[BFAD MEMORANDUM CIRCULAR NO. 11, June 01, 1992]

SAMPLES REQUIREMENT FOR THE PURPOSE OF REGISTRATION OF DRUGS AND DEVICES

Effective April 15, 1992, samples of products for analysis, as a requirement for registration, shall be submitted to Window 1 only when the Laboratory Services Division has scheduled the products for analysis.

After the documentary requirements shall have been evaluated and when the Laboratory Services Division has set the schedule for analysis of the products for registration, a notice to the applicant will be issued by the Laboratory Services Division thru Public Assistance, Information and Compliance Section (PAICS), for the Applicant to submit the required number of samples for testing.

To avoid unnecessary follow-ups, the applicant will be furnished a copy of the transmittal of the samples for laboratory analysis and the result of analysis of the same. The forms of the Notice for submission of samples for Laboratory Testing and the transmittal letters are hereto attached for reference.

For purposes, however, of evaluating the label and the commercial presentation of the product, the applicant will be required to submit a sample of the product in its commercial presentation, if possible and/or its labelling materials upon the submission of its application for registration.

Adopted: 1 June 1992

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