug products for human use, particularly in the review of the quality, non-clinical and clinical documents.

In line with this, the FDA is starting the call for nomination for experts in the following fields as a member of the HDRAC:

1. Pharmacology
2. Clinical/Public Health Epidemiology
3. Clinical Toxicology
4. Clinical Medicine/Medical Specialist (including but not limited to the following specializations: Allergology, Immunology, Infectious Disease, Rheumatology, Oncology, Cardiology, Nephrology)
5. Homeopathic Medicine
6. Pharmacognosy
7. Biostatistics
8. Clinical Research
9. Biotechnology
10. Vaccinology

The following are the required qualifications of the HDRAC members:

- Recognized specialist in their respective field of expertise;
- With at least 5 years of experience in their respective field;
- Willingness to disclose conflicts of interest

The nominees will be evaluated according to their educational attainment and field of expertise, relevance of work experience, relevance of training experiences within the last ten (10) years, publications and conflicts of interest.

We hope to receive the names and contact details of the nominees on or before 30 April 2024 and we shall reach out on the requirements and how to proceed with the application.

Kindly submit the list of the nominees at cdrr.rxinitial@fda.gov.ph. If you have any questions or concerns, please do not hesitate to contact us through the same email address.

Thank you very much.

DR. SAMUEL A. ZACATE
Director General