Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
Manila

31 March 2005

ADMINISTRATIVE ORDER
NO. 2005-0007

SUBJECT: **Amending Administrative Order No. 142, s. 2004 by providing exemption from the requirement of Certificate of Product Registration for all goods procured through UNICEF, UNDP, WHO, and GDF**

I. RATIONALE

Administrative Order No. 142, series of 2004 *re: Bureau of Food and Drugs (BFAD)'s Issuance of Certificate of Product Registration Foreign Assisted Projects Procurement and Laboratory Testing of Pharmaceutical and Biological Products Procured by and/or delivered to the Department of Health (DOH)*, was issued, among other things, to facilitate the issuance of Certificates of Product Registration (CPR) for the procurement of pharmaceutical and biological products and invasive medical devices of foreign assisted projects (FAPs).

Given however the urgency and indispensability of the pharmaceutical and biological products and invasive medical devices of FAPs for various preventive and curative health programs and services of the government, there is a need to examine and re-evaluate the present system in the light of the efficiency of the procurement system of international organizations and other internationally-recognized institutions, namely, the United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), World Health Organization (WHO), and Global Drug Fund (GDF), and given the strict quality assurance procedures to which commodities procured by these organizations are subjected to.

II. PURPOSE

The purpose of this Order is to establish the exemption from the requirement of the CPR all pharmaceutical and biological products and invasive medical devices procured through the UNICEF, UNDP, WHO, and GDF.

In providing for such exemption, this Department, through BFAD, does not in any way abandon, but hereby reiterates and consistently adopts, its

mandate and responsibility to ensure the safety, efficacy and good quality of products applied for registration.

III. SCOPE AND COVERAGE

Section III, part A of Administrative Order No. 142, s. 2004 provides:

"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."

The aforecited provision is hereby amended to read as follows:

"III. Guidelines

A. Issuance of CPR for pharmaceutical products being procured under competitive international bidding and funded by foreign assisted projects except those procured through the UNICEF and WHO.

1. As a general rule, all 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.

(a) 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.

(b) 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.

2. However, when the procurement is made through the UNICEF, UNDP, WHO, and GDF, no CPR shall be required."

IV. REPEALING CLAUSE

Section III (A) of Administrative Order No. 142, s. 2004 is accordingly amended while Section III, (B) (3) and (B) (5) thereof are hereby repealed. All other administrative issuances, bureau circulars, and memoranda inconsistent with this Order are hereby withdrawn, repealed and/or revoked accordingly.

V. EFFECTIVITY

This Order shall take effect fifteen (15) days after publication in two (2) newspapers of general circulation.

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Secretary of Health