Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

04 May 2012

FDA ORDER
No. 2012-001

SUBJECT: RULES OF PROCEDURE AND REQUIREMENTS FOR THE FOOD AND DRUG ADMINISTRATION'S ACCREDITATION OF PRIVATE TESTING LABORATORIES

I. RATIONALE

Pursuant to the declared policies under the 1987 Constitution mandating the State to protect and promote the right to health of the people and instill health consciousness among them; adopt an integrated and comprehensive approach to health development; and undertake appropriate health manpower development and research, responsive to the country's health needs and problems, Republic Act 3720, as amended by Executive Order 175, otherwise known as the "Food, Drugs and Devices, and Cosmetics Act", was enacted mandating the Department of Health, through the Bureau of Food and Drugs (now Food and Drug Administration) to adopt measures to ensure pure and safe supply of foods and cosmetics, and pure, safe, efficacious and good quality drugs and devices in the country.

Subsequently, Republic Act No. 9711 otherwise known as the "The Food and Drug Administration Act of 2009", was promulgated further amending Republic Act No. 3720, as amended empowering the Food and Drug Administration (FDA) to accredit private testing laboratories to increase the testing laboratories that may conduct testing, calibration, assay and examination of samples of health products. Finally, Section 2, Article IV, Book II of the Implementing Rules and Regulations (IRR) of Republic Act No. 9711 directs the FDA to promulgate the rules and regulations on the procedure for accreditation of private testing laboratories, hence, this Order.

II. SCOPE AND COVERAGE

This Order shall apply to all private testing laboratories as defined herein and in the IRR of Republic Act No. 9711.

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III. OBJECTIVES

In addition to the objectives laid down in the Rules and Regulations implementing Republic Act No. 9711, this Order is hereby formulated to:

1. Provide for the rules of procedure or process and requirements in the accreditation of private testing laboratories.

2. Ensure that the testing, calibration, assay, examination, measurement and analytical results/reports of health products from a validly accredited private testing laboratories conform with the standards, processes and specifications of the FDA.

IV. DEFINITION OF TERMS

For purposes of implementing this Order, the following terms are hereby defined as follows:

1. **Accreditation** - means an attestation conveying formal demonstration of a laboratory's competence and capability to carry out specific scientific and technical tests or analytical service with respect to health products.

2. **Assay -** means an analysis to determine the (1) presence of a substance and the amount of that substance, or (2) the pharmaceutical potency of a drug.

3. **Assessment** - is a process undertaken by an accreditation body to determine the competence, capability and conformance of a laboratory, based on particular standard(s) and other normative documents for a defined scope of accreditation. It is also a process that systematically examines the short and long term consequences, in terms of health and resource use of the application of a health technology, a set of related technologies or a technology related issue.

4. **Health Products** - means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulation as determined by the Department of Health, through its FDA.

5. **Private Testing Laboratory** - means a legal entity, other than a government testing laboratory, that engages in the business of conducting tests, calibration, assay, examination, measurements, or analytical services with respect to health products.

V. APPLICATION REQUIREMENTS FOR ACCREDITATION

All the requirements for accreditation identified below must be filed with the appropriate Accreditation unit of the FDA. The requirements must be complete in form and substance, otherwise it shall be rejected automatically.

Checklist of Requirements for Initial Application For Laboratory Accreditation

1. Duly notarized Accomplished Petition Form (Annex A)
2. Certified True Copy of valid ISO 17025 Certificate of Accreditation with defined Scope of Accreditation issued by the Philippine Accreditation Office (PAO) within the last six months prior to date of application with FDA
3. List of PAO Approved Signatories for the particular test or types of test covered by the Scope of Accreditation
4. Quality Manual and List of SOPs
5. Location Map of the laboratory
6. Copy of the latest PAO Assessment findings with corresponding Corrective and Preventive Action (CAPA)
7. Floor layout with appropriate scale reflecting laboratory areas

VI. PROCEDURE IN APPLYING

1. Present the accomplished and duly notarized Petition form with the complete attachments of requirements identified above to the appropriate Accreditation Unit for pre-evaluation and assessment of fees. Incomplete requirements shall be rejected automatically. If the application passed the pre-evaluation and the fees assessed, all documents shall be returned to the applicant and follow number 3 and succeeding procedure below.

