



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City



27 September 2004

BUREAU CIRCULAR

No. 13 s. 2004

TO: All Food, Drug, Devices and Cosmetics Establishments

SUBJECT: Clarification of par. a, Bureau Circular No. 6 s.1999
(Revised B.C. No. 4 s. 1999 "New Protocol for Registration
of Drugs, Foods, Cosmetics and Medical Devices)

Assessment of laboratory fees as prescribed in AO No. 50 s.2001 (Subject: Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs) IS included in the procedure for the acceptance of an application for registration of processed foods, drugs, cosmetics and medical devices. The laboratory fees charged and collected shall be for the expenses to be incurred in the conduct of laboratory analysis of products either at the time of application or when monitored in the market.

Please be guided accordingly.

Adelina Cifera Ramon
Fu Prof. LETICIA-BARBARA B. GUTIERREZ, M.S.
Director IV



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
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February 15, 1999

BUREAU CIRCULAR
No. 6, s. 1999

SUBJECT: REVISED BUREAU CIRCULAR # 4, s. 1999 "NEW PROTOCOL FOR REGISTRATION OF DRUGS, FOODS, COSMETICS AND MEDICAL DEVICES"

Effective immediately, the following changes in the registration protocol will be implemented:

- a. Samples for physico-chemical analysis are not required. However, sample product in commercial presentation shall be submitted for physical evaluation or specification verification;
- b. Complete documentation to support claims of safety, efficacy, identity and quality must be submitted. Approval/disapproval by Product Services Division will be after evaluation based on completeness and accuracy of submitted documents.
- c. No follow-up by regulatory officers or company representative will be entertained before the 90 days period following acceptance of the application as provided by PAICS.

For your guidance.


WILLIAM D. TORRES, Ph.D.
Director

