Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

REGISTRATION OF PHARMACEUTICAL/DRUG PRODUCTS

Frequently Asked Questions (FAQs)

Version 3.0

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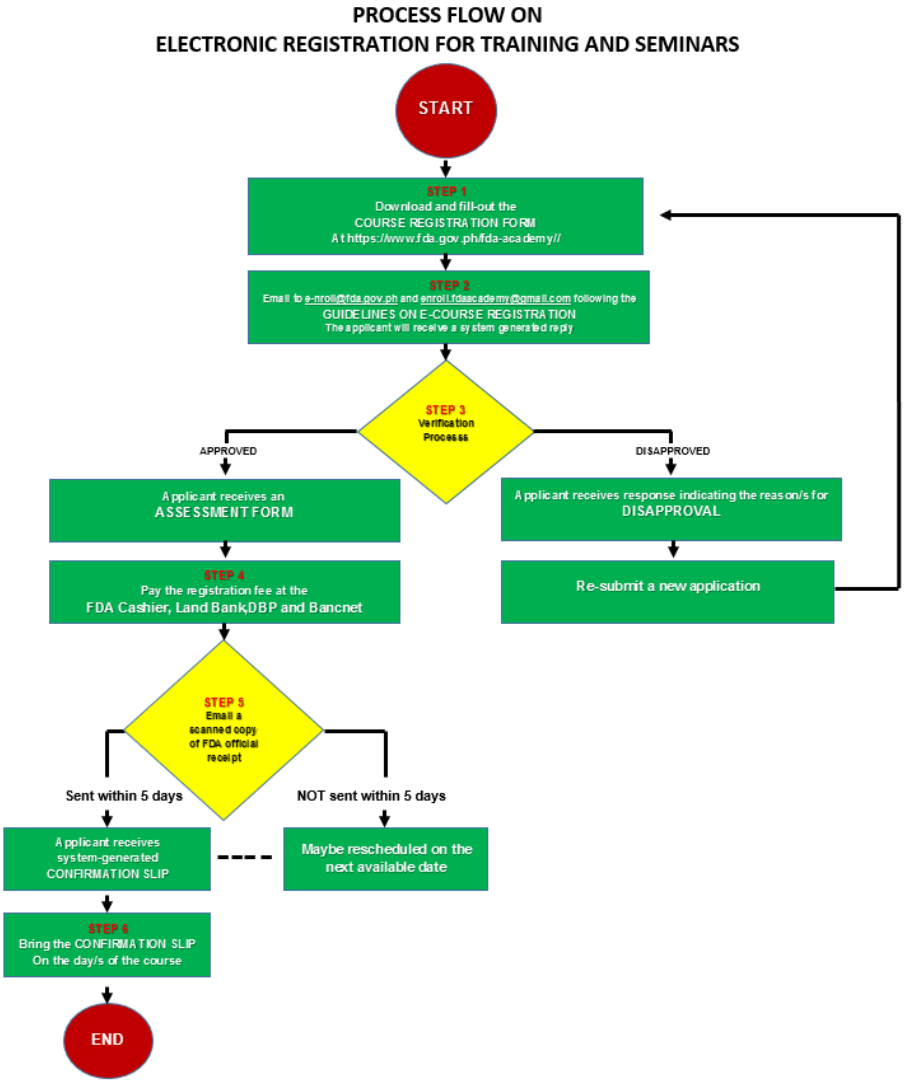
1. PHARMACEUTICAL DRUG PRODUCTS

1.1. General Procedures

1.1.1. Is there an orientation seminar conducted by the FDA for Regulatory Affairs (RA) Pharmacists/ Personnel?

Yes. There is a Qualified Personnel in Industry Regulatory Affairs – Center for Drug Regulation and Research (QPIRA – CDRR) Seminar conducted quarterly by the FDA Academy in coordination with CDRR. Intention to join the QPIRA – CDRR Seminar should be submitted through the following email addresses: e-nroll@fda.gov.ph or enroll.fdaacademy@gmail.com.

Refer to the link provided for the detailed description on the process of application: https://ww2.fda.gov.ph/industry-corner/downloadables/210-fda-academy-forms



1.1.2. Where can we access the online information regarding pharmaceutical/ drug product registration?

The main website of the FDA is: www.fda.gov.ph. Other information may be accessed through the old website: ww2.fda.gov.ph. Specific information pertinent to pharmaceutical/ drug product registration may be accessed through the Industry Corner > Downloadables section of the website. You may also refer to the link provided: https://ww2.fda.gov.ph/industry-corner/downloadables/343710-checklist-of-requirements.

1.1.3. How can we submit an application for registration of a pharmaceutical/ drug product?

Note: Only establishments with a valid License to Operate (LTO) from the FDA Philippines may apply for registration of a pharmaceutical/ drug product. (RA No. 9711). The information below is also accessible through the FDA Website, https://ww2.fda.gov.ph/industry-corner/downloadables/237-integrated-application-form-and-process.

Pursuant to FDA Circular No. 2014-003: Filing and Receiving of Registration, Licensing and Other Applications Using the Integrated Application Form (IAF), the following are the steps of the LTO and CPR Processing

Step 1. Download. The IAF in **XLS** (https://ww2.fda.gov.ph/attachments/article/148185/Integrated%20Application%20Form%20(97-2003%20Compatible).xls) or **XLSX** (https://ww2.fda.gov.ph/attachments/article/148185/Integrated%20Application%20Form%20(XLSX%20Format).xlsx) **format** is used for applications for registration of pharmaceutical/ drug products. The IAF is a two-page document: the first page being the Application Form and the second page is the Declaration Form which is required to be notarized.

Step 2. Fill up Form. *Make sure that the IAF is filled up completely and correctly*. The IAF has six parts: 1) General Information, 2) Establishment Information, 3) Product Information, 4) Supporting Information, 5) Sources and Clients, and 6) Applicant Information. If the subsequent part of the form is appropriately filled up, the composed body text (in the green box) will appear. Note that required fields will appear sequentially and shall be filled only after completely filling the information in the subsequent part.

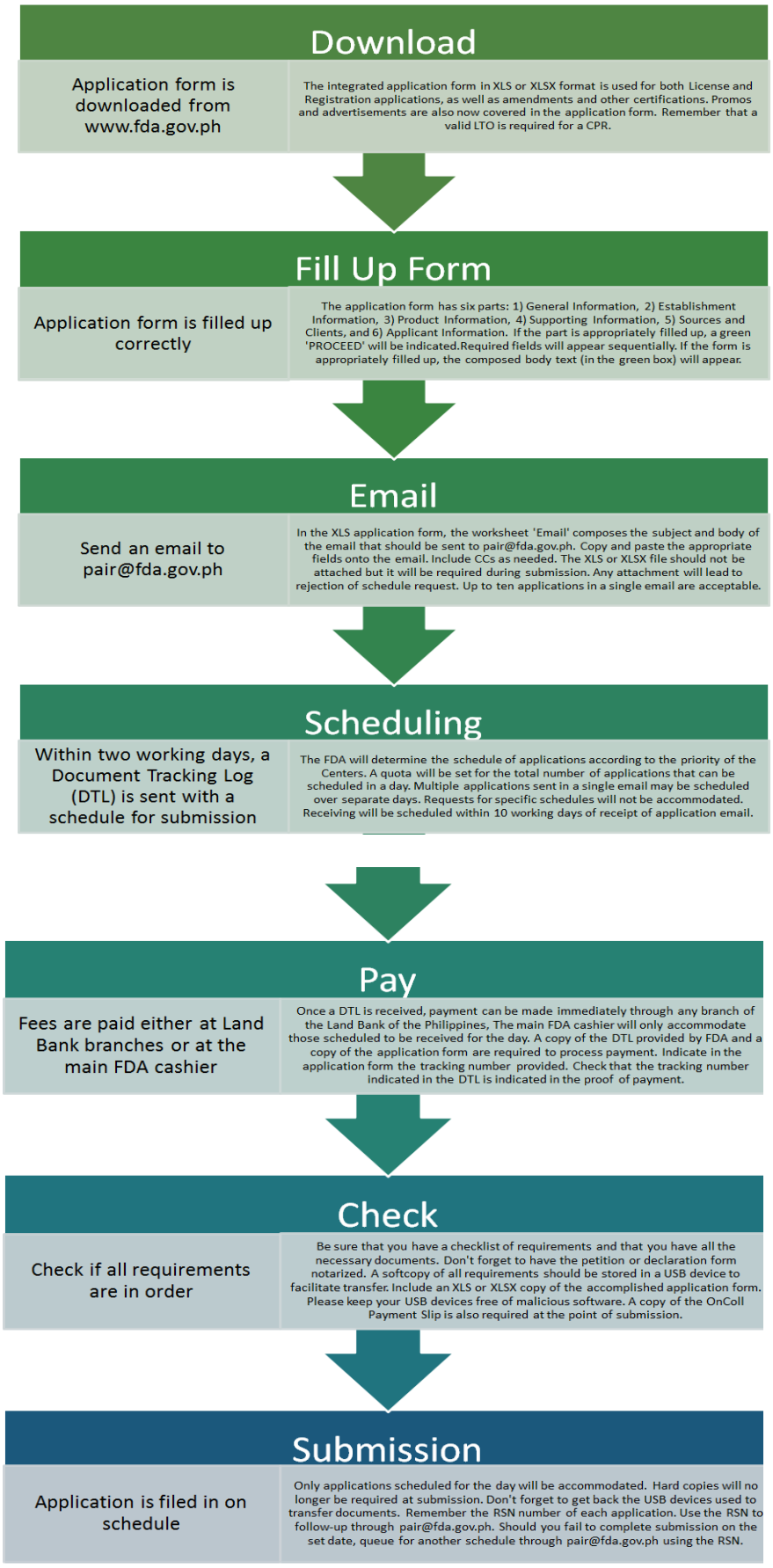
Step 3. Email. *Send an email to fdac@fda.gov.ph*. In the XLS application form, the worksheet 'Email' composes the subject and body of the email that should be sent to fdac@fda.gov.ph. Copy and paste the appropriate fields onto the email. Include CCs as needed. The XLS or XLSX file should not be attached but it will be required during submission. Any attachment will lead to rejection of schedule request. Only ten (10) applications in a single email will be acceptable.