2. Fees (audit and accreditation) shall be assessed in accordance with the existing schedule of fees, including the legal research fund the computation of which shall be based on the assessed accreditation fee.
   - For audit/assessment outside Metro Manila, additional fees shall be charged accordingly taking into consideration transportation cost and daily subsistence allowance.

   - The assessment and charging of the accreditation fee shall be based on the remaining years of the validity of PAO accreditation, provided that any fraction of a year shall be treated as one year.

3. Secure the Order of Payment from the Accounting Section, Administrative Division.

4. Proceed to the Cashier for payment. Payments made are non-refundable or non-transferable.

5. Submit all the requirements as enumerated above to the appropriate Accreditation Unit including proof of payment.

6. An application number shall be issued to the applicant for tracking purposes. Schedule of audit proper shall be made known to the applicant within one month.

7. The FDA shall audit the laboratory and furnish the applicant a written report with findings and recommendations.

    7.1 If there are no deficiencies, the FDA audit team shall recommend the issuance of the Certificate of Accreditation together with the Scope of Accreditation and Approved Signatories.

    7.2. If there are deficiencies, the applicant shall be required to rectify the deficiencies noted and submit to the appropriate Accreditation Unit its Corrective Action/Preventive Action (CAPA) Plan within thirty (30) days from receipt of the written deficiencies.

        7.2.1 If the CAPA is acceptable, whether or not verification is conducted when necessary, the FDA audit team shall recommend the issuance of the Certificate of Accreditation together with the Scope of Accreditation and approved signatories;

        7.2.2 Non-compliance to the deficiencies shall deem the application abandoned or expired or if the CAPA is not acceptable, the FDA shall deny the application.

    7.3 The period stated above to comply the deficiencies shall be non-extendible except in cases of fortuitous events or force majeure but in no case to exceed another thirty (30) days.

8. The FDA shall issue Certificate of Accreditation with the Scope of Accreditation and approved signatories, the effectivity of which shall be dependent on the validity of the Certificate of Accreditation issued by PAO but in no case shall it

be for a maximum period of five (5) years subject to compliance to, and application of, Book II of The Rules and Regulations Implementing RA 9711 FDA Act of 2009, Article 4 (Laboratory Accreditation).

Any changes in the accreditation respecting the approved defined Scope of Accreditation issued by the PAO, list of PAO-approved signatories for the particular test or types of test covered by the Scope of Accreditation, location of the laboratory, floor layout, or other changes that will trigger the change in the accreditation issued by the PAO shall be treated as new and requires the filing of new application following the above requirements and procedure.

Only the testing, calibration, assay, examination, measurement or analytical results/reports of health products from private testing laboratories duly accredited by the FDA shall be recognized whether for authorization purposes, for admission as evidence in administrative proceedings before this Office or any other legal purposes subject to the transitory provision provided hereunder.

VII. RENEWAL OF ACCREDITATION

Applications for renewal of Certificate of Accreditation issued by the FDA shall be filed within three (3) months prior to the expiration of the existing accreditation but after renewal of the laboratory's accreditation with the PAO. The above procedure shall be followed submitting only a duly notarized accomplished petition Form, Certified True Copy of valid (renewed) ISO 17025 Certificate of Accreditation with defined Scope of Accreditation issued by the PAO, and payment of the prescribed renewal accreditation fee including audit fee and legal research fund.

Provided that, if the application for renewal with the PAO of the existing laboratory accreditation is only applied within the three months mentioned above, the application duly received by the PAO shall be submitted in lieu of the renewed ISO 17025 Certificate of Accreditation with defined Scope of Accreditation. Provided in such a case, the FDA Certificate of Accreditation shall only be issued once the renewed PAO certificate is submitted with the FDA and upon compliance with the above procedure.

The rules on surcharges or penalties provided under the Rules and Regulations implementing RA 9711 for renewal of any accreditation received after its date of expiration shall apply.

VIII. TRANSITORY PROVISION

All testing laboratories already recognized by this Office pursuant to Bureau Circular No. 06 s. 2005, except those identified as government counterpart laboratories, are enjoined to file their application for accreditation immediately from the effectivity of this Order, provided they have prior accreditation from the PAO.

With respect to those FDA-recognized private laboratories but are not yet accredited by the PAO, the same are required to file their application for FDA accreditation submitting as part of the requirements their application duly received by the PAO in lieu of the ISO 17025 Certificate of Accreditation with defined Scope of Accreditation. The FDA Certificate of Accreditation shall only be issued once the PAO Certificate of Accreditation is submitted with the FDA and upon compliance with the above other requirements and procedure.

