

UPGRADING OF DRUG MANUFACTURING FACILITIES IN CONSONANCE WITH CGMP REQUIREMENTS BEGINNING 1996 UP TO YEAR-END 1999

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This is to confirm formally the information disseminated by FDRO of Regulation Division II during the regular inspections in their notices to comply with GMP requirements during such inspection that the period within which to upgrade drug manufacturers facilities is between 1994 up to year-end of 1999. Therefore, beginning the year 2000, all drug manufacturers who will not be able to comply with the current GMP guidelines will not be issued a License to Operate as such.

With this Circular, it is understood that the basic CGMP guidelines which have been substantially disseminated during the regular conduct of inspection.

Adopted: 14 May 1998

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