

REPUBLIC OF THE PHILIPPINES

DEPARTMENT OF HEALTH BUREAU OF FOOD AND DRUGS

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16 April 2010

FDA CIRCULAR 2010-009

To

All Drug Establishments and Parties Concerned

Subject

Amendment to Memorandum Circular No. 5 s.

1994 dated April 20, 1994 regarding Reports on

Adverse Drug Reaction

Amendment is hereby made on the last paragraph of the Memorandum Circular No. 5 s. 1994 dated April 20, 1994, to read as follows:

Serious adverse drug reaction report(s) shall be submitted to BFAD within 72 hours (3 working days) and no later than 7 working days, after receipt of the same. Other adverse drug reactions report shall be submitted every 30th day of the first month of each quarter of the year.

In case of low efficacy/low potency of any pharmaceutical product, submit corresponding report using the prescribed Pharmaceutical Product Problem Report.

For strict compliance.

T. TACANDONG, RPh, MPA

Director IV