

Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

September 29, 1999

ADMINISTRATIVE ORDER No. 41-A s. 1999

SUBJECT: Fee for Re-submission of Application for Initial or Renewal Registration of Pharmaceutical Products Previously Disapproved Pursuant to Bureau of Food and Drugs (BFAD) Circular No. 6 s. 1999.

By virtue of Article 17, Item (d) of Republic Act No. 7394, otherwise known as "The Consumer Act of the Philippines" and in consonance with DOH Administrative Order No. 67 s. 1989, an application fee of One Thousand Pesos (P1,000.00) shall be collected by Bureau of Food and Drugs (BFAD) from drug establishment for re—submission of application for initial or renewal registration of pharmaceutical products.

This shall cover applications received starting January 4, 1999 which were disapproved for non—compliance with the requirements for product registration pursuant to BFAD Bureau Circular No. 6 s. 1999 (Subject: Revised Bureau Circular No. 4 s. 1999 "New Protocol for Registration of Drugs, Foods, Cosmetics and Medical Devices").

The resubmission fee shall only be for applications resubmitted within six (6) months from the date of notice of disapproval of the same application. Applications submitted after six (6) months from the date of notice of disapproval shall be considered as initial registration.

Signed AO Received in the Records Section on 10/19

ALBERTO G. ROMUALDEZ, JR., MD
Secretary of Health