AMENDMENT TO ADMINISTRATIVE ORDER NO. 19, SERIES OF 2003

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Department of Agriculture (DA) Administrative Order No. 19, series of 2003 re: Good Manufacturing Practice Certification and Audit of Manufacturing Plants producing Animal Health Products is hereby amended such that the said Order shall include the following:

1. All drug manufacturing plants/laboratories of animal health products shall be required to comply with the internationally-recognized standards of current Good Manufacturing Practice (GMP) program under the guidelines of duly recognized bodies such as Codex Alimentarius, World Health Organization and Section 26a of Republic Act 3720 or the Food, Drugs and Devices and Cosmetics Act as per Memorandum of Agreement between the DA-Bureau of Animal Industry (BAI) and Department of Health-Bureau of Food and Drugs on September 25, 1991.

2. An independent certification body duly-recognized and accredited by the BAI shall conduct training/seminars on GMP under the strict supervision and monitoring of BAI.

3. The GMP Certificate of Training shall be signed by both the recognized/accredited certification body and the BAI.

4. The BAI shall create an Inspection and Audit Team which shall be composed of trained and competent BAI technical personnel who shall perform the following functions:

a. Review and evaluate plant layouts submitted by new drug manufacturing plants/laboratories prior to the construction of their buildings/facilities;

b. Suggest revisions, if there are any, in the submitted layouts and recommend approval of same after compliance with GMP guidelines;

c. Conduct the inspection and audit of drug manufacturing plant/laboratory facilities in compliance with GMP guidelines prior to the issuance of their License to Operate (LTO);

d. Recommend the approval and issuance of LTO to drug manufacturing plants/laboratories which have complied with the GMP guidelines;

e. Supervise and monitor the conduct of GMP training/seminars by BAI accredited/recognized body; and

f. Perform all other functions in relation to GMP implementation.

5. The BAI shall issue the Certificate of GMP Compliance (CGMPC) to drug manufacturing plants/laboratories which have complied with GMP requirements. Issuance of CGMPC shall be done in conjunction with the issuance of their LTOs.

This Order shall take effect immediately upon approval and shall supercede all other Orders and other issuances inconsistent thereof.

Adopted: 03 Oct. 2005

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(SGD.) DOMINGO F. PANGANIBAN
Secretary

Recommending Approval:

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