Step 4. Scheduling. *Expect a response within two (2) working days*. A Document Tracking Number (DTN) is sent with a schedule for submission. The FDA will determine the schedule of applications according to the priority of the Centers. A quota will be set for the total number of applications that can be scheduled in a day. Multiple applications sent in a single email shall be scheduled over separate days. Requests for specific schedules will not be accommodated. Receiving will be scheduled within ten (10) working days of receipt of application email.

Step 5. Pay. *Fees may be paid through any Land Bank branches or at the FDAC cashier*. Once a DTN is received, payment can be made immediately through any branch of Land Bank of the Philippines. The FDA cashier will only accommodate those payments for the applications that are scheduled to be received for the day. Printed copies of the DTN and of the IAF are required to be presented to process payment/s. Note that it is required to indicate in the IAF the DTN provided. Check the consistency of the DTN indicated in the issued OnColl Payment Slip or Official Receipt (O.R.) and in the submitted IAF.

Step 6. Check. *Check the documentary requirements for submission*. Make sure that complete and correct documentary requirements appropriate for the application for submission are available in a .pdf format. Softcopies of the documentary requirements, including the softcopies of the accomplished IAF in .XLS or .XLSX format and of the OnColl Payment Slip (for online payments), should be stored in a flash drive to facilitate transfer. Please keep your USB devices free of malicious software.

Step 7. Submission. *Applications may only be submitted on the scheduled dates*. Only applications scheduled for the day will be accommodated by the FDAC personnel for receiving. Softcopies of the documentary requirements, including the softcopies of the accomplished IAF in .XLS or .XLSX format and the scanned copy of the OnColl Payment Slip (for payments made through LBPI), should be stored in a flash drive to facilitate transfer. Please keep your USB devices free of malicious software. Hard copies will no longer be required at the time of submission. Back up copy/ies of the documentary requirements must be secured by the QPIRA at the time of submission. Failure to submit the application/s on the scheduled date shall require an email request through fdac@fda.gov.ph for re-scheduling. Be reminded that only applications scheduled for the day will be accommodated by the FDAC personnel for receiving.


Download
Application form is downloaded from www.fda.gov.ph
The integrated application form in XLS or XLSX format is used for both License and Registration applications, as well as amendments and other certifications. Promos and advertisements are also now covered in the application form. Remember that a valid LTO is required for a CPR.
Fill Up Form
Application form is filled up correctly
The application form has six parts: 1) General Information, 2) Establishment Information, 3) Product Information, 4) Supporting Information, 5) Sources and Clients, and 6) Applicant Information. If the part is appropriately filled up, a green 'PROCEED' will be indicated.Required fields will appear sequentially. If the form is appropriately filled up, the composed body text (in the green box) will appear.
Email
Send an email to pair@fda.gov.ph
In the XLS application form, the worksheet 'Email' composes the subject and body of the email that should be sent to pair@fda.gov.ph. Copy and paste the appropriate fields onto the email. Include CCs as needed. The XLS or XLSX file should not be attached but it will be required during submission. Any attachment will lead to rejection of schedule request. Up to ten applications in a single email are acceptable.
Scheduling
Within two working days, a Document Tracking Log (DTL) is sent with a schedule for submission
The FDA will determine the schedule of applications according to the priority of the Centers. A quota will be set for the total number of applications that can be scheduled in a day. Multiple applications sent in a single email may be scheduled over separate days. Requests for specific schedules will not be accommodated. Receiving will be scheduled within 10 working days of receipt of application email.
Pay
Fees are paid either at Land Bank branches or at the main FDA cashier
Once a DTL is received, payment can be made immediately through any branch of the Land Bank of the Philippines, The main FDA cashier will only accommodate those scheduled to be received for the day. A copy of the DTL provided by FDA and a copy of the application form are required to process payment. Indicate in the application form the tracking number provided. Check that the tracking number indicated in the DTL is indicated in the proof of payment.
Check
Check if all requirements are in order
Be sure that you have a checklist of requirements and that you have all the necessary documents. Don't forget to have the petition or declaration form notarized. A softcopy of all requirements should be stored in a USB device to facilitate transfer. Include an XLS or XLSX copy of the accomplished application form. Please keep your USB devices free of malicious software. A copy of the OnColl Payment Slip is also required at the point of submission.
Submission
Application is filed in on schedule
Only applications scheduled for the day will be accommodated. Hard copies will no longer be required at submission. Don't forget to get back the USB devices used to transfer documents. Remember the RSN number of each application. Use the RSN to follow-up through pair@fda.gov.ph. Should you fail to complete submission on the set date, queue for another schedule through pair@fda.gov.ph using the RSN.

1.1.4. What are the documentary requirements to secure a Certificate of Product Registration (CPR)?

The documentary requirements will depend on the classification and status of the pharmaceutical product for registration. You may refer to the links provided below:
https://ww2.fda.gov.ph/industry-corner/downloadables/343710-checklist-of-requirements
https://ww2.fda.gov.ph/attachments/article/646515/Proposed%20Citizen%20Charter%202019.pdf

1.1.5. How can we track the status of our lodged applications?

Visit the FDA website (Link: https://www.fda.gov.ph/fda-kiosk/), then input the tracking ID of the Document Tracking Log given to you, which is also called the Document Tracking Number or DTN of the application.

1.2. General Technical Information

1.2.1. What are the products under Center for Drug Regulation and Research (CDRR) jurisdiction?

The Center for Drug Regulation and Research (CDRR) regulates the manufacture, importation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of drugs (to include veterinary medicine, vaccines, and biologicals), and when appropriate, certify batches of antibiotic and antibiotic preparations.
[Republic Act (RA) No. 9711 and Department Circular (DC) No. 2011-0101]

1.2.2. What is a pharmaceutical/ drug product?

a. Articles recognized in the official pharmacopoeias and formularies, including official homeopathic pharmacopoeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA;
b. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
c. Articles (other than food) intended to affect the structure or any function of the body of human beings or animals; or
d. Articles intended for use as a component of any articles specified in clauses (1), (2), or (3), but do not include devices or their components, parts or accessories.

[RA No. 9711, DC No. 2011-0101, RA No. 9502 and Joint DOH–DTI–IPO–BFAD Administrative Order (AO) No. 2008-01]

1.2.3. What is a biological product?

Administrative Order No. 2014-0016 [Subject: Adoption of the World Health Organization "Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)" for the Registration of Biosimilar Products] defines biological products or biological medicinal products or biologics or biotherapeutic product as any product of biological origin, prepared with biological processes, derived from human blood and plasma, or manufactured by biotechnology, consisting of substances of higher molecular weight whose purity, potency, and composition cannot readily and reliably be determined by chemical or physicochemical analysis.

Biological products include insulins, erythropoietins, heparin, enoxaparin, monoclonal antibodies, vaccines, plasma-derived products (immunoglobulins, albumin, and coagulation factors), etc.

