Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
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02 December 2008

Administrative Order
No. 2008- 0033

Subject: **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, chloramphenicol, 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 Order 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 batch 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 intended 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 Physician 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 Exemption

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 Preparations* *Solid Preparations*[1]	 1 ampoule or vial *per* presentation 1 vial

[1] *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.*

2.3 Notification Fee which includes payment of antibiotic drug products' post – market surveillance activity in the amount of Five Thousand Pesos (Php **5,000.00**). The BFAD is authorized to increase the above amount 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 the 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 investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of such drugs, for purposes of exemption from the required batch certification.

3.2. The BFAD-LSD shall examine the Notification together with the above-required attachments so submitted by the manufacturer or distributor/importer. The notification shall only be accepted if the information required in the notification form is completely supplied and the documents and samples required above are complete as well. Once accepted, the applicant company will be issued an Order of Payment (OP).

3.3. The applicant company shall then proceed to the Accounting Section for verification of the OP.

3.4. After OP verification, the applicant company shall pay the required fee at the Cashier section.

3.5. The Official Receipt (OR) shall be presented to the LSD which shall indicate the OR number in the Notification form, stamp and assign the corresponding notification number as acknowledgement of receipt of the same and traceability prior to signing by the authorized signatory.

3.6. Notifications filed and accepted in the morning shall be released in the afternoon and Notifications filed and accepted in the afternoon shall be released the next working day.

3.7. Once the notification is released and received by the establishment the manufactured or imported batch or batches of antibiotic drug product/s can now be released for sale, offer for sale, distribution, transfer, donation, or offer as physician samples.

4. Post Monitoring Surveillance

Notwithstanding compliance with the above procedures, the same shall not constitute as an agreement by BFAD, in anyway, that the particular batch of the antibiotic drug product produced or imported meets all other pertinent regulatory requirements, such as but not limited to, the product's conformance to its registered specification or approved labeling. For this purpose and to insure full compliance of the product to existing standards, the BFAD shall endeavor to undertake strict post monitoring surveillance that will involve the active, systematic, scientifically valid collection, analysis and interpretation of data and other information about the marketed antibiotic drug.

VII. Grounds for Revocation of Exemption

For the effective implementation of this Order, the BFAD is authorized to revoke, without need of a hearing, the grant of exemption from certification of any batch or batches of antibiotic drug product/s notifying only the concerned establishment of such revocation on the grounds of commission or the presence of any or all of the following instances, *to wit:*

1. In the event that there is subsequent findings of misrepresentation or falsification in any of the information supplied in the notification form and the data indicated in the required documents or the same are fraudulently filed by any manufacturer, trader or distributor/importer; and/or
2. In case the samples submitted or samples belonging to the same batch or batches of antibiotic drug product/s collected through post monitoring surveillance shall be found not to conform to the product's registered specifications or approved labeling.

In case any of the above circumstances comes to the knowledge of any concerned division of the BFAD, the same shall be reported immediately to the Legal, Information and Compliance Division for appropriate action. The revocation shall be immediately executory.

VIII. Effect of the Revocation on the grant of Exemption from Batch Certification or on Antibiotic Drug Product/s Released in the Market without prior Exemption

Any batch or batches of antibiotic drug product/s granted exemption from batch certification which has been automatically revoked shall be:

1. Deemed misbranded pursuant to Section 19 (k) of Republic Act No. 3720 as amended or mislabeled pursuant to Article 89 (j) of Republic Act No. 7394 and their prior release for sale or distribution shall be deemed in violation of Section 11 (a) and (b) Republic Act No. 3720 as amended, or Article 40 (a) and (b) of Republic Act No. 7394, respectively; and/or

2. Treated as if it was released without batch certification in violation of Section 11(m) of Republic Act No. 3720 as amended or Article 40 (m) of Republic Act No. 7394.

The above shall likewise apply when a batch or batches of antibiotic drug product/s manufactured or distributed/imported has been released for sale, offer for sale, -distribution, transfer, donation, or offer as Physician Samples without the required notification filed by the manufacturer, trader or distributor/importer with, and the same approved by, BFAD.

IX. Administrative Procedure and Sanctions.

The procedure in the conduct of administrative proceeding existing at the BFAD shall be observed, but the manufacturer, trader or distributor importer shall automatically cease and desist from further distribution the batch or batches of the antibiotic product in question upon receipt of the notice of revocation and pending the administrative proceeding.

The penalty imposable under Section 22 of Executive Order No. 175 amending Section 29 of Republic Act No. 3270, or Article 39 of Republic Act No. 7394 shall be imposed after notice and hearing.

X. Authority to Require Batch Certification or Revoke this Order

Nothing in this Administrative Order shall be construed to prohibit the Department of Health, upon recommendation of the Bureau of Food and Drugs, from requiring a batch or batches of either one or more antibiotic drug product/s of a particular manufacturer, trader or distributor/importer, or from revoking this Administrative Order in cases where the safety, efficacy and quality of an antibiotic drug product/s or public health and safety requires the resumption of Batch Certification process for such one or more or all antibiotic drug product/s.

