



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



April 20, 2001

BUREAU CIRCULAR

No. 4 s. 2001

TO : Clients of BFAD in the Pharmaceutical Industry
Staff of the Product Services Division

Subject : Extension of the Validity of Monitored Release Study

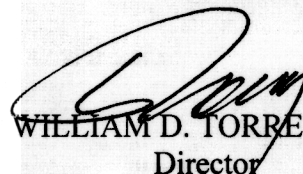
In response to queries as to when the validity period of the Monitored Release Study can be extended, the Bureau of Food and Drugs seeks to clarify and answer such queries. All communications regarding request for the extension should be submitted to the Office of the Director. Each request will be evaluated based on its own merits. Grounds for extension shall be appropriately screened and acted upon. Reasons for extension may include:

1. Non-implementation of the study: the study was never started at all.
2. Inadequate number of subjects compared to what was required of the study.

Such reasons as stated above and others that may arise during the course of the study and shall be closely scrutinized as to the rationality of both request and underlying reasons.

This circular shall take effect immediately.

Very truly yours,


WILLIAM D. TORRES, Ph.D.
Director

FPG/jhet
/BC-ext. of mrs

"Smoking is Dangerous to your Health"