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ADMINISTRATIVE ORDER
No. 142 s. 2004

SUBJECT: Bureau of Food and Drugs (BFAD)'s issuance of Certificate of Product Registration for Foreign Assisted Projects Procurement and Laboratory Testing of Pharmaceutical and Biological Products Procured by and/or delivered to the Department of Health (DOH)

I. Rationale

The laws and regulations of the country require that manufacture, sale and distribution of pharmaceutical and biological products should have a Bureau of Food and Drugs' Certificate of Product Registration (CPR) and have undergone laboratory testing before sale, acceptance and distribution to the public concerned.

On the other hand, Republic Act 9184 or "An Act Providing for the Modernization, Standardization and Regulation of the Procurement Activities of the Government and for Other Purposes" requires a 90-day maximum period of action from opening of bids to award of contract for each procurement activity. Moreover, for the procurement of these products funded by foreign assisted projects (FAPs), the CPR as one of the prerequisites for participating in procurement is considered restrictive and inconsistent with the agreements among member countries.

To comply with these various laws and regulations, and because of the urgency and indispensability of drugs, medicines, vaccines and other medical goods for the various preventive and curative health programs and services of the government specially the Department of Health, the mandatory requirement of CPR for the procurement of pharmaceutical and biological products of FAPs, and technical acceptance of all pharmaceutical and biological products procured by the DOH shall be governed by the following rules.

II. Scope

This order covers all pharmaceutical and biological products and invasive medical devices procured by the DOH

III. Guidelines

A. Issuance of CPR for pharmaceutical products being procured under competitive international bidding and funded by foreign assisted projects

1. Foreign bidders belonging to member countries of international funding agencies of DOH projects may be allowed to participate in a DOH bidding even without a CPR; however, no award or contract shall be made unless and until the appropriate CPR is issued by BFAD.

2. The foreign bidder without a CPR shall already submit the document requirements for application of CPR at the time it makes its bid. After bid opening, when the bidder would appear to be the lowest but not yet complying, the bidder will have to make the application for CPR to BFAD within ten (10) days including submission of sample in commercial presentation.

3. Within ten (10) days from submission of said application, the BFAD should process the same subject to the pertinent provisions of various BFAD Circulars and requirements for registration of pharmaceutical products.

B. Laboratory Testing of Procured and/or delivered Pharmaceutical and Biological products

1. For DOH procured and/or delivered pharmaceutical products, BFAD Laboratory Services Division shall conduct appropriate tests not exceeding the following days from actual receipt of the drugs and medicines and medical devices in sufficient quantity and samples based on BFAD Circular 4-A dated June 2001 and BFAD Circular 12 dated October 5, 2002.

   1.1 For anti-tuberculosis drugs - 15 calendar days
   1.2 For injectables & medical devices that require sterility test – 30 calendar days
   1.3 For all others drugs and medical devices that do not require sterility test - 20 calendar days

2. All WHO, UNICEF and GDF procured and/or delivered vaccines and other immunobiological products are exempted from Lot Release certification and testing

3. For DOH procured and/or delivered vaccines and other immunobiological products not supplied by WHO and UNICEF, the BFAD Laboratory Services Division shall conduct Lot Release Certification process, including visual examination of the lot samples and labels as required by Administrative Order No. 27 series of 2001. Lot Release certificate shall be issued within 7 working days from receipt of samples.

4. After having conducted the preceding examinations, should BFAD determine that further laboratory tests be required, said tests shall be done through a WHO recognized laboratory.

5. For WHO, UNICEF and GDF procured and/or delivered drugs without an equivalent local BFAD registered product and for which the Laboratory Services Division does not have the capability to test, a certification of analysis that the drug has passed the required laboratory analysis by the national pharmaceutical drug laboratory of the country of origin and a copy of the test procedure undertaken and reference standards used shall be required. The certification must be authenticated by the Philippine consular office located at the country of origin.

C. Payment of the laboratory fees

1. The Finance Service shall initially sub-allot P100,000 to the BFAD at the beginning of each year solely for BFAD test analysis. A separate sub-allotment guidelines shall be issued by the Finance Service for the use, liquidation and replenishment of the P100,000 based on COA Circular No. 94-013 dated December 13, 1994.

2. Payment of laboratory fees shall be taken from the budget from the Office of the Secretary.

3. Payment of laboratory fees shall not be a prerequisite by BFAD for the laboratory analysis of these DOH procured and/or delivered goods.

4. The Material Management Division with the BFAD representative of the inspection committee shall initiate the requests for laboratory analysis for delivered goods at the central office.

D. The BAC Secretariat, or the Procurement Division and the Material Management Division of the Procurement and Logistics Service and all units concerned shall lend support to this undertaking ensuring that the BFAD gets notified properly and immediately of the procurement and deliveries. The BFAD shall get the samples within 2 days from notification that delivery was made.

Similar arrangement by the Centers for Health Development and DOH hospitals shall be made. All other administrative issuances with provisions that are inconsistent with the provisions of this order are hereby amended, modified, repealed and/or revoked accordingly.

This order takes effect April 25, 2004.

MANUEL M. DAYRIT, M.D., MSc.
Secretary of Health