



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS

Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City



MALAYA AT MALUSOG
NA PAMAYANAN

9 February 2006

BUREAU CIRCULAR

No. 002 s. 2006

**SUBJECT : IMPLEMENTATION OF BUREAU OF FOOD AND DRUGS QUALITY SEAL
PROGRAM IN LINE WITH THE FOURmula ONE for HEALTH INITIATIVE.**

I. RATIONALE

Recently the Department of Health has adopted the Fourmula One for Health strategic concept as a framework for instituting health reforms. This is formalized by the issuance of DOH AO 2005-0025 s. 2005 providing guidelines as to its implementation.

Under the Health Regulation component, in which the Bureau of Food and Drugs (BFAD) is a part, one of the strategies formulated is the establishment of the "seal of approval system" for health products. Such seal shall indicate that a certain level of standard or competency has been achieved, assuring providers and clients that fair and ethical standards are met. The presence or absence of such seals shall enable consumers to make informed decisions and demand quality products and services.

In line with this, BFAD will continue implementing its Quality Seal Program to assess the level of compliance of pharmaceutical manufacturers to the requirements of Good Manufacturing Practice.

A JOINT BFAD INSPECTORATE TEAM is being created to carry out activities relative to the above, in coordination with the Centers for Health Development.

II. Duties and Responsibilities:

A. The BFAD Inspectorate Group

Regulation Division II

- * Organizes the Inspection
- Acts as the Lead Auditor
- Collates data for the preparation of the inspection report

Product Services Division

- Acts a team member
- Reviews and verifies that all product dossiers approved by BFAD are properly implemented
- Prepares preliminary report of all deficiencies with regard to market authorization



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Laboratory Services Division

- Acts as a Team member
- Reviews all aspects pertaining to Quality Control, which includes among others personnel and organization, systems and procedures and steps necessary in order to ensure that materials are not released for use, nor products released for sale, until their quality has been judged to be satisfactory.
- Prepares preliminary report of all deficiencies with regard to quality control

B. Centers for Health Development

- * Acts a member of the team
- * Facilitates travel in the concerned area of audit
- * Assists RD II in the conduct of GMP Audit

III. MECHANICS IN THE CONDUCT OF GMP AUDIT

The companies will be audited based on criteria of compliance with cGMP, 2-year LTO validity, and no pending case for the last two (2) years in operation.

The audit team will break up into GMP and GLP groups. If there are sufficient auditors available, the GMP group may divide into 2 GMP sub-groups to cover the different areas/departments as identified earlier.

The Lead Auditor should chair the Opening Meeting to be held with the auditee's management and those responsible for the areas to be audited. The meeting may include the following:

- mutual introduction of participants
- review of audit objectives and scope
- agreement on the audit time-table and other relevant arrangements with the auditee
- confirmation of communication links between the audit team and the auditee
- confirmation of any resources and facilities needed by the audit team
- confirmation of matters relating to confidentiality
- confirmation of relevant work safety, emergency and security procedures
- confirmation of availability of any guides

The auditors should start their respective audit in the designated areas and may follow defined audit trails.

Collected evidence should be evaluated against the audit criteria to generate the audit findings.

The audit team should review the audit findings at suitable stages during the audit and in particular prior to the closing meeting with the auditee.



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During the audit, the Lead Auditor should periodically communicate the status of the audit and any concerns to the auditees as appropriate.

Where the available evidence indicates that the audit objectives are unattainable, the Lead Auditor should report the reasons to the auditee to determine the appropriate action that may include termination of the audit or a change in the audit objectives.

The audit team should confer prior to the Exit/Closing Meeting in order to :

- review the findings and any appropriate information collected during the audit
- prepare a list of audit findings
- reach consensus on the audit conclusions
- discuss subsequent audit follow-up, if necessary

A Closing Meeting, chaired by the Lead Auditor, should be held with the auditee's management and those responsible for the functions audited. The purpose of this meeting is to present audit conclusions in such a manner as to ensure that they are clearly understood and acknowledged by the auditee. Records of the closing meeting (example, attendance record) should be maintained.

The Lead Auditor is responsible for the preparation, accuracy and completeness of the audit report. The audit report should provide an accurate record of the audit and should contain conclusions such as compliance to GMP. The audit report should be issued within the agreed time period unless with valid reasons for the delay.

The audit is completed when all the activities in the audit plan have been concluded including issuance of audit report.

The auditee is responsible for determining and initiating any corrective action needed to overcome any non-compliance.

Corrective action and subsequent follow up actions that may include additional audits should be completed within an agreed time period.

All the drug manufacturers must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use; comply with the requirements of the marketing authorization and not place patients at risk due to inadequate safety, quality or efficacy.

For information and guidance of all concerned.


PROF. LETICIA BARBARA B. GUTIERREZ, M.S.
Director IV