[BFAD MEMORANDUM CIRCULAR NO. 5, s, 1994, April 20, 1994]

REPORT ON ADVERSE DRUG REACTION

The Bureau of Food and Drugs (BFAD), pursuant to the mandate of R.A. 3720, otherwise known as the "Food, Drugs and Devices and Cosmetics Act," to ensure the purity, safety, efficacy and quality of drugs, and by virtue of the powers vested in it by the aforesaid law, hereby adopts and implements a system of reporting of adverse drug reactions.

Accordingly, all drug establishments and parties concerned are hereby enjoined to submit to the Office of the Director, BFAD reports of:

a - All suspected reactions to NEW DRUGS, especially DRUGS OF CURRENT INTEREST
b - All suspected drug interactions, and
c - Reactions to other drugs which are suspected of significantly affecting a patient's management, including reactions which could cause:

1. Death
2. Danger to Life
3. Admission to hospital
4. Prolongation of hospitalization
5. Absence from productive activity
6. Birth defects

Serious adverse drug reaction report(s) shall be submitted to BFAD within two (2) weeks after the receipt of the same. Other adverse drug reactions reports shall be submitted on or before the 15 of January of each year.

This Circular takes effect immediately.

Adopted: 20 Apr. 1994

(SGD.) QUINTIN L. KINTANAR
Director