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CERTIFICATION OF REGISTRATIONS’ ANNOTATION OF SUSPENSION/CANCELLATION OF DRUG OR DRUG PRODUCT COMBINATION FOUND TO BE ADULTERATED/MISBRANDED

BFAD BUREAU CIRCULAR NO. 11, S. 1999, June 01, 1999

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Republic Act No. 3720 as amended, otherwise known as Food, Drugs, Devices and Cosmetic Act, states among other things that the policy of the state is to ensure safe and good quality supply of drugs and to regulate the manufacture, sale and traffic of the same to protect the health of the people.

Pursuant thereto and in relation to Section 3(c) and 26(a) of RA 3720 as amended, the following rules and regulations are hereby adopted to properly regulate the manufacture, distribution, sale and traffic of drug or drug combinations which have been found unsafe, inefficacious or of doubtful therapeutic value.

- Whenever a drug or drug product combination is found to be unsafe, inefficacious or of doubtful therapeutic value or otherwise declared to be violative of RA 3720 as amended, Section 11(a) for being adulterated or misbranded, and such finding was confirmed to be correct after due notice and hearing, there should be a corresponding annotation at the back of the Product's Certificate of Product Registration, showing that the drug product was subject of a case before the BFAD, stating therein the case number.

- The corresponding suspension/cancellation of the drug products Certificate of Registration, if provided in the case decision, should be properly annotated at the back thereof, stating therein the duration of the suspension as well as the date when the suspension was lifted.

- The Product Services Division of this Bureau shall cause the annotation of the suspension/cancellation of the Product's Certificate of Registration.

Adopted: 1 June 1999

(SGD.) WILLIAM D. TORRES, PH.D
Director

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