For biologicals, the concept of biosimilar is applicable. Biosimilar, also known Similar Biotherapeutic Product (SBP), is highly similar to an original biotherapeutic product (that is, the Reference Biotherapeutic Product or RBP) and has been developed and assessed according to the regulatory guidelines that ensure an adequate comparison of the SBP with its RBP. A medicinal product that has not been compared and shown to be similar to a reference product should not be called "biosimilar" or an SBP.

Refer to Administrative Order No. 2014-0016:
https://ww2.fda.gov.ph/attachments/article/151256/Administrative%20Order%20No.%202014-0016%20-%20Biosimilars.pdf

1.2.4. What is a Certificate of Product Registration (CPR)?

A Certificate of Product Registration (CPR)/ Marketing Authorization is the proof of approval of application for registration of a pharmaceutical/ drug product. A CPR/ Marketing authorization covering a particular health product shall be prima facie evidence of the registrant's marketing authority for said health product in connection with the activity/ies permitted pursuant to LTO.
[RA No. 9711]

1.2.5. What are the products that need to secure a Certificate of Product Registration (CPR)/ Marketing Authorization in the Philippines?

Products that are within the definition of pharmaceutical/ drug product, as defined in RA No. 9711, DC No. 2011-0101, RA No. 9502 and Joint DOH–DTI–IPO–BFAD AO No. 2008-01, must secure a CPR/ Marketing Authorization before manufacture, importation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of drugs (to include veterinary medicine, vaccines, and biologicals).

1.2.6. Do I need to secure a CPR/ Marketing Authorization for the Raw Materials that I will import for my own use as manufacturer?

No. Raw materials of finished drug products are not required to be registered. However, importation of raw materials for own use of a local drug manufacturer should be applied as a variation, i.e., additional activity, of the LTO of a Drug Manufacturer/ Trader.

1.2.7. What are the classifications of pharmaceutical/ drug product (based on dispensing practices)?

a. Prescription/ Ethical medicines refer to medicines which can only be dispensed by a pharmacist to a patient, upon presentation of a valid prescription from a licensed physician, dentist, or veterinarian and for which a pharmacist's advice is necessary.
b. Over–the–Counter (OTC) medicines refer to medicines used for symptomatic relief of minor ailments and which may be dispensed without a prescription.
c. Household Remedies (HR) refer to any preparation containing pharmaceutical substances of common or ordinary use to relieve common physical ailments and which

may be dispensed without a medical prescription in original packages, bottles, or containers, of which the nomenclature has been duly approved by the FDA.
[RA No. 10918]

1.2.8. Is the GMP Certificate issued by the FDA Philippines required upon submission of the application for initial registration?

Yes, it is required. To secure a GMP Certificate issued by the FDA Philippines, refer to AO No. 2013-0022 and FDA Circular No. 2014-016.

1.2.9. What is the timeline for processing applications for registration?

The Citizen's Charter specific for the processing of applications for registration may be accessed through the link provided:
https://ww2.fda.gov.ph/attachments/article/646515/Proposed%20Citizen%20Charter%202019.pdf

1.2.10. How do you know if a product is FDA Philippines approved?

Approved pharmaceutical/ drug products may be checked on the FDA website or through this link: https://verification.fda.gov.ph. The main website of the FDA is: www.fda.gov.ph. Other information may be accessed through the old website: ww2.fda.gov.ph. Or may submit an inquiry form (https://ww2.fda.gov.ph/attachments/article/343612/CDRR%20Technical%20Inquiry%20form%203.0.docx) to the FDAC.

1.2.11. Does the FDA allow the same brand name for the same product?

Brand Name is the proprietary name assigned to the product by the Marketing Authorization Holder (MAH) (AO No. 2016-0008). Usage of same brand name is only allowed for products with the same generic name under the same MAH.

1.2.12. Is FDA approval of the brand name mean intellectual property rights over the brand name?

Any matter regarding intellectual property rights is not under the purview of the FDA. In the event that any interested party notifies the FDA, formerly known as BFAD, in writing of any alleged or prior or existing intellectual property rights over the brand name of the product pending registration, the FDA shall immediately respond to said party, in writing, that intellectual property matters are beyond the legal mandate of the FDA and that their proper recourse should be from the Intellectual Property Office of the Philippines or the appropriate courts of competent jurisdiction.
[AO No. 2005-0016]

1.2.13. Are food supplements the same with drug products?

No. There are differences with the RENI. Vitamins and Minerals levels are computed by % RENI as per Office Order No. 22 s.1991 to be classified as food supplements. The maximum limit is 150% RENI for Water Soluble Vitamins and 105% RENI for Fat Soluble Vitamins. For minerals, PDRI 2015 & ASEAN can be used as reference for the maximum limit.

1.2.14. How can we know if a product is considered a pharmaceutical/ drug product aside from those mentioned in 1.2.2.?

Since Vitamins and Minerals levels considered as food supplements are computed by % RENI as per Office Order No. 22 s.1991, exceeding the 150% maximum limit shall mean registration of the product as vitamin/s and/or mineral/s. Herbals and Botanicals that cannot be computed since it has no % RENI requires a justification for the safety and test for toxicity study (LD50 Toxicity Test) and/or inclusion in the GRAS list or Official Pharmacopeia Listing.

1.2.15. What are the officially–recognized Reference Monographs of the FDA Philippines?

a. Philippine Pharmacopoeia (PP)
b. United States Pharmacopoeia (USP)
c. British Pharmacopoeia (BP)
d. European Pharmacopoeia (Ph. Eur.)
e. Japanese Pharmacopoeia (JP)
f. International Pharmacopoeia (Ph. Int.)

1.2.16. How can we determine the Pharmacologic Category of the Finished Pharmaceutical Product (FPP) to be reflected in the labeling materials?

The World Health Organization-Anatomic Therapeutic Chemical (WHO-ATC) Classification System shall be followed or as determined by the FDA Philippines.

1.2.17. What is a Principal Certificate of Product Registration (PCPR)?

A Principal Certificate of Product Registration (PCPR) means the first, or prior, existing and valid CPR of a particular pharmaceutical product with a particular pharmaceutical formulation issued to the owner/ holder thereof who/ which grants to third persons the authority or license to export, import, distribute, market and/or sell the same pharmaceutical formulation.

[AO No. 2005-0031]

1.2.18. What is a Certificate of Listing of Identical Drug Product (CLIDP)?

Certificate of Listing of Identical Drug Product (CLIDP) is the certificate issued by the FDA, formerly known as BFAD, as proof that its pharmaceutical product has been officially listed with the FDA as identical, in terms of the manufacturer and of the pharmaceutical formulation, to the pharmaceutical product already covered by a Principal CPR.

[AO No. 2005-0031]

1.2.19. Is there a guideline for Expedited Review of pharmaceutical/ drug products?

Yes, refer to CDRR Memorandum No. 0003 s. 2013 or as follows.

a. Products to be manufactured exclusively for export;
b. New drug products considered to be a major therapeutic advance;
c. The first five (5) products of newly licensed establishments without any registered pharmaceutical/ drug products yet to its name;
d. Products for government programs and projects; and
e. Imported prequalified vaccines.

1.2.20. How can we verify the registration status of a particular registered Finished Pharmaceutical Product (FPP)?

A formal inquiry letter or email through the FDA-CDRR official email: cdrr.od@fda.gov.ph may be submitted.

1.2.21. Are we allowed to register a Finished Pharmaceutical Product (FPP) manufactured in different sites with the same brand name?

Yes, it is allowed. However, a separate application for registration shall be submitted to this Office.

1.2.22. Is there a need to register the diluent (vial/ ampoule) separately from the Finished Pharmaceutical Product (FPP) intended for reconstitution?

No. However, the (a) complete dossier of the diluent [Part II Quality: Drug Substance/ Active Pharmaceutical Ingredient (API) (where applicable) and Finished Drug Product (FPP)] and (b) Good Manufacturing Practice (GMP) Certificate, for locally manufactured pharmaceutical/ drug product, or Foreign GMP Clearance (fGMP), for imported products, of the diluent manufacturer should accompany the application for registration of the FPP.

1.2.23. If the diluent has been previously registered, can this be used in the registration of an FPP intended for reconstitution (as part of a kit)?

Yes. The applicant company should attach the copy of the valid CPR in the submission.

1.2.24. Are we allowed to register a kit of Finished Pharmaceutical Product (FPP) and diluent (vial/ ampoule) even if their manufacturers are different?

Yes, it is allowed. Provided, that the (a) complete dossier of the diluent [Part II Quality: Drug Substance/ Active Pharmaceutical Ingredient (API) (where applicable) and Finished Drug Product (FPP)] and (b) Good Manufacturing Practice (GMP) Certificate, for locally manufactured pharmaceutical/ drug product, or Foreign GMP Clearance (fGMP), for imported products, of the diluent manufacturer are provided upon submission.

