

[BFAD BUREAU CIRCULAR NO. 8-A, S. 1999, April 19, 1999]

GUIDELINES IN THE COLLECTION AND SUBMISSION OF SAMPLES OF FOOD, DRUGS, COSMETICS, AND MEDICAL DEVICES FOR PHYSICO-CHEMICAL ANALYSIS

Bureau Circular No. 4, s. 1999 provides that samples for physico-chemical analysis are not required in the registration of food, drugs, cosmetics and medical devices.

In order to ensure the safety, efficacy, identity and quality of the said products, and for the interest of consumer protection the following guidelines are hereby adopted:

1. The BFAD shall randomly collect samples of registered food, drugs, cosmetics, and medical devices from the retail outlets and from the manufacturer's plant, importer or distributor's warehouses for submission to the Laboratory Services Division for physico-chemical analysis.
2. The collection of samples shall be done in accordance with Section 28 of RA 3720 as amended and Administrative Order No. 72, s. 1983.
3. The collected samples shall be properly tagged stating the name of the product, the source, date and the name of the collection officer and the purpose of the collection.
4. In case the result of the analysis renders the product adulterated, misbranded or mislabeled or counterfeit, BFAD shall notify the registrant company of such fact with the complete data supporting the same. The registrant company is given a non-extendible period of 15 days from receipt thereof to file its answer and its opposition thereto.

In the meantime, the Certificate of Product Registration of the said product shall be suspended pending the resolution of the case but in no case shall the same exceed thirty (30) days from the receipt of the notice. The registrant shall hold in abeyance the manufacture, sale or distribution of the subject product or recall the same at their own cost.

The penalties imposed under existing rules and regulations in RA 7394, RA 3720 as amended or RA 8203 shall be applied as the case maybe.

5. The cost for the collection of samples shall be considered as part of the fees collected at the time of registration at an amount equivalent to actual cost of sample plus the cost of collection per sample.
6. No CPR shall be processed for renewal if the cost for the collection has not been paid.