Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

03 September 2013

FDA Circular
No. 2013-023

To : **All Drug Establishments, FDA Personnel and Other Concerned Parties**

From : **KENNETH Y. HARTIGAN-GO, MD**
Acting Director General

SUBJECT : **CLARIFICATION ON THE PROVISIONS OF ADMINISTRATIVE ORDER No. 2013-0022, ON THE GUIDELINES FOR CURRENT GOOD MANUFACTURING PRACTICE (cGMP) CLEARANCE AND INSPECTION OF FOREIGN DRUG MANUFACTURERS**

With the recent implementation, in part, of Republic Act No. 9711, otherwise known as the Food and Drug Administration (FDA) Act of 2009, which specifies the establishment of centers by product categories, the Center for Drug Regulation and Research (CDRR) was created.

The provisions of the Department of Health (DOH) Administrative Order No. 2013-0022, on the Guidelines For Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers, as signed by the Secretary of Health on August 13, 2013, is hereby clarified:

1. Annex A. NOTES ON APPLICATION FORM TO REQUEST FOR GMP EVIDENCE EVALUATION

   a. On item No. *1. This application form is for requesting the GMP evidence evaluation. The completed application form must be submitted together with the GMP evidence to the Food and Drug Administration Philippines - Regulation Division II.*

      Regulation Division II is a former division of the Bureau of Food and Drugs (BFAD), and under the FDA organization and structure based on product categories, this is now the **Center for Drug Regulation and Research**.

b. On item No. 6. *The complete application form and GMP evidence must be sent to:*

Regulation Division II
Food and Drug Administration Philippines
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Regulation Division II is a former division of the BFAD, and under the FDA organization and structure based on product categories, this is now the **Center for Drug Regulation and Research**.

2. On page 15. FOR OFFICIAL USE ONLY. *Remarks : To be routed to GMP Clearance Unit – Regulation Division II for Assessment.*

In the former BFAD, the **GMP Clearance Unit** was headed by a supervisor in-charge of conducting cGMP inspection under Regulation Division II. However, under the FDA organization and structure based on product categories, this is now the **Center for Drug Regulation and Research**.

3. On page 17. ANNEX D. Application Form for Foreign Manufacturer GMP Inspection

Postal: The Director
Food and Drug Administration
Civic Drive, Filinvest Corporate City,
Alabang, Muntinlupa City, Philippines

In the former BFAD, a Director heads the BFAD, but the FDA is now headed by the Director General. **The Director** should read **The Director General**.

4. On page 27. Section C. Additional Information.

Regulation Division II
Food and Drug Administration Philippines
Civic Drive, Filinvest Corporate City,
Alabang, Muntinlupa City, Philippines 1781
Telephone No.: 809-4390 loc 1281; 807-2843

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For more information and inquiry, kindly email the FDA via info@fda.gov.ph. To report any health product-related incidence, experience or problem, please email us via report@fda.gov.ph.