XI. Separability Clause

If any part, term or provision of this Administrative Order shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Order shall be construed as if it did not contain the particular invalid or unenforceable part, term or provision.

XII. Repealing Clause

The provisions of Item III (C) and (D) of Administrative Order No. 103 series of 2002 and other previous administrative issuances, bureau circulars, and memoranda inconsistent with this Administrative Order are hereby withdrawn, repealed and/or revoked accordingly.

XIII. Effectivity

This Order shall take effect fifteen (15) days after publication in a newspaper of general circulation.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

ANNEX A

ANTIBIOTIC DRUG PRODUCT BATCH NOTIFICATION

BATCH NOTIFICATION NUMBER	
TO BE FILLED UP BY BFAD OFFICIAL	
Received by	
Signature	
Date	
PAYMENT DETAILS	
Amount	
OR No.	
Date	

Date: _____

THE DIRECTOR
Bureau of Food and Drugs
Filinvest Corporate City, Alabang
City of Muntinlupa

ATTENTION: LABORATORY SERVICES DIVISION
Antibiotics Section

Sir/Madam:

In accordance with Administrative Order No. 2007- ___, we wish to apply and notify the Bureau of our intention to have our batch of antibiotic product, more particularly described below, exempted from the required batch certification:

PRODUCT PARTICULARS		
Generic Name/s		
Brand Name		
Dosage Strength	**Dosage Form**	
Registration Number	**CPR Validity**	
Batch Size	**Batch / Lot Number**	
Theoretical Yield in Number of Units	**Actual Yield / Volume of Importation in Number of Units (as indicated in the commercial invoice):**	
Manufacturing Date	**Expiry Date**	
Packaging	**Presentation or Pack Size**	
COMPANY PARTICULARS:		
Manufacturer	**LTO No.**	**Validity**
Trader	**LTO No.**	**Validity**
Importer	**LTO No.**	**Validity**
Distributor	**LTO No.**	**Validity**
Repacker	**LTO No.**	**Validity**

DECLARATION

In support of our exemption from batch certification, I, the undersigned, hereby declare under oath that:

1. I am duly authorized to bind the establishment I represent pursuant to the authority attached to this Notification form (Board Resolution in case of corporation and Special Power of Attorney in all other cases both of which should be duly notarized);
2. In behalf of my company, the antibiotic drug product identified in the notification meets all the legal requirements, and conforms to all existing standards and specification requirement applicable to the above product subject of exemption.
3. I declare that the particulars given in this notification are true and all data and information of relevance in relation to the exemption have been supplied, as well as, the documents attached herein are authentic or true copies.
4. I agree that the acceptance and signing of this Notification shall not constitute as an agreement by BFAD in anyway, that the particular batch of the antibiotic drug product produced or imported meets all other pertinent regulatory requirements, such as but not limited to, the product's conformance to its registered specification or approved labeling.
5. I agree that the grant of exemption shall be automatically revoked by the Bureau in the event that there is subsequent findings by BFAD of misrepresentation in any of the data indicated in the required documents or any of the said documents is subsequently found to be falsified or fraudulently filed; and/or in case the samples belonging to the same batch or batches of antibiotic drug product/s collected through post monitoring surveillance shall be found not to conform to the product's registered specifications or approved labeling.
6. The company I represent shall automatically cease and desist from further distributing the batch or batches of the antibiotic product subject of revocation upon receipt of the notice of revocation and pending any administrative proceeding until further notice of the BFAD.
7. I or my company undertake to:

    i. Ensure that the product's technical and safety information is made readily available to the Bureau of Food and Drugs (BFAD) anytime when requested, and to keep records of the distribution of the products for product recall purposes;
    ii. Notify the BFAD as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge of any fatal or life threatening serious adverse event if the cause, whether proximate or otherwise, of such adverse events is the use of the antibiotic product subject of the exemption;
    iii. Report to the BFAD of all other serious adverse events that are not fatal or life threatening as soon as possible, and in any case, no later than 15 calendar days after first knowledge, using the Adverse Drug Event Report Form if the cause, whether proximate or otherwise, of such adverse events is the use of the antibiotic product subject of the exemption;
    iv. Keep or hold BFAD free and harmless against any and all third party claims arising from the above adverse events or from the exemption of the subject antibiotic product; and
    v. Respond to and cooperate fully with the Food- Drug Regulatory Officers with regard to any subsequent post-marketing activity initiated by the BFAD.
8. I understand that our company or establishment cannot place reliance on the acceptance of our antibiotic drug product notification by the BFAD in any legal proceedings concerning the above product, in the event that said product has failed to conform to any of the standards or specifications previously declared to the BFAD.

_____

[Signature over printed name of officer of the company duly authorized]

_____ _____

[Company stamp] [Date]