[FDA CIRCULAR NO. 2014-003, February 17, 2014]

FILING AND RECEIVING OF REGISTRATION, LICENSING AND OTHER APPLICATIONS USING THE INTEGRATED APPLICATION FORM

I. Rationale

Republic Act No. 9485, the Anti-Red Tape Act of 2007, was enacted to improve efficiency in the delivery of government services and to establish effective practices aimed at the prevention of graft and corruption in government. Government agencies and offices are mandated to promote transparency with regard to the manner of transacting with the public. Further, these measures shall encompass a program for the adoption of procedures to reduce red tape and expedite transactions in government. Section 5 of the same law states that all offices and agencies which provide frontline services shall undergo evaluation and improvement of their transaction systems and procedures and re-engineer the same if deemed necessary to reduce bureaucratic red tape and processing time.

Section 3 of Republic Act No. 9711, the Food and Drug Administration Act of 2009, has declared it "a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to:" .... "help establish and maintain an effective health products regulatory system ....". Section 5 of the same law amending Section 4 of Republic Act No. 3720 provided the FDA with the authority "to prescribe standards, guidelines, and regulations with respect to information, advertisements, and other marketing instruments and promotion, sponsorship, and other marketing activities about the health products as covered in this Act;".

II. Objectives

With the intention of promoting accountability and transparency through greater use of information and communication technologies, the Integrated Application Form is hereby adopted to simplify and streamline the requirements for FDA authorization, and the application process dependent on the same form is prescribed.

III. Scope

This issuance shall cover FDA-regulated products and establishments under the Center for Drug Regulation and Research (CDRR), Center for Food Regulation and Research (CFRR) and the Center for Cosmetic Regulation and Research (CCRR).

The following authorizations are served by the Integrated Application Form:

1) License to Operate, including initial, renewal, compliance, and amendments;

2) Certificate of Product Registration, including initial, renewal, amendments, re-application, Principal CPR, and Certificate of Listing of Identical Drug Product;
3) Promo and Advertisement Permits;
4) Certificate of Free Sale;
5) Export Certificate;
6) Certificate of Pharmaceutical Product;
7) Generic Labeling Exemption;
8) Certificate of Compliance with Good Manufacturing Practice (GMP);
9) Certificate of Compliance with Hazard Analysis and Critical Control Points (HACCP);

IV. Guidelines

A. Principles

1. The Integrated Application Form is the primary documentary requirement for any authorization issued by the FDA.

    a. The Integrated Application Form satisfies the requirement for any of the following documents required by any Center of the FDA for purposes of licensing, registration, or other authorization: application letter, application form, petition letter, petition form, declaration form, electronic copy affidavit, and the affidavit of undertaking.
    b. The assessment of fees is incorporated into the form and no separate assessment form shall be further required.
    c. A completed Integrated Application Form is required for a Document Tracking Log to be issued by the FDA.

2. The Integrated Application Form is of an electronic file format, publicly accessible, able to be accomplished independent of guidance by an FDA officer, at a pace and in a facility determined by the applicant;

    a. The electronic file of the Integrated Application Form is comprised of four documents:
        i. Application Form (ANNEX I);
        ii. Petition Form for License Applications (ANNEX II);
        iii. Declaration Form for Non-Drug Registration Applications (ANNEX III); and
        iv. Declaration Form for Drug Registration Applications (ANNEX IV);
    b. For licensing application, the Integrated Application Form is a two-page document: the first being the Application Form and the second a Petition Form;
    c. For registration application, the Integrated Application Form is a two page-document: the first being the Application Form and the second a Declaration Form;
    d. or all other applications, the Integrated Application Form is a one-page document comprising of the Application Form.
    e. Only the Petition and Declaration Forms require notarization.

3. All information and documents submitted to the FDA in satisfaction of any authorization will be collected and verified.

4. The applicant establishment, represented by the individuals signing the application form, agrees to be bound to the terms of the petition and declaration forms as appropriate.

5. Hardcopies shall no longer be required upon submission, including original authorization

    a. All copies of original authorization issued by the FDA shall be surrendered prior to release of a renewed authorization at the Central Releasing;
    b. Hardcopies of the requirements in support of an application shall always be made available and submitted upon request of the Center in the process of evaluation.
    c. Hardcopies of original documents including Certificates of Free Sale are not required to be submitted but must be presented to officers of the FDA during onsite audits.

B. Requirements

The following documents are expected to be presented at the point of receiving during the appointed schedule:

1. Complete application documentary requirements in a preferred document format stored in a USB device:

    a. Include the Integrated Application Form in the format it was accomplished, and a scanned copy of the signed and notarized form as appropriate.

    b. Store all files relevant to a single application in a single folder labeled with the document tracking number issued by the FDA;

    c. Each required document comprising a single application must be submitted as an independent file and named as the requirement that it satisfies:

        E.g. 1) the PDF of the Certificate of Free Sale is named as 'Certificate of Free Sale';
        E.g. 2) the PNG of the floor plan of the ground floor of a facility is named as 'Floor Plan for the Ground Floor';

    d. For multiple applications, each application must have a separate folder;

    e. Preferred document formats:

        i. PDF;
        ii. Word 97-2003;
        iii. PNG for image files;

    f. Images are preferred to be at least 150 dpi.

2. Two (2) hardcopies of the Document Tracking Log issued by the FDA