1.2.25. Do I need to file a separate application for initial registration if the product will also be exported?

No. The issued marketing authorization/ CPR is allowed for distribution to local and foreign market.

Post-Approval Change application/ Amendment application of Packaging Design for an export product shall be done and labeling materials in the language of the importing country shall also be submitted.

1.2.26. If my product will be distributed exclusively for export, do I need to comply with the local labeling regulations?

No. Labeling materials of products exclusive for export market shall only comply with the existing labeling regulations of the importing country or country of destination of the products.

1.2.27. If my product is both for local and export market, what labeling regulations will I need to comply for product registration?

Only the labeling materials intended for the Philippine market are required to follow the applicable provisions of AO No. 2016-0008.

2. REGISTRATION OF PRESCRIPTION GENERIC DRUG PRODUCTS FOR HUMAN USE

2.1. General Procedures

2.1.1. What are the requirements for the Initial registration of Generic Prescription Products?

The requirements shall be based on AO No. 2013-0021, Adoption of the ASEAN Common Technical Dossier and ASEAN Common Technical Requirements. The complete list of requirements can be found on the FDA website > Industry Corner > Downloadables > Center for Drug Regulation and Research > Drug Registration Requirements.

Refer to this link: https://ww2.fda.gov.ph/industry-corner/downloadables/343710-checklist-of-requirements

2.1.2. How much is the registration fee and how many years is the validity of a CPR?

Refer to the tabulation below for the fees for initial registration of generic pharmaceutical/ drug products:

Classification	Total Fees	Application fee	Legal and Research Fee (LRF) (corresponding to 10% of the application fee)
Branded	₱ 15,150.00 Valid for five (5) years + ₱ 510.00 per proposed brand name	₱ 3,000.00 for one year + ₱ 500.00 per proposed brand name	₱ 30.00 + ₱ 10.00 per proposed brand name
Unbranded	₱ 10,100.00 Valid for five (5) years	₱ 2,000.00 for one year	₱ 20.00

[AO No. 50 s. 2001]

2.1.3. How can the applicant company (or the Pharmaceutical/ Drug Product Manufacturer) submit the closed/ restricted part of Drug Master File (DMF) to the FDA Philippines?

The applicant company (or the Pharmaceutical/ Drug Product Manufacturer) shall send the documents through an email directly to the FDA-CDRR through its official email address: cdrr.od@fda.gov.ph. The Marketing Authorization Holder (MAH) shall coordinate the current status of the application with the Pharmaceutical/ Drug Product manufacturer. To ensure the traceability of the application, the DTN of the appropriate application for initial registration shall be mentioned in the email.

2.2. ASEAN Common Technical Dossier (ACTD)

2.2.1. Does the FDA Philippines accept ICH-CTD format?

Yes. This format is acceptable provided the products are approved in ICH member countries and the country-specific requirements are submitted. It must be emphasized,

however, that certain sections of the ICH-CTD should still comply with the ASEAN Harmonized Requirements (including drug product stability studies), when applicable.

2.2.2. Are we required to submit hardcopies of original Certifications during filing of application for initial registration?

As per FDA Circular No. 2014-003 (Subject: Filing and Receiving of Registration, Licensing and Other Applications Using the Integrated Application Form), hard copies of original documents are not required to be submitted but must be presented to officers of the FDA during onsite audits.

2.2.3. What is the required format of the Certificate of Pharmaceutical Product (CPP)?

The CPP shall follow the World Health Organization (WHO) format.

2.2.4. When is the CPP considered as valid if its validity date is not indicated?

The CPP is considered as valid within 1 year after its issuance. The application for initial registration is therefore required to be submitted within this period.

2.2.5. If a country does not issue a CPP. What other document/s can be submitted?

For countries not issuing CPP, the following shall be submitted:

a. Current Good Manufacturing Practice (CGMP) Certificate issued by the drug regulatory authority of the product's country of origin; and
b. Certificate of Free Sale (CFS).

2.2.6. What is the legal basis on the evaluation of labeling materials for drug products for human use?

The issuance is Administrative Order No. 2016-0008 (Subject: Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use).

2.2.7. Can we use the information stated on the labeling materials/ Summary of Product Characteristics (SPC) of the innovator product for our generic product?

Yes. Applicants/ Marketing Authorization Holder (MAH) of generic products may refer to the labeling materials/ SPC of innovator products. However, intellectual property/ data exclusivity attributable to certain information (e.g., results of innovator sponsored clinical studies) should be considered.

2.2.8. What are the options of submission of "S" or "Substance" part?

There are three options in the submission of "S" or "Substance" part which are the following:

a. Full submission (S1-S7);
b. Valid CEP; and
    i. European Pharmacopoeia as reference –S1, S2.1, S4.4, S7*
    ii. Other pharmacopoeias as reference –S1, S2.1, S4.1 to S4.5, S7*
        - *Required if the re-test period is not indicated
b. Drug Master File (DMF)/ Active Pharmaceutical Ingredient Master File (APIMF) open and closed parts*
        - Refer to **FAQ No. 2.1.3.** for the submission of DMF (closed part)

2.2.9. What is a CEP?

CEP pertains to the Certificate of Suitability to the monographs of the European Pharmacopoeia. It provides centralized evaluation for manufacturers of raw materials for pharmaceutical use. This is issued by the European Directorate for the Quality of Medicines and Healthcare (EDQM). For more information kindly visit www.edqm.eu.

2.3. ASEAN Common Technical Requirements (ACTR)

2.3.1. ASEAN Guideline on Submission of Manufacturing Process Validation for Drug Registration

2.3.1.1. What documentation under P 3.4 Process Validation and/or Evaluation are required for submission to the FDA Philippines?

In the Philippines, the data submission must include both the validation scheme/ protocol and the validation report on three (3) consecutive successfully validated production batches.

2.3.1.2. What is the acceptable range permitted for critical process parameters?

A nominal or target value for the critical process parameter with an allowable normal operating range should be defined and justified. There are no fixed formulae for this. The range is established based on scientific data available, process robustness and the expected impact of the critical process parameter on critical quality attributes defined in product specification.

2.3.1.3. Can bracketing/ matrixing approach be adopted for process validation?

This approach is not recommended unless it can be justified.

2.3.1.4. Should validation batches be placed on stability program?

It is not a requirement but it would be good practice to place at least one (1) concurrent validation batch or three (3) prospective batches on stability program. This provides efficient use of resources as well as fulfills the commitment to submit stability data on three (3) full scale batches.

2.3.2. ASEAN Guideline for the Conduct of Bioavailability and Bioequivalence Studies

2.3.2.1. What are the issuances related to Bioequivalence?

a. Administrative Order No. 67 s. 1989
b. FDA Circular No. 2013-014
c. FDA Circular No. 2016-019

**All pharmaceutical products shall also follow the latest ASEAN and World Health Organization (WHO) Guidelines, e.g., Technical Report Series (TRS).*

2.3.2.2. Are there any locally-accredited Bioequivalence (BE) Testing Centers?

Yes. There are currently four (4) locally-accredited BE testing centers, namely:

a. Center for Excellence in Drug Research, Evaluation, and Studies (CEDRES), Inc.;
b. Pharmalytics Corp.;
c. De La Salle Health Sciences Institute – Center for Biopharmaceutical Research; and
d. United Laboratories-BA Unit.

2.3.2.3. Where can we find the list of the FDA Philippines-recognized comparator products?

Refer to the FDA Website > Industry Corner > Downloadables > CDRR > Drug Registration Requirements or through this link: https://ww2.fda.gov.ph/industry-corner/downloadables/343710-checklist-of-requirements.

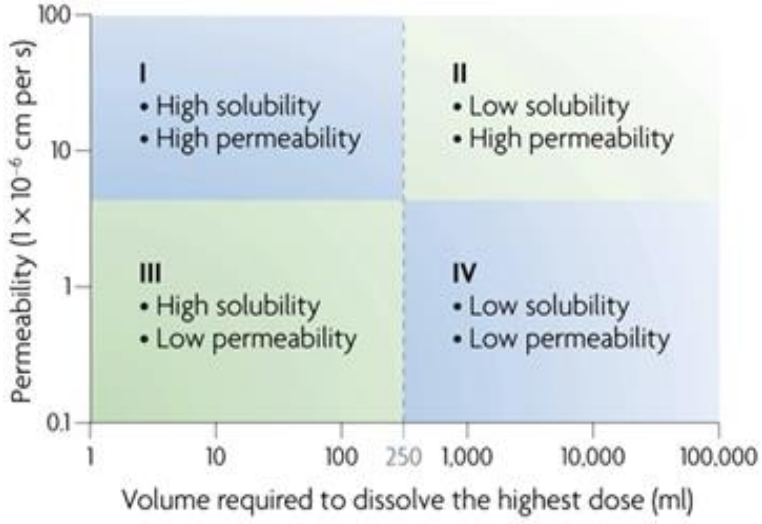
2.3.2.4. What if the recognized comparator product is not locally available in the market?

