Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

16 September 2013

FDA MEMORANDUM CIRCULAR
No. 2013-038

TO: All Establishments Seeking to, or Currently Engaged in the Manufacture, Import, Export, Distribution and Retail of Health Products in the Philippines

FROM: KENNETH Y. HARTIGAN-GO, MD
Director
Food and Drug Administration

SUBJECT: **Filing and Receiving of Registration and Licensing Applications**

I. Rationale

Republic Act No. 9485, also known as the Anti-Red Tape Act of 2007, was enacted to improve efficiency in the delivery of government service to the public and to establish effective practices aimed at the prevention of graft and corruption in government.

This same law mandates all government agencies and offices to take appropriate measures to promote transparency with regard to the manner of transacting with the public. Further, these measures shall encompass a program for the adoption of simplified procedures to reduce red tape and expedite transactions in government.

Likewise, Section 5 of RA 9485 (*Re-engineering of Systems and Procedures*) provides 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.

II. Objectives

Consistent with the provisions of RA 9485, the FDA adopts the mechanism of central filing and receiving of registration and licensing applications to render fast, efficient, convenient and reliable frontline service.

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 existing system in the filing and receiving of applications for medical devices and diagnostic reagents remains with the Center for Device Regulation, Radiation Health, and Research (CDRRHR) located in DOH Compound, Sta. Cruz, Manila.

IV. Guidelines

A. Requirements

1. Electronic copy of the application document in accordance with the checklist of requirements stored in a USB device:
   - 1.1 Store all files relevant to a single application in a single folder labeled with the document tracking number issued by the FDA;
   - 1.2 For multiple applications, each application must have a separate folder;
   - 1.3 Preferred document formats:
     - 1.3.1 PDF
     - 1.3.2 Word 97-20003
     - 1.3.3 PNG for image files
   - 1.4 Images are preferred to be at least 150 dpi.

2. Hardcopies of the application shall always be made available and submitted upon request of the Center in the process of evaluation.
   - 2.1 Hardcopies shall no longer be required upon submission.

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

4. Two (2) hardcopies of the accomplished and duly notarized Application Form signed by the company pharmacist/ company representative and owner/ manager/ president. This Form shall also contain the following information :

   - 4.1 the company pharmacist/company representative's PRC license number and expiry date *(if applicable)*
   - 4.2 the company pharmacist/company representative's Tax Identification Number (TIN)
   - 4.3 the owner/manager/president's PRC license number *(if applicable)*
   - 4.4 the owner/manager/president's Tax Identification Number (TIN)

5. Original copy of Proof of payment of appropriate fees and charges (machine validated payment slip or the original copy of the official receipt issued by the FDA Cashier).

6. One (1) representative sample in commercial presentation for registration application of pharmaceuticals (contained in a bubble wrap package), food supplements and household pesticides.

   - 6.1 Samples of products not mentioned are not required at initial submission of application.

B. Procedure

1. Download the appropriate APPLICATION FORM from the FDA website (www.fda.gov.ph).

2. All applicable fields should be completely filled-up.

3. Send application email to pair@fda.gov.ph.

a. Up to ten (10) application details may be sent in a single email.
b. Subsequent email communication will be through the email used to submit the application form to FDA, unless other channels are indicated by the applicant.

4. A Document Tracking Log (Annex A) is sent via email to the applicant within 2 working days of receipt of application form by FDA.
   a. A separate Document Tracking Log will be issued for every application.
   b. The RSN indicated in the Document Tracking Log is the unique application identifier that will be used in payment, follow-ups and publication.
   c. The schedule of submission of application will be indicated in the Document Tracking Log.

5. Scheduling
   a. Schedule will be set within 10 working days of receipt of application form through pair@fda.gov.ph.
   b. Applications will be received daily.
   c. A daily quota on the number of applications scheduled for submission will be set by the FDA.
   d. Only complete application forms will be scheduled.
   e. The FDA reserves the authority to schedule the receipt of applications.

6. Payment Collection
   a. Land Bank of the Philippines
      i. Proceed to any LBP branch for payment;
      ii. Fill-out an OnColl Payment Slip (see Annex B

Table 1 FDA Accounts

Center for Cosmetics Regulation and Research	0392-2220-06
Center for Device Regulation and Radiation Research	0392-2220-30
Center for Drug Regulation and Research	0392-2220-14
Center for Food Regulation and Research	0392-2220-22

      iii. Present the Oncoll Payment Slip to LBP tellers together with the printed application form and document tracking log and the corresponding cash/ check payment.
      iv. Bank service fee of forty pesos (Php 40.00) for every payment transaction made shall be shouldered by the clients.
      v. A validated OnColl Payment Slip and assessment form will be returned by the teller as proof of payment in lieu of the issuance of an Official Receipt.

   b. FDA Main Office Cashier
      i. Proceed to the Cashier for payment;
      ii. Present the application form and document tracking log and the corresponding cash/ check payment;
      iii. An Official Receipt is issued by the Cashier as proof of payment

7. Receiving
    a. Only applicants scheduled for the day will be accommodated by the FDA;
    b. The applicant proceeds to the FDA Central Receiving on the schedule indicated in the Document Tracking Log;
    c. The documents identified in Section A. Requirements, Chapter IV. Guidelines of this issuance are submitted;
    d. The FDA downloads the electronic copy of the application documents from the USB device of the applicant;
    e. The Central Receiving returns the following documents to the applicant:
        i. USB device of the applicant with the following file(s):
            1. **Updated Document Tracking Log indicating the receipt of the application;**
            2. Other FDA issued documents as approved;
        ii. One copy of the application form;
        iii. Original copy of Proof of payment.