In both instances above, the laboratories covered can conduct, in the meantime, testing, calibration, assay, examination or measurement of health products but the result or report generated as a result of such activity must be subject to validation by this Office, whether for authorization purposes, for admission as evidence in administrative proceedings before this Office or any other legal purposes.

The failure of any private testing laboratory recognized pursuant to the aforementioned Bureau Circular to submit before this Office the required applications within six (6) months from the effectivity of this Order shall mean refusal to be covered under this Order and shall render their recognition pursuant to Bureau Circular No. 06 s. 2005 revoked and their testing, calibration, assay, examination, measurement and analytical results/reports of health products not to recognize by this Office whether for authorization purposes, for admission as evidence in administrative proceedings before this Office or any other legal purposes.

IX. SEPARABILITY AND REPEALING CLAUSES

In the event that any provision(s) is(are) held to be invalid, the validity of the other provisions shall not be affected thereby.

All existing FDA- issued rules and regulations or issuances inconsistent with this Order are hereby modified, revoked or repealed accordingly.

X. EFFECTIVITY

This Order shall take effect immediately after its publication in a national newspaper of general circulation and a copy deposited with the University of the Philippines Law Center.

SUZETTE H. LAZO, M.D., FPSECP
Acting Director IV

Republic of the Philippines
DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City
Website: www.bfad.gov.ph

IN THE MATTER OF

_____
(Name of Natural or Juridical Person)
PETITIONING TO APPLY FOR ACCREDITATION OF A TESTING LABORATORY OF HEALTH PRODUCT(S);

PETITION

The Petitioner, through the undersigned and unto the Food and Drug Administration, Department of Health, Alabang, City of Muntinlupa, respectfully manifests that it:

1. Is a _____
(Proprietor/Partnership/Corporation/Cooperative/etc.)
duly organized under Philippine laws operating under the name _____
(Name of Laboratory)
with address located at _____
_____;
Tel No.: _____; Fax No.: _____; E-mail: _____;

2. Desires to apply for accreditation of a testing laboratory for health product(s) with scope of tests as follows (Note: Should be those covered by the scope of tests specified in the Scope of Accreditation approved by PAO):

For the scope of tests: *(Attach separate sheet if necessary)*

Type of Product	Test conducted	Method reference

For the applicant signatories: *(Attach separate sheet if necessary)*

List of signatories	Test conducted	Type of product	Method reference

Quality Assurance Manager: _____

3. Hereby declares, pursuant to Section 3, Article IV, Book II of the Rules and Regulation implementing Republic Act No. 9711, that it:

    a) shall be responsible to maintain its accreditation and to keep abreast with the latest relevant standard and requirements concerning laboratory testing of health products;

    b) shall allow the FDA full access to other records, such as but not limited to, raw data, contracts and receipts, any laboratory equipment and facilities and shall provide the FDA, when it so requests, test reports, raw data and methods of analysis and other pertinent data;

    c) shall inform and notify FDA in writing any cases of findings of non-conformance in the test results/analysis conducted of a marketed health products within forty-eight (48) hours after the result of analysis has been prepared;

    d) shall provide the FDA test reports, raw data, methods of analysis and other pertinent documents, when so requested by the Administration;

    e) shall notify FDA of any change in its PAO accreditation.

4. Hereby agrees to change the business name in the event that there is a similar or same name registered with the Food and Drug Administration;

WHEREFORE, the Petitioner respectfully prays that a Laboratory Accreditation be granted in its favor after audit thereof and after compliance with the requirements, and rules of procedure of the Food and Drug Administration.

METRO MANILA, PHILIPPINES _____ 20_____.

Respectfully submitted:

_____

Printed name and signature of Applicant
(Note: Appropriate Authorization, i.e. SPA or Board Resolution, of Applicant must be attached)

Republic of the Philippines
DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION
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Website: www.bfad.gov.ph

SUBSCRIBED AND SWORN to before me this _____ day of _____ 20____. Affiant exhibited to me his/her Residence Certificate No./Identification No./Passport No. _____ issued at _____on _____ 20_____.

_____
NOTARY PUBLIC

Doc No. _____
Book No. _____
Page No. _____
Series of _____

Application/Assessment Fee: Php_____
OR No.: _____