Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

20 SEP 2017

FDA CIRCULAR
No. 2017-011

TO : **ALL CONCERNED PHARMACEUTICAL ESTABLISHMENTS**

SUBJECT : **New Batch Notification Form and Procedure**

I. RATIONALE

Pursuant to Section 5 (Reengineering of Systems and Procedures) of Republic Act No. 9485, otherwise known as the Anti-Red Tape Act of 2007, *"All offices and agencies which provide frontline services are hereby mandated to regularly undertake time and motion studies, 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"*, the Common Services Laboratory (CSL) is hereby revising the Batch Notification (BN) Form as well as the procedure in the submission of the application for Batch Notification and release of the same. The need to revise the existing application form and process is deemed necessary to ensure coherence with the most recent reforms initiated by the President in the delivery of public goods and services.

II. OBJECTIVES

This Circular aims to achieve the following:

1. Facilitate the expeditious processing and immediate release of BN for Antibiotic products;
2. Provide a more detailed, clearer and abbreviated procedure in the submission of application for BN; and
3. Ensure adherence to the requirements of the Anti-Red Tape Act of 2007 or Republic Act 9485.

III. SPECIFIC INSTRUCTIONS

1. Requirements:
   a. Two (2) original hardcopies and notarized Antibiotic *Drug Product Batch Notification Application Form* (completely and correctly filled out by the **current company pharmacist**). The new Batch Notification Form (BN Form) is accessible and downloadable at the FDA website (www.fda.gov.ph).
   b. Electronic copy (Excel format) of the BN Form.

c. Two (2) clear photocopies of valid *License To Operate* (LTO) of the :
   - Manufacturer (if applicable)
   - Wholesaler (if applicable)
   - Trader
   - Importer

d. One (1) clear photocopy of valid Certificate of Product Registration (CPR) and/or Certification for Variation (COV) application.

e. One (1) clear photocopy of Certificate of Analysis of the Finished Product reflecting similar batch/lot number with the sample submitted, batch size, theoretical and actual yield.

f. For imported products: (1) clear copy of commercial invoice and/or packing list reflecting the expiry date and batch/lot number of the product or any document to prove actual volume of importation; and (2) airway bill/bill of lading for the particular shipment. The actual volume of importation must be the same in the application form.

g. Antibiotic products with Principal CPR and identical drug products may qualify as one application if the batch manufacturing record or production record shows that the mother and baby batches came from the same process. However, if the identical drug product will come as a separate shipment from the mother drug product, this will be treated as an individual application.

h. Products whose dosage form is in powder or granules for reconstitution which are of different presentation or pack size though of the same batch/lot should be applied individually.

i. Imported products of the same batch/lot number but of separate shipment should be applied individually (single payment per shipment).

j. Representative sample (as illustrated below) including the product insert and box in commercial presentation.

SAMPLE TYPE	QUANTITY REQUIRED
Tablet or Capsule	1 blister pack or foil strip
Oral Suspension	1 bottle per presentation
Granules or Powder for Suspension	1 bottle
Cream or Ointment	1 tube per presentation
Ophthalmic, Otic, Nasal Drops	1 bottle per presentation
Injectables Liquid Preparations Solid Preparations	 1 ampoule or vial per presentation 1 vial

2. Submission of Application

a. Marketing authorization holders shall be allowed to submit a **maximum of twenty (20) notification applications per day.**

b. Submission schedule will be from Mondays **to Fridays, 8 am to 3 pm only**. However, issuance of queueing number is up to 2 pm only.

c. Companies are given **five (5) working days after the evaluation date** to submit the application together with the proof of payment for final acceptance.

d. No alterations, erasures, corrections, or additions of any kind on the hardcopies of the BN Form shall be allowed in accordance with existing ISO standards.

e. The date of application and date of acknowledgement before a notary public **should be after the production of batch and not earlier**. Likewise, the same dates should be within the week of actual submission of the BN Form.

f. Notification application requiring clarification and/or with pending renewal registration application with the Center for Drug Regulation and Research (CDRR) shall require the submission of the updated status of said applications as reflected in the Document Tracking Log (DTL) and/or approval from the CDRR, whichever is applicable. The subsequent denial of the said applications shall *ipso facto* result in the revocation of the BN and shall be a cause for the mandatory recall of the products covered by the BN.

3. Collection of Sample

a. The Common Services Laboratory (CSL) shall signal the Regional Field Offices to collect samples of the particular batch of the antibiotic drug product which needs further assessment through laboratory testing.

b. The following number of samples (including the product insert and box) shall be collected :

SAMPLE TYPE	PACK SIZE	NUMBER OF UNITS REQUIRED
Tablet or Capsule		Minimum of 200 pieces
Oral Suspension	10 mL 60 mL 120 mL	30 bottles 30 bottles 30 bottles
Granules or Powder for Suspension	10 mL 60 mL 120 mL	30 bottles 30 bottles 30 bottles
Cream or Ointment	5 g to 10 g 15 g to 30 g 50 g	30 tubes 30 tubes 30 tubes
Ophthalmic, Otic, Nasal Drops	Less than 5 mL 5 mL to 10 mL	30 bottles 30 bottles
Injectables Liquid Preparations	1 to 2 mL 5 to 10 mL 20 to 100 mL	60 units 60 units 60 units
Solid Preparations	Less than 500 mg 500 mg to 1000 mg More than 1000 mg	60 units 60 units 60 units

IV. PROCEDURE

1. Applicant secures queuing number from the security guard on duty (number for Batch Notification application and number for Cashier).

2. Applicant submits the hardcopies of the documentary requirements, softcopy of the BN Form and sample for evaluation at the CSL Counter. File name of electronic copy shall be the batch/lot number of the antibiotic product.

3. The CSL frontline officer shall:

   3.1. receive the application and sample;
   3.2. check the documents against actual sample submitted;
   3.3. if found acceptable, assign and stamp BN Number; and
   3.4. save electronic copy of the application at the computer terminal.

4. Applicant proceeds to Cashier Section for payment of appropriate fees based on existing guidance on fees and charges.

5. Applicant submits to the CSL Counter hardcopies of the application and sample together with the issued Official Receipt from the FDA Cashier.

6. CSL frontline officer provides details on the Payment Information portion, affixes name and signature on the application form and releases the signed BN form to the applicant.

V. REPEALING CLAUSE

Bureau Circular No. 2009-002 and other related issuances inconsistent or contrary to the provisions of this Circular are hereby repealed, amended or modified accordingly.

VI. EFFECTIVITY

This Circular shall take effect fifteen (15) days after publication in the official gazette and in a newspaper of general circulation.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
Director General/Undersecretary