



Republic of the Philippines
Department of Health
BUREAU OF FOOD AND DRUGS
Filinvest Corporate City
Alabang, Muntinlupa City

20 November 2001

BUREAU CIRCULAR
No. 16 s. 2001

SUBJECT: GUIDELINES FOR THE IMMEDIATE PROCESSING OF APPLICATIONS FOR INITIAL REGISTRATION OF PHARMACEUTICAL PRODUCTS.

Complementary with the adoption by the Bureau of BC No. 15 s. 2001 providing for the automatic renewal of registration of pharmaceutical products and consistent with the directive of the Secretary of Health, the Bureau hereby issue the following modified guidelines in the processing of initial applications for the registration of pharmaceutical products.

- 1) All pending as well as incoming applications for initial registration shall henceforth be processed within a period of sixty (60) working days from date of filing, provided that all submissions in support thereof are complete in all respects in form and substance as provided under existing regulations.
- 2) Applications that are incomplete or otherwise found insufficient will be issued a "Notice of Deficiency". The notice will include a list of all deficiencies and a date for an appointment which will not exceed thirty (30) days following the date of notice so that applicant can submit and complete the deficiencies.
- 3) All follow-ups will be made strictly on appointment basis. No other inquiries will be entertained.
- 4) If appointments are not kept or met the pertinent application will automatically be relegated to the "inactive file."
- 5) The period during which the application is issued a Notice of Deficiency or is relegated to the "inactive file" shall not be computed for purposes of determining the registration period provided in this circular.
- 6) These guidelines are applicable only to "tried and tested" drugs and do not include "new chemical entities" or those without proven track record.
- 7) This circular is intended to ensure the orderly, systematic and faster evaluation of applications and do not in any way preclude nor affect the final determination of each application.

This circular shall take effect immediately.

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