

[BFAD MEMORANDUM CIRCULAR NO. 13, October 31, 1990]

PROVISIONAL REQUIREMENT FOR LICENSING OF ESTABLISHMENTS TO ENGAGE IN THE MANUFACTURE, DISTRIBUTION AND SALE OF DIAGNOSTIC REAGENTS FOR LABORATORY USE

Diagnostic reagents use in vitro in clinical laboratory, although falling within the general definition of drugs, are manufactured and utilized by professionals who are not pharmacists. Therefore there is a need for a separate set of rules and regulations governing its manufacture and distribution, among others. The formulation of the said rules and regulations governing the issuance of License to Operate to establishments who shall engage in the business involving diagnostic reagents is still in process. Meanwhile, there are applications for exemption from the requirement of employing a pharmacist.

Pending the promulgation of rules governing licensing and registration of diagnostic reagents, applications for such licenses shall be granted under the rules and regulations governing drug establishments. However, such licenses may be provisionally granted to establishments who shall engage in the manufacture, distribution and sale of diagnostic reagents for laboratory use without employing a pharmacist. The applicant may instead employ a certified pathologist, registered bio-chemist, chemist or a medical technologist who has had additional education or training in the preparation and quality control of diagnostic reagents in lieu of a pharmacist. The LTO that may be issued, whenever proper, shall be subject to whatever rule or regulation that will be approved pertaining to diagnostic reagents establishment.

Adopted: 31 Oct. 1990

(SGD.) TOMAS P. MARAMBA, JR.

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