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

15 May 2001

ADMINISTRATIVE ORDER
No. 14 s. 2001

Subject: Interim Accreditation Guidelines for DOH Drugs and Medicines Suppliers

Background and Rationale:

The department of Health (DOH) purchases drugs and medicines in order to promote various public health and clinical services. These drugs and medicines have to be safe, effective and of good quality. The Department recognizes the role of the Bureau of Food and Drugs in ensuring this condition.

Drug companies must never assume that the privilege of supplying drugs and medicines to the Department is automatically given to them as a right by virtue of their issuance of BFAD license. Furthermore, drug companies must also not assume that Certificates of Product Registration (CPR) granted to them for their registered product is automatically considered as safe, effective and of good quality.

The DOH, in the interest of making drug and medicine procurement to be advantageous to the government, will screen licensed drug companies for eligibility as DOH drug suppliers, taking into consideration various parameters, and their technical and financial capability to participate in the bidding process and to supply these drugs and medicines. This system of accreditation imposes a higher standard in order to transact business with government, since it uses people's taxes to provide health care to people who do not have the means to pay for it. Since the department is the purchaser of medicines, it reserves the right to identify the best suppliers to deliver to the Department.

I. Minimum Qualifications

A. For Drug Suppliers
   1. A drug supplier should fall under any of the following classification:
      a. distributor
      b. importer
      c. manufacturer
      d. traders
   2. The suppliers must have a valid license to Operate issued by BFAD.
   3. The Suppliers must have a proof of Security and Exchange Commission (SEC)
   4. A certificate of clearance from BFAD indicating that there is no pending case against the company because of violations.
   5. Latest bank certificate of company's credit facilities, and the financial balance sheet of the previous year as submitted with Securities and Exchange Commission (SEC) or as examined by independent auditors duly contained in its report.
   6. Certificate showing that the company is a member of a BFAD-DOH recognized industry association (Annex A).
   7. Submission of signed application form, and other annexes indicated and attached to the application form.

8. A signed commitment or undertaking, duly notarized, that the applicant shall abide by the rules and regulations of BFAD and its accreditation procedures; that any violation by the company and/or its specific products being applied for accreditation, may be accordingly recalled, suspended or denied rules and regulations of that Office and other such requirements that may be allowed.

B. For Drug and Medicines products

1. The products applied for approval by the supplier-candidate should have a valid Certificate of Product Registration (CPR) issued by BFAD.
2. These products must fall under the specifications of the current edition of the Philippine National Drug Formulary (5^{th} ed. Year 2000). Exemptions to this list may be permitted as determined by the DOH on a case to case basis following (E.O. 49 s. 1993).
3. Satisfactory bioavailability and bioequivalence results are required for generic drug products if and when such procedures for testing are available in the country.
4. The specific product submitted for inclusion into the accreditation listing should not be:
   a. found violating BFAD regulations as initially determined from BFAD Laboratory (LSD) analysis;
   b. pending investigation or resolution before the BFAD Legal Information and Compliance Division (LICD) against the company for BFAD violations: or
   c. On appeal pr pending resolution before the Department Secretary and courts of competent jurisdiction.
5. Clearance should be obtained from the appropriate divisions of BFAD and submitted to the Accreditation committee.(if a violation, LSD to issue clearance. If already a case, then LICD to issue clearance).

II. Accreditation Procedures

A. Only the holder of CPR can join bid activities unless the holder authorizes another accredited drug supplier as the agent to represent them. Hence, a statement or proof that an agent has been authorized by a principal (holder of CPR) is needed. The holder of the CPR is responsible for their products, this is in consonance with the principle that only CPR holders may join the bid activities.

B. Current holders of accreditation status valid until 2002 will be recognized; however, those products covered under I B (3) shall remain suspended until otherwise cleared by BFAD and submitted to the Accreditation Committee. Clearance should be obtained from the appropriate BFAD office and submitted to the Accreditation Committee.

C. Application period for his interim accreditation is from May 16-May 30, 2001. Application forms can be secured from and submitted for accreditation evaluation and approval will be entertained in the next cycle of evaluation to be determined by the Committee.

III. BFAD Inspection, Laboratory Tests and issues of payment

A. Within a period of thirty (30) days from receipt of delivery, a 100% payment arrangement shall be made to the company upon receipt of satisfactory results of analyses from BFAD.

B. If, however, by thirty (30) days from receipt of delivery, BFAD cannot release the results of laboratory analysis, the company shall be paid 50% of the due satisfactory BFAD report analysis.

C. Pending BFAD analysis, said products should not be distributed to end-users nor shall it be used until such time is cleared by BFAD laboratory testing.

D. If BFAD inspection or results of laboratory analysis show major violations (Annex B). The entire product line of the drug is temporarily suspended from accreditation, regardless of the batch or lot in question.

IV. Procedures on Violations

A. Drug supplier automatically loses its accreditation status if and when their License to operate (LTO) is revoked, or if the drug company fails to renew its license according to existing BFAD rules and regulations.

B. Drug products found violative by BFAD Laboratory analysis shall be meted a suspension from accreditation regardless of whether BFAD has revoked the Certificate of Product Registration (CPR) or not. Revocation of CPR by BFAD automatically cancels the accreditation status of the said product.

C. Should there be stocks of drugs and medicines in questions, but the same have been delivered to DOH. These shall be put on hold until such time the product is cleared by BFAD as safe, effective and of good quality

D. Because the accreditation evaluation is active and looks at the track record of the company's performance and products throughout the procurement process, the company may be disqualified from participating further f a major violation of their approved product is documented. This includes those who have already been given Notices of Award. The second lowest qualified bidder/supplier shall then be awarded the contract.

E. The list of violative products will be known as the Negative List, shall be updated on a daily basis at BFAD and n the website. Products in the negative list as determined by the laboratory automatically get suspended from the accredited listing of approved products

F. This negative list is forwarded by the BFAD LSD to the LICD for investigation or resolution. The list of pending case will be updated on a weekly basis at BFAD by the Legal Information and Compliance Division. If by the LICD that the product is presumed violative and hence, is temporarily suspended from bidding activities.

G. To avoid duplication, the accreditation committee will not undertake informing the violative company of their violations or status or pending case. It is the responsibility of the drug supplier to refer to this listing for the status of their companies and/or products.

H. The list of violative products and the list of pending cases of products in question will be posted at DOH website on a weekly basis and circularized for distribution

to various bids and awards committees of the Central office, the Centers for Health Development and DOH retained and specialty hospitals. Because of the nature of the list posted at the DOH website, this becomes public domain.

I. Bids and awards committees are enjoined to check the DOH website on the status of the negative list prior to any bidding.

Existing issuances and orders related to the subject, which are inconsistent with this Administrative Order is hereby rescinded or revoked.

This order shall take effect immediately.

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