8. Forfeit of Schedule
    a. The following conditions shall render the schedule for submission forfeit:
        i. Incomplete requirements during submission, including failure to provide proof of payment;
        ii. Failure to appear as scheduled;
        iii. Failure to complete transfer of electronic copy from applicant to FDA;
        iv. Other situations that lead to the failure of the completion of the receiving process.
    b. Applicants with forfeited schedules must send to pair@fda.gov.ph the Document Tracking Log of the original schedule and will be processed for rescheduling.

V. **Effectivity**
    a. The application forms will be available for download from www.fda.gov.ph starting 16 September 2013
    b. Emails will be received through pair@fda.gov.ph starting 23 September 2013.
    c. Schedules for submission will be set starting 30 September 2013.
    d. All applications will have to be scheduled through the process defined by this Memorandum Circular starting 15 October 2013.
    e. Hardcopies will no longer be required upon submission effective 15 November 2013.

This Memorandum Circular shall take effect 30 September 2013.

Annex A – Document Tracking Log

Republic of the Philippines
Department of Health
Food and Drug Administration
Alabang, Muntinlupa

RSN

DOCUMENT TRACKING LOG

Name of Applicant Company

Tracking ID: [redacted]
20130916123311

Source: Full Name of Establishment

Subject: LTO Application

Contact Information:

Tel. No. +6321234566

EMail abcde@fghij.com

123 ABCDE Street, Barangay FGHIJ, KLMNO City

Remarks:

Date	Details
9/16/2013 12:36:58 PM	Scheduled on 13 October 2013, 10 AM CDRR-LTO-Initial-NCR Amount Due: Php 50,000.00 Remarks by: PGYChua
9/16/2013 12:36:58 PM	Received by PGYChua

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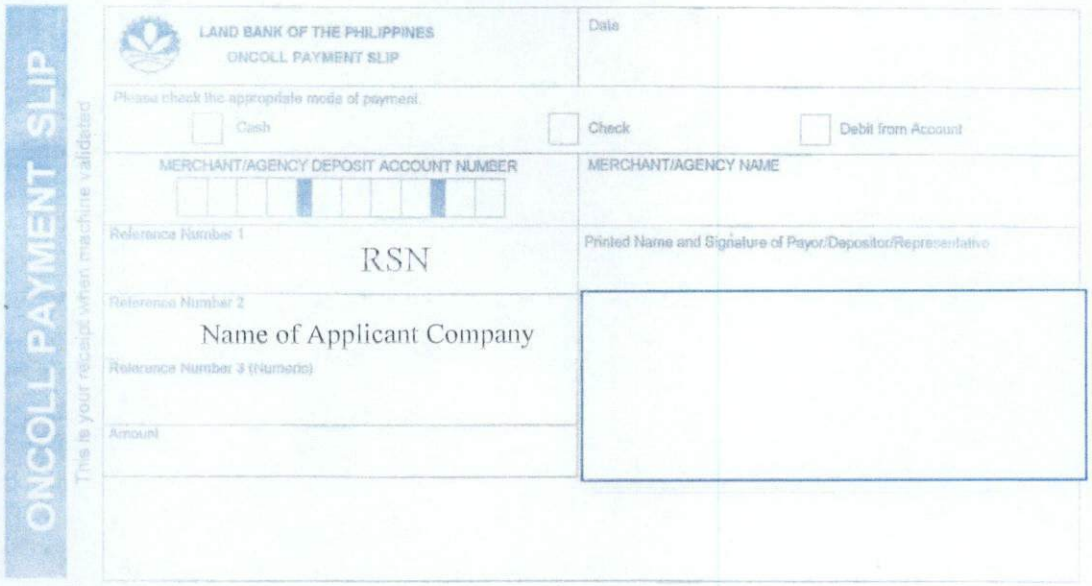
Annex B – Oncoll Payment Slip of Land Bank of the Philippines



ONCOLL PAYMENT SLIP

This is your receipt when machine validated

LAND BANK OF THE PHILIPPINES
ONCOLL PAYMENT SLIP

Date

Please check the appropriate mode of payment

☐ Cash ☐ Check ☐ Debit from Account

MERCHANT/AGENCY DEPOSIT ACCOUNT NUMBER

MERCHANT/AGENCY NAME

Reference Number 1

RSN

Printed Name and Signature of Payor/Depositor/Representative

Reference Number 2

Name of Applicant Company

Reference Number 3 (Numeric)

Amount