15 March 2014

FDA CIRCULAR
No. 2014-009

SUBJECT: Filing and Submission of Applications for the Approval of Clinical Trial Protocol, Compassionate Special Permit (CSP), Import Permit for Investigational Drug Products, Pharmacovigilance, Adverse Events/Adverse Reaction Reports, and Other Related Documents

I. Rationale

Republic Act 9711 otherwise known as the Food and Drug Act of 2009 empowers the FDA to develop and issue policies, guidelines and regulations that cover establishments, facilities and health products.

Under Republic Act 9485 or the Anti-Red Tape Act of 2007, all government agencies and offices providing frontline services are mandated to regularly undergo evaluation and improvement of their transaction systems and procedures.

II. Objectives

In consonance with the regulatory reforms implemented by the FDA to improve efficiency and quality of services rendered, this guideline is issued to prescribe/establish the procedure in filing and submission of applications for Clinical Trial Protocol approval, Compassionate Special Permit, Import Permit for Investigational Drug Products and other related documents. Adoption and implementation of this guideline seek to provide a simplified, transparent and convenient procedure to all concerned industry partners.

III. Scope

This directive covers all establishments/institutions/organizations applying and seeking approval of Clinical Trial Protocol, Compassionate Special Permit, Import Permit for Investigational Drug Products, and other related documents as well as the submission of Adverse Events/Adverse Reaction Reports, Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report (PBRER), Safety Updates for Package Inserts, Risk Management Plan (RMP) as defined in R.A. 9711 and FDA-promulgated issuances.

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IV. Procedure and Requirements

a. Applications for the approval of Clinical Trial Protocol, Compassionate Special Permit (CSP), Import Permit for Investigational Drug Products, Adverse Events/Adverse Reaction Reports, Pharmacovigilance (i.e. Safety Update Request for Approval, PSUR, PBRER) and Other Related Documents shall be filed and received at the Public Assistance, Information and Receiving (PAIR) Unit daily from 8:00 am to 5:00 pm. **Submissions need not require sending e-mail requests to PAIR Unit for the appointment schedule.**

b. Applications/requests for additional indication/product labeling/dosing regimen/patient population/inclusion of clinical information extending the usage of the product should be filed as VARIATION application with appropriate fees following the ASEAN Variation Guidelines (AVG) (please refer to FDA Circular No. 2014-008).

   Applications for additional dosage strength and/or form, should be submitted using the PAIR procedure following the existing ACTD/ACTR or national guidelines requirements, whichever is applicable.

c. All documentary requirements pertinent to the application/request should be scanned as PDF file and stored in a USB device. A separate covering letter duly signed by the regulatory affairs officer should be printed and submitted in duplicate copies together with the USB device.

   Administrative and technical requirements based on existing FDA regulations and guidances shall be followed for each type of application/request.

d. Payment shall be made at the FDA Cashier prior to the submission of the application/request to the PAIR Unit receiving staff. Assessment of appropriate fees shall be done by the company applicant using the attached Assessment Slip (please see Annex 1).

e. Requesting party shall proceed to the receiving counters of the PAIR Unit for the submission of the application/request letter together with the copy of the assessment slip reflecting the amount paid, Official Receipt (OR) Number and OR date as well as the USB device.

f. PAIR staff receives the application/request through the Document Tracking System (DTS) and copies the electronic version of the documentary requirements. The USB device is returned to the applicant immediately after the transfer of the data together with the receiving copy of the application/request.

g. A Document Tracking Slip containing the fourteen (14) - digit Document Tracking Number (DTN) and duly signed by the PAIR staff is provided to the company applicant. The DTN serves as the reference number for tracking purposes.

V. Repealing Clause

This issuance supersedes previously issued guidances or other regulations inconsistent herewith.

VI. Effectivity

This Circular takes effect on 07 April 2014.

KENNETH Y. HARTIGAN-GO, MD
Director General

FDA
Food and Drug Administration
PHILIPPINES

ASSESSMENT SLIP

DTN _____

To: AFO - Cashier
Please collect the amount indicated hereunder from:
Company

_____

For the payment of the evaluation on:
product

_____

_____

- ☐ PMS Protocol/Clinical Study Protocol
- ☐ Protocol Amendment
- ☐ Product Classification
- ☐ Protocol Amendment
- ☐ Rationale
- ☐ Product Classification
- ☐ Reclassification
- ☐ Compassionate Special Permit (CSP)
- ☐ Import Permit for Investigational Drug Product
- ☐ Others (pls specify):

_____

FEE + LRF: _____ TOTAL AMOUNT : _____
Prepared: _____ O.R. No.: _____
Date: _____ Date: _____

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ASSESSMENT SLIP

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- ☐ Product Classification
- ☐ Reclassification
- ☐ Compassionate Special Permit (CSP)
- ☐ Import Permit for Investigational Drug Product
- ☐ Others (pls. specify) :

_____

FEE + LRF : _____ TOTAL AMOUNT : _____
Prepared: _____ O.R. No.: _____
Date: _____ Date: _____