In case the comparator drug product is not available in the Philippines, the global innovator (or in its absence, an alternative comparator) should be purchased from a well regulated market with stringent regulatory authority (SRA). Documentary proof of purchase, shipping and storage of the comparator product from the site of purchase to the BE testing center should be provided. In addition, provide proof that the comparator product is no longer locally available.

2.3.2.5. What is the Biopharmaceutics Classification System (BCS)?

The Biopharmaceutics Classification System (BCS) is a scientific framework for classifying active pharmaceutical ingredients (API) based upon their aqueous solubility and intestinal permeability. It is divided into four (4) classes namely: BCS Class I, II, III and IV (see image below).

**Refer to WHO TRS 1003 Appendix 2*



2.3.2.6. Is the Bioequivalence (BE) study conducted on the highest strength acceptable as basis for the approval of the biowaiver based on dose-proportionality of formulations for the lower strength if the highest strength is not marketed nor is intended to be registered in the Philippines?

No. The quality, safety, and efficacy of the highest strength shall be established and therefore, require its registration in the Philippines. If the registration of the highest strength is unsuccessful, the registration of the lower strength will not proceed.

In such a case, the lower strength can only be registered if a BE study is conducted against the comparator drug of the same strength.

2.3.2.7. Is it acceptable to submit a BE Study Report conducted by a BE testing center that has already been closed or no longer in operation?

No. There should be a valid proof of accreditation and/or recent inspection reports issued by the National Regulatory Authority (NRA) of the BE testing center showing its proof of compliance to Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) principles.

2.3.2.8. What if the Biopharmaceutics Classification System (BCS) of a fixed-dose combination product falls under different classes, e.g., BCS Class 2 and BCS Class 3? What will be the acceptable proof of interchangeability for the FDC?

Fixed-dose combination products with systemic action or at least one of the substances requiring an in vivo study, shall provide satisfactory in vivo equivalence evidence (Bioequivalence Study) upon initial registration.

2.3.2.9. Is it acceptable to use a comparator drug of different dosage form from the test drug, e.g., Capsule vs. Tablet?

This is not acceptable for *in vitro* equivalence testing, since the dissolution rates between the two pharmaceutical dosage forms are different. However, for *in vivo* equivalence testing, it is acceptable as long as both the comparator and test drug have the same release mechanism and dose of administration.

2.3.2.10. Is it acceptable to submit a clinical study instead of an in vivo or in vitro equivalence study?

No. The generic equivalent of an established drug (classified under regular initial registration) requires in vitro or in vivo equivalence evidence to demonstrate interchangeability.

2.3.2.11. What pharmaceutical dosage forms require the mandatory submission of product interchangeability?

All oral solid pharmaceutical dosage forms with systemic action including powder/ granules for oral suspension and prepared oral suspension.

2.3.2.12. Is BE Study Protocol required to be approved only by Ethics Committee or also by the regulatory body?

No. Only the approval from the Ethics Committee on BE Study Protocol is required prior to the conduct of the BE study.

2.3.2.13. What if the strength of the reference drug needed is not already available in the market and other strengths are available, is it acceptable to use the equivalent amount of the other strengths?

Yes, using multiple units of either the test drug or reference drug (whichever is applicable) may be done to achieve equivalent administration dose in BE studies.

Example:

(1)

Test drug	Reference drug	Market status
100 mg	100 mg	Phased out
	50 mg (x2)	Available

(2)

Test drug	Reference drug	Market status
50 mg (x2)	100 mg	Available
	50 mg	Phased out

2.3.3. ASEAN Guideline on Stability of Drug Product (version 6.0)

2.3.3.1. What comprises a Stability Report?

A stability report must include the Stability Summary, Post-Approval Stability Protocol and Commitment, Stability Protocol, and Data.

2.3.3.2. If the product is intended to be used immediately after reconstitution/ dilution, should we still need to submit in-use stability data?

No, it is not required. But no claims of in-use stability should be mentioned on the labeling materials.

2.3.4. ASEAN Guideline for Validation of Analytical Procedures

2.3.4.1. What documentation under P 5.3 Validation of Analytical Procedures are required to be submitted to the FDA Philippines?

In the Philippines, the data submission must include both the method validation protocol and the method validation report (complete attachments, e.g., spectra, chromatograms, raw data sheet).

2.3.4.2. Is verification of compendial methods, in all cases, confined to accuracy and precision parameters only?

Verification of compendial methods should depend on the type of test to be verified. For example, LOQ should be a key parameter in verifying the quantitative assay of impurities. As stated in the USP-NF, Validation of Compendia method, the characteristic of accuracy is not required.

2.3.4.3. How to ensure the method transfer, e.g., fully validated test method, from a mother company to the receiving company is efficient?

Comparative testing is the most common analytical method transfer option used.

3. REGISTRATION OF NEW DRUGS/ NEW CHEMICAL ENTITIES/ NEW MOLECULE FOR HUMAN USE

IMPORTANT: Information in this section **does not** include those for Monitored Release registration of Biologicals/Large molecules and Vaccines (please refer to Section 4.2) and Veterinary Drugs (refer to Section 6.2)

3.1. General Procedures

3.1.1. How much is the fee for Monitored Release Registration and how many years is the validity of its CPR?

In compliance with FDA Circular No. 2018-012, which states that an approved CPR under MR status should be valid for three (3) years, MR registration fee is ₱ 25,760.00 for branded products and ₱ 25,250.00 for unbranded products.

Classification	Total Fees	Application fee	Legal and Research fee (LRF) (corresponding to 10% of the application fee)
Branded	₱ 20,200.00 valid for three (3) years + ₱ 5,050.00 for Clinical Review + ₱ 510.00 per proposed brand name	₱ 20,000.00 for three (3) years + ₱ 5,000.00 for Clinical Review + ₱ 500.00 per proposed brand name	₱ 200.00 + ₱ 50.00 + ₱ 10.00
Unbranded	₱ 20,200.00 + ₱ 5,050.00 for Clinical Review	₱ 20,000.00 for three (3) years + ₱ 5,000.00 for Clinical Review	₱ 200.00 + ₱ 50.00

[AO No. 50 s. 2001]

Note: Consistent with FDA Circular No. 2018-012, the applicable fee for the review of Phase IV Study Protocol is ₱ 2,525.00 (inclusive of LRF).

3.1.2. What are the requirements for Monitored Release registration?

The requirements shall be based on AO No. 2013-0021, Adoption of the ASEAN Common Technical Dossier and ASEAN Common Technical Requirements. The complete list of requirements can be found on the FDA website > Industry Corner > Downloadables > Center for Drug Regulation and Research > Drug Registration Requirements.

Refer to this link: https://ww2.fda.gov.ph/industry-corner/downloadables/343710-checklist-of-requirements

3.1.3. In reference to FDA Circular No. 2018-012, are existing registered products under Monitored Release registration and MR applications submitted before the issuance (that are still pending) of the mentioned Circular required to submit a Phase IV study?

No. Only MR applications submitted after the issuance of the mentioned Circular, i.e., August 2018, should comply with the requirements of FDA Circular No. 2018-012.

3.1.4. How should we submit the proposed Phase IV study in compliance to FDA Circular No. 2018-012?

The application for a Phase IV protocol study, in relation to an MR application covered by the mentioned Circular, should **not** be submitted or included in the product dossier/ submission for MR registration application. Instead, it should be submitted as a **separate application and with a separate DTN**.

3.1.5. What are the requirements for MR to Regular Initial application?

ACTD Parts I & II (only), Risk Management Plan (RMP), Periodic Safety Update Report (PSUR), and Phase IV Study results/ report* (if applicable).

**Only applicable to MR products that were issued before FDA Circular No. 2013-004.*

Refer to this link: https://ww2.fda.gov.ph/industry-corner/downloadables/343710-checklist-of-requirements

3.1.6. What application type should we put in the IAF if we are applying for an MR to Regular Initial registration?

Application type should be **Initial**. MR to Initial applications that are lodged as Automatic Renewal or Regular Renewal shall be disapproved.

