REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Civic Drive, Filinvest Corporate City
Alabang, City of Muntinlupa
Tel. No.: 8094390
Website: www.bfad.gov.ph

19 January 2009

BUREAU CIRCULAR
No. 2009- 002

TO: **ALL CONCERNED**

SUBJECT: **Specific Operational Instructions Implementing Administrative Order No. 2008-0033 dated December 2, 2008, 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

The issuance of Administrative Order No. 2008- 0033 created the need to further define activities that must be undertaken and the identification of key personnel who shall be responsible and accountable for the effective implementation of the said Order.

II. Objectives

Given the premises so stated above, this Circular is issued in order to:

1. To define supplementary specific systems and procedures that would support the implementation of the reference Administrative Order;
2. To define the roles and responsibilities of key personnel/post who would be involved in the implementation.

III. Scope

This Circular shall apply to antibiotic drug products as well as manufacturers or traders of antibiotic drug products and distributors/importers in case such antibiotic drug products are imported.

IV. Specific Instructions

1. Submission of Application

a. Applications for Batch Exemption shall be submitted every Tuesdays, Wednesdays and Thursdays from 8 AM until 3 PM only, to the Laboratory Services Division, Office of the Chief.

b. The application shall only be accepted if the information required in the Antibiotic Drug Product Batch Notification Form is duly accomplished and the documents and samples are complete.

c. LSD shall appropriately advice applicants should there be deficiencies in their submission, otherwise, their application shall be processed and released. Applications filed and accepted in the morning shall be released in the afternoon and those that were submitted in the afternoon shall be released the next working day.

d. With regards to antibiotic drug products covered under the Principal Certificate of Product Registration and Listing of Identical Drug Product scheme provided in AO No. 2005-0031 dated 07 December 2005, only one submission for batch notification is required if they belong to the same batch. The company applicant shall however separately fill up the notification form for every product.

2. Requirements for Application for Batch Exemption

a. Documentary Requirements (Forms to be accomplished correctly and completely)

i. Two (2) original copies of Antibiotic Drug Product Batch Notification Form, duly notarized (ANNEX "A")
- For imported products, should there be any discrepancy on the declared batch size and on the declared volume of importation being sought for Batch Exemption, the commercial invoice may be submitted to justify the discrepancy.

b. Attachments

i Photocopies of valid License to Operate (LTO) of the:
- Manufacturer
- Trader
- Importer/Distributor

ii. Photocopy of valid Certificate of Product Registration (CPR)

iii. Photocopy of Certificate of Analysis of the Finished Product (CA)

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.***

d. Notification fee of Php 5,000.00 which includes payment for the antibiotic drug product's post-market surveillance activity.

3. **Coding System of the Application for Batch Exemption**

a. Each Batch Notification Form shall be coded with a corresponding notification number (alphanumeric system) as acknowledgement of receipt of the application and for traceability purposes.

b. A database system shall be maintained by the Laboratory Services Division (LSD) to track the batches of antibiotic drug products that had been applied for batch notification

4. **Procedure for Batch Exemption**

a. Upon receipt of the Batch Notification at the LSD, Office of the Chief, the assessors shall examine the notification together with the above-mentioned required attachments and samples so submitted by the company applicant. Should there be no deficiencies noted, an Order of Payment shall be issued to the applicant which shall be verified by the Accounting Section prior to payment at the Cashier's Section.

b. The LSD shall indicate the Official Receipt (OR) number in the Notification Form and a corresponding notification number shall be assigned and stamped on the Notification Form.

c. The Notification Form shall be signed by the LSD Division Chief or the Officer-In-Charge prior to release.

d. Once the signed notification form is released and received by the establishment, the manufactured or imported batch or batches of antibiotic

drug products can now be released for sale, offer for sale, distribution, transfer, donation, or offer as physician samples.

5. **Post Marketing Surveillance (PMS)**

   a. The PMS Task Force shall utilize a risk-based sample surveillance approach to select products for analysis that have the greatest risk of quality problems and/or health impact especially when the following are observed:

      i. adulteration or misbranding is noted or suspected
      ii. follow up to a drug related complaint or adverse effect
      iii. deficiencies in labeling and packaging

   b. Sampling and testing of finished antibiotic drug products shall be carried out routinely from any of the following establishments:

      i. Manufacturer
      ii. Trader
      iii. Importer/Distributor
      iv. Drug Outlet

   c. The BFAD-LSD, through the PMS Task Force shall signal the inspectors of the Regulation Divisions I and II to collect samples of the particular batch of the antibiotic drug product which needs further assessment through laboratory testing.

   d. 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* *Solid Preparations*	 1 to 2 mL 5 to 10 mL 20 to 100 mL Less than 500 mg 500 mg to 1000 mg More than 1000 mg	 60 units 60 units 60 units 60 units 60 units 60 units

V. Effectivity

This Circular shall be effective on February 1, 2009.

PROF. LETICIA-BARBARA B. GUTIERREZ, MS
Director

ANNEX A

ANTIBIOTIC DRUG PRODUCT BATCH NOTIFICATION

BATCH NOTIFICATION NUMBER **BN-09-**		
Maria Lourdes C. Santiago, M.Sc., MM Chief, Laboratory Services Division		
TO BE FILLED UP BY BFAD OFFICIAL		
Assessed and 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. 2008- 0033, 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.

COMPANY PHARMACIST
Signature _____
Name (print or type) _____
Position (print or type) _____
Date _____

ACKNOWLEDGEMENT

SUBSCRIBED AND SWORN TO BEFORE ME this _____ personally appeared the following:

Name	Residence Certificate	Date Issued	Place Issued

Known to me and to me known to be the same persons who executed the foregoing instrument and they acknowledged to me that the same is their free and voluntary act and deed.

WITNESS MY HAND AND SEAL on the date and place first above written

Doc No. _____
Page No. _____
Book No. _____
Series of _____