[DOH ADMINISTRATIVE ORDER NO. 2008-0033, December 02, 2008]

RULES AND CONDITIONS IN EXEMPTING ANTIBIOTIC DRUG PRODUCTS FROM THE BATCH CERTIFICATION REQUIREMENT AMENDING FOR THIS PURPOSE ITEM III (C) AND (D) OF ADMINISTRATIVE ORDER NO. 103 S. 2002 "BATCH CERTIFICATION OF ANTIBIOTICS", AND FOR OTHER PURPOSES

I. Rationale

On 23 April 2002, Administrative Order (AO)No. 103 series of 2002 was issued to effectively implement the provision of Republic Act No. 3720 as amended by Executive Order No. 175 or the Food, Drug and Cosmetic Act, as well as, Republic Act No. 7394 or the Consumer Act of the Philippines requiring the batch certification, prior to the release for sale or distribution, of a batch of drugs which purport to be, or is represented as a drug composed wholly or partly of insulin or of any kind of penicillin, streptomycin, chlortetracycline, chlorampenicol, bacitracin, or any other antibiotic drug or any derivative thereof. The same Administrative Order, consistent with the above-cited laws, provided for the exemption from the requirement of batch certification with certain exceptions (conditions).

Recently, Republic Act No. 9502, otherwise known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008" and its Implementing Rules and Regulations (IRR) were enacted. One of the objectives under the said law is to ensure adequate access to quality and affordable drugs and medicines. It is, thus, imperative to redefine the conditions set forth under Administrative Order No. 103 series of 2002 to align to the above objective.

Hence, this Order is issued redefining the rules and conditions in exempting antibiotic drug product(s) from the batch certification requirement and for other purposes.

The issuance of this Order is further reinforced by the legal mandate, which is hereby adopted as a policy, that in case of drugs, pharmaceuticals or poisons sold in their original packings, the seal of which has not been broken or tampered with, the liability that may arise because of their quality and purity, rests upon the manufacturer or in its absence, upon the importer, the distributor, representative or dealer who is responsible for their distribution or sale.

II. Authority/Basis

This Order is issued by virtue of the authority provided under Section 22 (b) and (c) of Republic Act No. 3720 as amended by Executive Order No. 175, and Article 34 (b) and (c) of Republic Act No. 7394, which authorize the Secretary of Health to promulgate regulations exempting antibiotic drug or class of such drugs from the

requirements of batch certification whenever in his judgment such requirement is not necessary to insure safety and efficacy of use and good quality.

III. Objective

This Order is issued to: (i) redefine the exemption of antibiotic drug product(s) from the requirement of batch certification as laid down under AO No. 103 series 2002 to align to the objective of ensuring adequate access to quality and affordable drugs and medicines; (ii) provide for the rules and conditions in exempting antibiotic drug product/s from the batch certification requirement, (iii) prescribe the guidelines for the implementation of the exemption from batch certification and remedies and sanctions in case of infringement of this Order; (iv) provide for remedies and sanctions in the event that this Orders is infringed.

IV. Scope

This Order applies to antibiotic drug product/s as defined in Item V below, as well as, manufacturers or traders of antibiotic drug product/s and distributors/importers in case such antibiotic drug product/s is/are imported.

V. Definition of Terms

The following terms are hereby defined for purposes of this Order:

1. **Batch Certification -** refers to the process of determination by the Bureau of Food and Drugs (BFAD), from the technical documents and conduct of analysis of the samples of products subject of certification submitted by the companies, that a batch of antibiotic drug product/s has been found to have such characteristics of identity, strength, quality and purity as prescribed by existing regulations as necessary to insure their safety, efficacy of use and good quality.

2. **Antibiotic drug product -** refers to any drug product in tended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance)

3. **Batch Notification -** refers to the filing by a manufacturer, trader or distributor/importer of a notice to the Department of Health, through the BFAD, concerning the manufactured or imported batch or batches of antibiotic drug product/s prior to release for sale, offer for sale, distribution, transfer, donation, or offer as Physicians Samples of such particular batch or batches of drug product/s.

VI. Guidelines for Exemption

1. **Notification**

For purposes of exemption from the required batch certification all manufacturers, traders or distributors/importers of antibiotic drug product/s shall notify BFAD of all their manufactured or imported batch or batches of antibiotic drug product/s prior to their release for sale, offer for sale, distribution, offer as physician samples (if they belong from the same batch, otherwise a separate notification is required), transfer, donation, of such particular batch or batches of drug product/s, otherwise, Item IX below shall apply. Provided that with regards to antibiotic products covered under the Principal Certificate of Product Registration and Listing of Identical Drug Products

scheme provided in Administrative Order No. 2005-0031 dated 07 December 2005, one notification is required if they belong to the same batch.

2. **Conditions for Exemptions**

2.1 The manufacturer, trader or distributor/importer of the antibiotic drug product/s is a holder of a valid License to Operate;

2.2 The manufacturer, trader or distributor/importer files a duly notarized two (2) copies of Antibiotic Drug Product Batch Notification using the template attached to this Order as Annex "A"[*] together with the following technical documents and samples relating to the product subject of the exemption:

a. Certificate of Analysis of the Finished Product;

b. Valid Certificate of Product Registration; and

c. 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]	1 bottle
Cream or Ointment	1 tube per presentation
Ophthalmic, Otic, Nasal Drops	1 bottle per presentation
Injectables:	
Liquid Presentations	1 ampoule or vial per presentation
Solid Preparations[1]	1 vial

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

2.3 Notification Fee which includes payment of antibiotic drug products' post-market surveillence activity in the amount of Five Thousand Pesos (PhP**5,000.00**). The BFAD is authorized to increase the above amounts as the need arises with prior information to concerned parties.

3. **Procedure**

3.1 The manufacturer, trader or distributor/ importer shall notify BFAD, by filing at he Laboratory Services Division (LSD) a duly notarized two (2) copies of Antibiotic Drug Product Batch Notification, of all the manufactured or imported batch or batches of antibiotic drug product/s prior to their release for sale, offer for sale, distribution, transfer, donation, or offer as Physician Samples of such particular batch or batches of drug product/s, or prior to the intended investigation use by experts qualified by scientific training and experience to investigate the