3.2. Monitored Release Registration

3.2.1. How do we classify products under Monitored Release registration?

MR products include New Drugs/ NCEs/ New Molecules that are first to register in the Philippine market, and generic products of a registered MR product (either the global innovator or a generic of the innovator that was first to register in the country). To classify, these are the possible options:

a. FDA Website verification; OR
   i. On your browser, open the FDA website (www.fda.gov.ph or ww2.fda.gov.ph). In the search tab at the upper right corner of the site, input the generic name, dosage strength and form of your product.
   ii. If the search tab yielded no results, then the product is considered as MR.
   iii. If the search results show an already registered product/s (of the same generic name/ active ingredient, dosage form and strength), the status of this product/s should be verified with our Office. To do this, refer to the next option (Option B). The status of your product **should follow** the status of the registered product. If the registered product is under MR status, then you need to apply under the said registration status

b. Technical Inquiry through phone call, face-to-face inquiry at the FDAC-CDRR counter, or submission of technical inquiry form at the FDAC-CDRR counter.

3.2.2. Can an existing registered drug product be considered as MR if it has structural modification, or of a different form or strength?

This is on a case-to-case basis.

- For structural modification, i.e., new salt form: **MR registration**
- For new dosage form, i.e., registered product is an immediate release tablet, while the proposed product is a sustained release tablet; or, registered product is a capsule, and the proposed product is a powder for solution for injection: **MR registration**
- For new dosage strength:
  a. If proposed is of higher strength, i.e., registered product is 75 mg film-coated tablet, while the proposed product is 150 mg film-coated tablet: **MR registration**
  b. If proposed is of lower strength, wherein its daily dosage regimen completes that of the higher strength, i.e., registered product is 150 mg film-coated tablet recommended for **once** daily use, while the proposed product is 75 mg film-coated tablet recommended for **twice** daily use: **Initial registration** (considering that the registered strength has a regular CPR, i.e., Initial or Renewal status, **otherwise, it should be MR registration**)
  c. If proposed is of lower strength, wherein the daily dosage regimen is lower than that of the higher strength, i.e., registered product is 150 mg film-coated tablet recommended for **once** daily use, while the proposed product is 75 mg film-coated tablet recommended for **once** daily use: **MR registration**

3.2.3. If my product is a generic of a registered global innovator/ reference product which is currently under MR status, what data on safety and efficacy can we submit?

a. If the product is in **solid dosage form**, submission of a satisfactory Bioequivalence study, i.e., compliant to the ASEAN Guideline for the Conduct of Bioequivalence and Bioavailability Studies and latest WHO Guidelines/ TRS, will suffice to prove therapeutic equivalency (efficacy) of the product with the innovator/ reference product. Submission of PSUR and RMP will constitute the safety of the product in the global market and/or country of origin.
b. If the product is in dosage form **other than solid dosage form**, e.g., parenteral, topical, etc., submission of published literature studies on the safety and efficacy of a **similar product,** i.e., product with the same active ingredient, dosage form and strength, to the intended/ proposed population and disease will suffice. Submission of PSUR and RMP will constitute the safety of the product in the global market and/or country of origin.

Note: The proposed indication/s of the generic product should be exactly the same with the innovator product.

3.3. MR to Regular Initial registration

3.3.1. Can we apply for extension of our CPR while waiting for our MR to Initial application to be processed, similar to AR and RR applications?

Yes. Submit a request letter and attach the original CPR to the FDAC using the same DTN of your MR to Initial application.

3.3.2. My current CPR (under MR) has already been extended for two (2) years and yet, its MR to Initial application is still unprocessed. Can we apply for another CPR extension?
No. If you do so, your request will only be denied. However, it is encouraged that in the event that your MR to Initial application is still unprocessed and its CPR is extended for 2 years already, kindly submit a follow-up through a letter, follow-up form (dropbox) or e-mail us at cdrr.od@fda.gov.ph with the subject: [MR TO INITIAL] CPR EXTENDED FOR 2 YEARS (DTN 2020xxxxxxxxxx)

4. REGISTRATION OF BIOLOGICALS AND VACCINES FOR HUMAN USE

4.1. General Procedures

4.1.1. My product is now classified as a biological product but was previously registered as a human drug (DR-XY; DR; DRP). What will I do?

Since your product has been classified as a biological, you have two options:

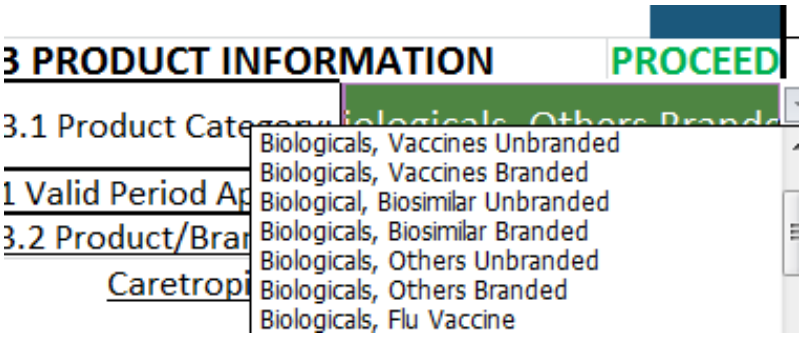
a. If you wish to convert prior to the expiration of the Certificate of Product Registration (CPR), you should do so by submitting the following to the Food and Drug Action Center (FDAC):
   i. Letter of request for conversion to BR.
   ii. Original CPR

   This is free of charge. However, any other request for changes aside from the registration number shall be automatically disregarded.

b. Or upon renewal, you have to submit the documents for renewal registration of biological products (See Section III, Question 1).

4.1.2. In the IAF, which product category should I choose?

The IAF contains the specific categories applicable to biological products (see image below)



It is important to properly classify the application so that it is transmitted to the proper unit for processing. Improper classification will result to reclassification, redecking, and delay of the review of the application.

4.1.3. Do all biologicals have to apply for lot or batch release certification?

In accordance to Administrative Order No. 47-a s. 2001 (Subject: Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products), all batches or lot of established, new and developmental biologic products that are to be sold and used in the Philippines shall require lot or batch release certification, except UNICEF/ WHO-procured biological products by the Department of Health (DOH).

4.1.4. Are representative samples required for all biologic applications?

In accordance to Administrative Order No. 47-a s. 2001, representative sample is required for monitored release, initial, and renewal registration applications.

In addition, samples to be submitted must be properly labeled and kept in a protective plastic bag/ ziplock with the following information:

a. Product name (International Nonproprietary Name (INN), brand name);
b. Dosage strength and form;
c. Manufacturer;
d. Marketing Authorization Holder (MAH); and
e. Document Tracking Number (DTN).

It should be stored under the required condition as provided in the stability data (e.g., 2-8°C) included in the application file. Samples must only be submitted upon request of the evaluator.

4.1.5. The foreign GMP clearance (FGMPC) only covers the manufacture of "sterile" drug products. Is this applicable to biological products?

No, sterile drug products do not cover biologicals. The FGMPC should clearly state that manufacturer is capable of producing biologicals. In some cases, the specific pharmaceutical category (e.g., monoclonal antibody, vaccine) or technology (e.g., recombinant) used to manufacture the biological product is reflected in the FGMPC. This is acceptable if it corresponds with the biological product being applied.

4.1.6. Is there a "generic biological" product?

No, the concept of "generic" does not apply to biological products. For biologics, it is impossible to state that one biologic is the same or equivalent as the other. Variabilities will apply due to the relatively large and complex molecules of biological origin which are more difficult to characterize due to the inherent heterogeneity of biological products.

4.1.7. What type of biological products can qualify as SBP?

All biological products except for vaccines, plasma-derived products, and their recombinant analogues may be considered as SBP.

4.1.8. What are the requirements for the registration of SBPs?

The requirements for the registration of SBPs are provided in Administrative Order No. 2014-0016 (Subject: Adoption of the World Health Organization "Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)" for the Registration of Biosimilar Products). (Link: https://ww2.fda.gov.ph/attachments/article/151256/Administrative%20Order%20No.%202014-0016%20-%20Biosimilars.pdf)

4.1.9. What is a head-to-head comparability exercise?

Administrative Order No. 2014-0016 defines head-to-head comparability exercise as the direct head-to-head comparison of a biotherapeutic product with a licensed originator product also known as the Reference Biotherapeutic Product (RBP) with the goal to establish similarity in quality, safety, and efficacy. Products should be compared in the same study using the same procedures.

4.1.10. Where can I find the list of Reference Biotherapeutic Products (RBP)?

The list of RBP is provided by FDA Circular No. 2015-004 [Subject: List of Reference Biotherapeutic Products (RBPs) for Head-to-Head Comparability Studies of Similar Biotherapeutic Products (SBPs]. (Link: https://ww2.fda.gov.ph/attachments/article/233126/FDA%20Circular%20No.%202015-004.pdf)

4.1.11. What if the SBP to be registered has no corresponding RBP on the provisional list?

The applicant may submit a letter of inquiry to Center for Drug Regulation and Research (CDRR) via the Food and Drug Action Center (FDAC), indicating the information (i.e., INN, dosage strength and form, manufacturer, and the list of countries where the product is registered and marketed) of the candidate SBP, as well as the RBP to be used.

