Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA MEMORANDUM CIRCULAR
No. 2014-001

DATE: **06 January 2014**

TO: **ALL CONCERNED PHARMACEUTICAL COMPANIES**

FROM: **KENNETH Y. HARTIGAN-GO, MD**
Acting Director General

SUBJECT: **EXTENSION OF DEADLINE TO SUBMIT ELECTRONIC COPY OF ALL REGISTERED DRUG PRODUCTS' DOSSIER**

Please be informed that the Center for Drug Regulation and Research is extending the deadline for the submission of electronic copy of all registered drug products, pursuant to FDA Memorandum Circular No. 2013-023, from 30 September 2013 to **30 June 2014.**

Submission requirements shall still follow Sec. 4, item 4.1 of FDA Memorandum Circular No. 2013-023. However, instead of using the DVD, a USB shall be used. The device will be returned to the Market Authorization Holder (MAH) once the dossier has been copied by FDA. Please take note that all data for the latest life cycle of a product must be submitted, i.e., for products existing for 12 years in the market, the 2nd renewal documents shall be submitted including any other documents (e.g. amendments, variations) submitted during its validity; for products existing for 4 years, the initial application documents shall be submitted including any other documents submitted during its validity. Please take note of the following documentary requirements for initial and renewal applications:

For approved applications under ASEAN Common Technical Dossier format:
Part I. Administrative Data and Product Information
Section A: Introduction
Section B: Table of Contents
Section C: Administrative Data and Product Information Documents
a. Notarized Letter of Application
b. Letter of Authorization
c. Copy of valid agreement between the manufacturer and

trader/importer/distributor
d. Copy of valid License to Operate (LTO) of the manufacturer/trader/ importer/distributor reflecting the corresponding sources (special license issued by DDB as additional requirement for prohibited/regulated drugs)
e. Original Certificate of Pharmaceutical Product
f. Site Master File
g. Labeling Materials (facsimile labels with actual color text, including SPC if applicable)
Part II. Quality
Section A: Table of Contents
Section B: Quality Overall Summary
Section C: Body of Data
Drug Substance
a. S1 General Information
b. S2 Manufacture
c. S3 Characterization
d. S4 Control of Drug Substance
e. S5 Reference Standards or Materials
f. S7 Stability
Drug Product
a. P1 Description and Composition
b. P2 Pharmaceutical Development
c. P3 Manufacture
d. P4 Control of Excipients
e. P5 Control of Finished Product
f. P6 Reference Standards or Materials
g. P7 Container Closure System
h. P8 Stability
i. P9 Product Interchangeability/Equivalence Evidence

Initial Application	**Initial**	**MR**	**Vaccines Biologics**	**Vet**
1. Notarized Letter of Application	√	√	√	√
2. Revised Form No. 8	√	√	√	√
3. Copy of valid agreement between the manufacturer and trader/importer/distributor	√	√	√	√
4. Copy of valid License to Operate (LTO) of the manufacturer/trader/ importer/distributor reflecting the corresponding sources (special license issued by DDB as additional requirement for prohibited/regulated drugs)	√	√	√	√
5. Unit Dose and Batch Formulation	√	√		√
6. Technical Specifications of all Raw Materials	√	√		√
7. Certificate of Analysis of active Raw Material(s) (both from supplier of API and manufacturer of	√	√		√

finished product)				
8. Technical Specifications of Finished Product	√	√		√
9. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	√	√		√
10. Master Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	√	√		√
a. Persons responsible for production and control of the product			√	
b. Source of materials, including their specifications and tests used to demonstrate compliance			√	
c. Information on the methods of manufacture, including description of the seed lot and cell substrate systems used, together with in-process, bulk and final product specifications and the tests used to demonstrate compliance			√	
d. Documentation used in the manufacturing and control procedures, including SOPs and protocols containing details of production and quality control testing carried out in all stages and production			√	
e. Information on the number system of the lots or batches, including individual component of the formulation			√	
f. Demonstration of lot to lot consistency of production			√	
11. Assay and Other Test Procedures including Assay with Data Analysis	√	√		√
12. Stability Studies	√	√	√	√
13. Labeling Materials (facsimile labels with actual color text, triplicate)	√	√	√	√
14. Bioavailability/Bioequivalence Studies (where applicable)	√	√		
15. Dissolution Profile (for drugs under List B Prime)	√			
16. Original Certificate of Pharmaceutical Product	√	√	√	√
17. Certificate of Analysis for Test of Migratable Substances/Leachability (for products in plastic container)	√	√		√
18. Assessment slip	√	√	√	√
19. Copy of FDA Approval on Pre-clinical and Clinical Protocol		√		√
20. Copy of FDA Approval on the rationale of Fixed Dose Combination Product (where applicable)	√	√		√
21. List of countries where the vaccine is already licensed and date of approval			√	
22. Description of the cold chain procedures			√	

employed from the origin to the point of entry and in the Philippines				
23. System for the reprocessing of the product in the event of rejection of the lot/batch by the manufacturer's QA/QC			√	
24. Names of the medical director of the importer/distributor and local manufacturer who will monitor event(s) reactions and prepare appropriate report to be submitted to FDA			√	
25. Other information or special condition of the product in the country of origin			√	
26. Report on pre-clinical and clinical trials, where applicable			√	
27. Summary Lot protocol			√	
28. For donated vaccine/biologic products that is already registered with FDA:				
a. Inventory of the number of vials per lot or batch to be donated			√	
b. Summary Lot or Batch Protocol with the Certificate of Lot/Batch release from the NRA of the exporting country per batch or lot to be donated			√	
c. Names of the medical director responsible for monitoring AEFI and prepare appropriate report to be submitted to FDA			√	

