

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 Be entertained before the 90 days period following acceptance of the application as provided by PAICS.

For your guidance.

(Sgd.) WILLIAM D. TORRES, Ph. D.
Director