4.1.12. For biological products with a designated RBP, is it possible to choose for Standalone biotherapeutic product or do I have to apply as SBP?

Whether to apply as SBP or standalone is within the discretion of the applicant.

The demonstration of an acceptable level of similarity between the SBP and RBP (through comparability exercises/ biosimilar studies) provides rationale for utilizing a reduced non-clinical and clinical data set to support the application for market authorization of the SBP.

If the head-to-head comparability exercise indicates that there are relevant differences between the intended SBP and RBP making it unlikely that biosimilarity will eventually be established, a stand-alone development to support a full Marketing Authorization Application should be considered instead. In this, product for registration could be licensed through the usual processes using a more extensive non-clinical and clinical data set or full licensing application.

***4.1.13.* Is there a separate guideline for the registration of human influenza vaccines?**

Yes. FDA Circular No. 2020-002 (Subject: Guidelines on the Registration of Human Influenza Vaccine) provides the procedures, requirements, validity, and fees for the registration of human influenza vaccines. (Link: https://www.fda.gov.ph/wp-content/uploads/2020/02/FDA-Circular-No.2020-002.pdf)

4.2. Initial and Monitored Release Registration

IMPORTANT: Information in this section **does not** include those for Monitored Release registration of New Drugs/New Chemical Entities/New Molecules (refer to Section 3) and Veterinary Drugs (refer to Section 6.2)

4.2.1. What are the requirements for Initial/ Monitored Release (MR) registration?

The requirements for the initial/ monitored release registration of biologicals may be found in Administrative Order No. 47-a s. 2001 and should follow the format provided by Administrative Order No. 2013-0021. For biosimilars, Administrative Order No. 2014-0016, Annex B shall be used as reference (Link: https://ww2.fda.gov.ph/attachments/article/151256/Administrative%20Order%20No.%202014-0016%20-%20Biosimilars.pdf)

4.2.2. What are the requirements for MR to Initial application?

The documentary requirements and payment shall be the same as that of Initial registration:

a. Complete ACTD Parts I-IV
b. RMP
c. PSUR
d. Copy of the post-approval commitment letter and the compliance documents required in the said letter (if any) attached to the approved MR CPR.

Additional requirements may be requested by the evaluator, e.g., summary of changes within the last five (5) years or certification that no changes were made in the past five (5) years.

4.2.3. What are the applicable fees for Initial/ MR applications?

In accordance to Administrative Order No. 50 s. 2001, the fees for the initial registration of biologicals are the same as that of human drugs, OTC, and veterinary products. For monitored release registration, the fees are as follows:

Classification	Total Fees	Application fee	Legal and Research fee (corresponding to 10% of the application fee)
Branded	₱ 20,200.00 valid for three (3) years + ₱ 5,050.00 for Clinical Review + ₱ 510.00 per proposed brand name	₱ 20,000.00 for three (3) years + ₱ 5,000.00 for Clinical Review + ₱ 500.00 per proposed brand name	₱ 200.00 + ₱ 50.00 + ₱ 10.00
Unbranded	₱ 20,200.00 + ₱ 5,050.00 for Clinical Review	₱ 20,000.00 for three (3) years + ₱ 5,000.00 for Clinical Review	₱ 200.00 + ₱ 50.00

Note: Consistent with FDA Circular No. 2018-012, the applicable fee for the review of Phase IV Study Protocol is ₱ 2,525.00 (inclusive of LRF).

4.2.4. For initial registration of biologicals, do we have to submit Parts 3 and 4 (Non-clinical and Clinical documents)?

Yes, refer to Administrative Order No. 47-a s. 2001 and Administrative Order No. 2013-0021, and Administrative Order No. 2014-0016 for biosimilars.

4.2.5. Can I register multiple manufacturers with the same activity in one CPR?

One line of production per CPR should be maintained. Therefore, multiple manufacturers with the same activity cannot co-exist in one CPR. Addition of alternate manufacturer (i.e., drug substance, drug product, lot release site, packaging, etc.) is acceptable but only upon filing of an initial/ monitored release registration.

4.3. Renewal Registration

IMPORTANT: Information in this section **does not** include those for Renewal Registration of Prescription generic drug products for Human Use/Small molecules, OTC/HR/TM/HM and Veterinary drugs (refer to Section 7.2).

4.3.1. Can I apply for Automatic Renewal (AR) for biological products?

No, in accordance to Administrative Order No. 47-a s. 2001, only regular renewal application is allowed for biological products.

The requirements are as follows:

a. IAF (as excel file and as scanned pdf file, notarized)
b. Periodic Safety Update Report (PSUR)
c. Risk Management Plan (RMP)
d. 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 shall be incorporated.
e. Labeling Materials (actual/ commercial labeling materials)
f. Actual commercial sample (to be submitted upon request of the evaluator)
g. Valid Foreign GMP clearance
h. Post-marketing commitments (if any)
i. Summary Lot Protocol (applicable to all biologicals as per AO No. 47-a s. 2001)
j. Valid License to Operate

Additional requirements for vaccines:

k. List of countries where the vaccine is already licensed and the date of approval
l. Adverse Event Following Immunization report (Summary of Annual Reports)

The list of requirements is also posted on the website (link: https://ww2.fda.gov.ph/attachments/article/343710/Checklist%20of%20Requirements%20for%20Biological%20Products.pdf)

4.3.2. What are the applicable fees for renewal application?

The fees for the renewal registration of biologicals, including surcharge, is the same as that of human drugs, OTC, and veterinary products. Refer to Administrative Order No. 50 s. 2001 or "Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs". (Link: https://ww2.fda.gov.ph/attachments/article/153569/ao%2050%202001.pdf).

All payments are subject to 1% or ₱ 10.00 (whichever is higher) Legal Research Fund (LRF).

4.3.3. How do I renew my MR application?

MR applications cannot be renewed. As per FDA Circular No. 2013-003 (Subject: Post Market Surveillance and Periodic Safety Update Report), Monitored Release applications that have finished their status as monitored release should apply for Initial registration. (See Section IV, Question 1).

4.3.4. Is it possible to file for Variation application at the same time as the renewal registration?

Yes. However, if the variation application shall be applied together with the renewal registration, the requirements for variation (Section II, Question 2) and renewal registration (Section III, Q1) must be submitted. The corresponding fees for variation and renewal registration must both be settled.

4.4. Post-Approval Change/ Variation

IMPORTANT: Information in this section **does not** include those for Post-Approval Change/Variation of Prescription generic drug products for Human Use/Small molecules, New Drugs/New Chemical Entities/New Molecules, OTC/HR/TM/HM and Veterinary drugs (refer to Section 7.3).

4.4.1. What should be the reference guideline for variation applications of biologicals and vaccines?

ASEAN Variation Guideline (AVG) should be used as the reference. However, in cases where the variation type does not fall under the categories identified in the AVG, the MAH shall classify the change as PH06, and shall refer to WHO TRS 993 Annex 4 and WHO TRS 1011 Annex 3 for the documentary requirements. For EMA approved changes, the MAH may submit an assessment report and refer to EMA Variation Guidelines for the documentary requirements.

In addition to this, AVG and FDA Circular No. 2014-008 (Subject: Application Process and Requirements for Post-approval Changes of Pharmaceutical Products), also states that the FDA may require additional information as deemed necessary to ensure that the product maintains its safety, efficacy and quality.

Refer to FDA Circular No. 2014-008 (Link: https://ww2.fda.gov.ph/attachments/article/148395/FC2014-008%20-%20Application%20Process%20and%20Requirments%20for%20Post-Approval%20Changes%20of%20Pharmaceutical%20Products.pdf)

4.4.2. What are the applicable fees for variation applications?

Payment is on a per product per change basis. For example, one DTN has two changes, i.e., MiV-PH06 = ₱ 510.00, MiV-PA2 = ₱ 510.00 [or two unclassified changes under two MiVPH6 (2 x ₱ 510.00)], the payment that should be made is ₱ 1,020.00.

For the classification of variation applications and their corresponding fees, refer to FDA Circular No. 2014-008: https://ww2.fda.gov.ph/attachments/article/148395/FC2014-008%20-%20Application%20Process%20and%20Requirments%20for%20Post-Approval%20Changes%20of%20Pharmaceutical%20Products.pdf

4.4.3. Why do I need to submit the National Regulatory Authority (NRA) approval for variation applications?

In accordance to Administrative Order No. 47-a s. 2001, the drug establishment shall submit a certificate of approval from the NRA of the exporting country or the country of origin for any changes in the manufacturer, status of cGMP, and manufacturing process.

