[BFAD MEMORANDUM CIRCULAR NO. 10, May 27, 1992]

CLARIFYING FDA (BFAD) MEMORANDUM CIRCULAR NO. 001 S. 1983, SEC. 4.2.2 OF CHAPTER 1 AND SECTION 4.2.1, CHAPTER II OF A.O. 56 S. 1989

The burden of ensuring that lot number and expiry date of drug product are indicated on the invoice covering the sales/transaction of said drug product shall rest on both the drug outlet and the drug distributor/supplier, and drug distributor/supplier and the manufacturer or importer, as the case may be.

The drug outlet, drug distributor/supplier and manufacturer are therefore liable for the failure to indicate the lot number and expiry date on a given invoice covering the drug products delivered, unless the drug distributor or manufacturer can prove by substantial evidence that the invoice subject to question is spurious and/or was not issued by the same distributor/manufacturer.

For the information of all concerned.

Adopted: 27 May 1992

(SGD.) QUINTIN L. KINTANAR, M.D., PH.D. Director - CESO I





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