BFAD QUALITY SEAL

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Current Good Manufacturing Practice (CGMP) Certification is being issued only upon request and after audit inspection where the establishment is found to have complied with the requirements as stipulated in A.O. 43, s. 1999, otherwise known as Amendment of Administrative Order No. 220, s. 1974, Current Good Manufacturing Practice.

Such certification is valid only for a period of one year from the date of issuance. As incentive, the Department of Health together with the Bureau of Food and Drugs will pursue its project on Quality Seal Award to those drug manufacturers that are compliant with the CGMP in accordance to level of compliance: 1st level - Commitment: 2nd Level - Compliance; 3rd Level - Quality.

The Bureau has created the JOINT BFAD INSPECTORATE TEAM as per Bureau Circular No. 10, s. 2005. The team will be composed of the staff from the Laboratory Services Division, Product Services Division and Regulation Division II of the Drug GMP Inspectorate Group in coordination of the regional FDROs. RD II will be the lead auditor in this group and this will start June until August before the Generics month in September.

Last 2004, 43 drug manufacturers were audited for the 1st level and will be reassessed on the level of compliance in all the elements covered under the cGMP Guide for Drugs. All the said companies will be reassessed based on their compliance with cGMP, with 2-year LTO validity, and no pending case/s for the last five years in operation.

All the drug manufacturers must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use; comply with the requirements of the marketing authorization and not place patients at risk due to inadequate safety, quality or efficacy.

For your information and guidance.

Adopted: 20 June 2005

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