Initial Applications	**TM**	**OTC/ HR**	**Medical Gases**
1. Notarized Letter of Application	√	√	√
2. Revised Form No. 8	√	√	√
3. Copy of valid agreement between the manufacturer and trader/importer/distributor	√	√	√
4. Copy of valid License to Operate (LTO) of the manufacturer/trader/ importer/distributor reflecting the corresponding sources (special license issued by DDB as additional requirement for prohibited/regulated drugs)	√	√	√
5. Unit Dose and Batch Formulation	√	√	
6. Technical Specifications of all Raw Materials	√	√	
7. Certificate of Analysis of active Raw Material(s) (both from supplier of API and Manufacturer of Finished Product)	√	√	
8. Technical Specifications of Finished Product	√	√	√
9. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	√	√	√
10. Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	√	√	√

a. Flowchart of the manufacturing procedure			√
11. Assay and Other Test Procedures including Identity, Purity Tests, and Assay with Data Analysis, where applicable	√	√	
12. Stability Studies	√	√	
13. Labeling Materials (facsimile labels with actual color text, triplicate)	√	√	√
14. For herbal medicines validated by the NIRPROMP of the PCHRD, a copy of the Memorandum of Agreement between NIRPROMP and the applicant; or a copy of approval of BFAD Committee on the registration of the said herbal medicine		√	
15. Original Certificate of Pharmaceutical Product		√	
16. Original Certificate of Traditionally-Used Herbal Product	√		
17. Certificate of Analysis for Test of Migratable Substances/Leachability (for products in plastic container)	√	√	
18. Assessment slip	√	√	√
19. Evidence of Safety and Efficacy		√	
20. Evidence of Safety	√		
21. Evidence of Claimed Application	√		
22. Copy of FDA Approval on the rationale of Fixed Dose Combination Product (for OTC)		√	
23. Complete quality control procedure for Finished Product			√
24. Certificate of Analysis issued by CIGI for the product			√
25. Philippine Standard (PS) Quality Certification Mark issued by the Bureau of Product Standards			√

Regular Renewal	**Rx OTC HR**	**Vet**	**Vaccines Biologic**	**TM**	**Medical Gas**
1. Notarized Letter of Application	√	√	√	√	√
2. Revised Form No. 8	√	√	√	√	√
3. Copy of latest Certificate of Product Registration (CPR)	√	√	√	√	√
4. Copy of valid agreement between the manufacturer and trader/importer/distributor					√
5. Copy of valid License to Operate (LTO) of the manufacturer/trader/ importer/distributor reflecting the corresponding sources (special license issued by DDB as additional requirement for prohibited/regulated drugs)	√	√	√	√	√
6. Unit Dose and Batch Formulation	√	√		√	
7. Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging Procedure					√

(including specification for container closure system)					
a. Flowchart of the manufacturing procedure					√
8. Technical Specifications of Finished Product	√	√		√	
9. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	√	√		√	√
10. Assay and Other Test Procedures including Assay with Data Analysis	√	√			
11. Stability Studies	√	√		√	
12. Labeling Materials (actual/commercial labels, triplicate)	√	√	√	√	√
13. Bioavailability/Bioequivalence Studies (where applicable)	√				
14. Dissolution Profile (for drugs under List B Prime)	√				
15. Assessment slip	√	√	√	√	√
16. Original Certificate of Pharmaceutical Product			√		
17. List of Countries where the vaccine is already licensed and date of approval			√		
18. Adverse event following immunization report (Summary of Annual Reports) for established and new biologics			√		
19. Phase IV clinical trial report for new biologic products			√		
20. Certification that there were no changes during the 5-year period. If there were any, the summary changes made by the manufacturer for the 5-year period.			√		
21. Summary of Lot Protocol			√		
22. Certificate of Analysis issued by CIGI for the product					√

Automatic Renewal
1. Notarized Letter of Application
2. Copy of valid License to Operate
3. Original copy of Certificate of Product Registration
4. PSDD Form (Annex D of B.C. No. 2006-005)
5. Copy of certification of approval on post-approval changes (if applicable)
6. Complete labeling materials (Primary, secondary, Package Insert)

For approved/acknowledged amendments and/or variations submitted during the specific lifetime of a product, please refer to PSD Memo 02-05 and/or ASEAN Variation Guidelines.

For your information and compliance.