## [FDA CIRCULAR NO. 2010-009, April 16, 2010]

## 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 30<sup>th</sup> 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.

(SGD.) NAZARITA T. TACANDONG, RPh, MPA Director IV



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