In addition to this, the AVG and FDA Circular No. 2014-008 also states that the FDA may require additional information as deemed necessary to ensure that the product maintain its safety, efficacy, and quality.

4.4.4. The NRA considers the change as non-reportable. Does this mean I don't have to report the change to the FDA as well?

Regardless of the classification of the change in the country of origin, all changes pertaining to the drug product must be filed as notification, variation application, or in some cases, initial/ MR registration, whichever is applicable. Notification through letters is not acceptable.

4.4.5. Since the change is considered non-reportable in the country of origin, we cannot provide an NRA approval. Is there an alternative document for it?

The MAH may submit approval letters from reference countries where the drug product is registered. If the drug product is not registered in other countries, the MAH may submit proof that the change is non-reportable in the country of origin. The proof can be a screenshot or a copy of the variation guidelines of the country of origin.

4.4.6. Can I apply for addition of alternative packaging material and/or manufacturer?

No. One line of production per CPR should be maintained. Therefore, multiple packaging material and/or manufacturers with the same activity cannot co-exist in one CPR. Addition of alternate packaging materials and/or manufacturer (i.e., drug substance, drug product including diluent, lot release site, packaging, etc.) is acceptable but only upon filing of an initial/ monitored release registration.

5. REGISTRATION OF OVER-THE-COUNTER DRUGS, HOUSEHOLD REMEDIES, TRADITIONALLY-USED MEDICINES AND HERBAL MEDICINES (OTC, HR, TM and HM)

5.1. General Procedures

5.1.1. What are the regulations/ policies for the registration of Over-the-Counter Medicines and Household Remedies?

Current regulations for Over-the-Counter Medicines are:

a. Administrative Order No. 67 s. 1989
b. Administrative Order No. 23-C s. 2000
c. Bureau Circular No. 5 s. 1997

Current regulations for Household Remedies are:

a. Administrative Order No. 67 s. 1989
b. Administrative Order No. 117 s. 1992
c. Memorandum Circular No. 17 s. 1992
d. Bureau Circular No. 5 s. 1997

5.1.2. What are the regulations/ policies for the registration of Herbal and Traditional Medicines?

Current regulation for Herbal Medicines is Administrative Order No. 172 s. 2004, and for Traditional Medicines is Administrative Order No. 184 s. 2004.

5.1.3. Do we need to submit our representative sample together with the initial documents?

Submission of the samples shall be upon receipt of instructions from the concerned officer once the application is already decked and undergoing evaluation.

5.2. Initial Registration

5.2.1. What if the country of origin, of my product, does not issue a Certificate of Pharmaceutical Product (CPP)?

In the absence of a CPP, you should submit a Certificate of Free Sale (CFS) and a Certificate of Good Manufacturing Practice (GMP) issued by the country of origin. This should also be authenticated by the territorial Philippine Consulate.

5.2.2. If imported, where can I get a Certificate of Authenticity of Plant Specimen?

In case of imported products, the certificate of authenticity of the plant shall be obtained from the authorized government agency in the country of origin and the Philippine consulate shall duly authenticate such document.

5.2.3. What is the regulation to follow for the stability study?

You may follow either the National Guidelines on Stability Study or the ASEAN Guidelines on Stability Study.

5.3. Labeling of OTC/ HR/ TM/ HM

5.3.1. What is the generic name, e.g., Sodium Ascorbate or Ascorbic Acid, that should be specified in the product labeling?

In accordance with AO No. 2016-0008, the generic name specified in the product labeling and in the generic box must be the active moiety based on the International Nonproprietary Name (INN) and consistent with the dosage strength indicated. As for the abovementioned example, it should be Ascorbic Acid, not Sodium Ascorbate.

*For prodrugs, the generic name shall be the INN of the prodrug itself and not its active chemical (metabolite) form. (e.g., where Enalapril is the prodrug and Enalaprilat is the active metabolite, Enalapril shall be indicated in the generic name).

6. REGISTRATION OF VETERINARY DRUGS

6.1. General Procedures

6.1.1. Where can I view the list of requirements for Initial and Monitored Release Registration of Veterinary Drug Products?

The list of requirements is provided in Section 4 of Administrative Order No. 111-A s. 1991 (Subject: Rules and Regulations on Registration of Veterinary Drugs and Products).

For Initial Registration

Part C-1. Standard Requirements

a. Signed/ Notarized IAF
b. Valid License to Operate for Local Drug Manufacturer, Importer, Distributor, Trader, etc.
c. Valid Foreign GMP Clearance for Foreign Drug Manufacturer
d. Unit Dose and Batch Formulation
e. Technical Specifications of **All** Raw Materials used
f. Certificate of Analysis of Active Raw Material
    - From the supplier (manufacturer) of the active raw material
    - From the manufacturer of the dosage form
g. Technical Specifications of Finished Product
h. Certificate of Analysis of Finished Product
i. Manufacturing Procedure, Facilities, Controls, Processing & Packaging
j. Assay & Other Test Procedures including Assay with Data Analysis
k. Stability Studies
l. Labeling Materials in Compliance to AO No. 2016-0008 and Joint AO DA AO 11 & DOH AO No. 105 s. 1991

Part C-2. Additional Requirements

For New Drug Applications (Monitored Release)

a. Pre-clinical Studies
b. Clinical Studies
c. Protocol for monitored release
d. Letter of approval of Post-Marketing Study (PMS) or Letter of Extension of Monitored Release status (where applicable)

For Imported Products

a. Certificate of Free Sale from Country of Origin
b. Government Certificate attesting registration status of manufacturer
c. Certificate of Pharmaceutical Product

6.1.2. Are the requirements for Automatic or Regular Renewal of a veterinary drug the same with that of a human drug?

No. You may refer to the requirements listed below.

For Automatic Renewal

a. Signed/ Notarized IAF
b. Scanned copy of old CPR

c. Valid License to Operate for Local Drug Manufacturer, Importer, Distributor, Trader, etc.
d. Valid Foreign GMP Clearance for Foreign Drug Manufacturer

For Regular Renewal

a. Signed/ Notarized IAF
b. Scanned copy of old CPR
c. Valid License to Operate for Local Drug Manufacturer, Importer, Distributor, Trader, etc.
d. Valid Foreign GMP Clearance for Foreign Drug Manufacturer
e. Unit Dose and Batch Formulation
f. Technical Specifications of Finished Products
g. Certificate of Analysis of Finished Product
h. Manufacturing Procedure, Facilities, Controls, Processing & Packaging
i. Assay & Other Test Procedures including Assay with Data Analysis
j. Stability Studies
k. Labeling Materials in Compliance to AO No. 2016-0008 and Joint AO DA AO 11 & DOH AO No. 105 s. 1991

6.1.3. What is the turnaround time (TAT) for veterinary drug evaluation and issuance of a CPR?

Type of Application	TAT
Initial/ MR	254 calendar days
Regular Renewal	68 calendar days
Automatic Renewal	33 calendar days
Post-Approval Change/ Variation	
Minor Variation – Notification (MiV-N)	Upon receipt
Major Variation/ Minor Variation – Prior Approval (MiV-PA)	52 calendar days
Permits/ Certifications	
Certifications (except Feed Certificate)	14 calendar days
Feed Certificate	3 calendar days/ 72 hours

6.1.4. How do we determine if our application is a major or minor variation?

The list of variation is listed on the ASEAN Variation Guideline for Pharmaceutical Products ver. 7.2, FDA Circular No. 2016-017, and Requirements for Philippines Specific Post-Approval Change/s.

6.1.5. How do we comply with the labeling requirements of veterinary drug products?

Labeling requirements for Veterinary Drugs follow the Administrative Order No. 51 s. 1991.

6.1.6. Are the requirements for CLIDP and PCPR for veterinary drugs the same with that of the human drug?

Yes. Please refer to AO No. 2005-0031, FDA Circular No. 2015-001, and B.C. No. 11 s. 2006 for requirements of application for PCPR and CLIDP.

6.1.7. What are the types of veterinary products under the jurisdiction of the FDA and what are the products that are to be registered with the Bureau of Animal Industry (BAI)?

Please refer to Bureau Circular No. 07 s. 2004 for the list of veterinary products under the jurisdiction of the FDA (formerly BFAD). Products that are not included on the list shall be considered within the jurisdiction of BAI (Joint DOH and DA AO No. 2013-0026).

Food and Drug Administration

Registration of Veterinary Drugs and Products

a. Finished pharmaceutical dosage forms such as but not limited to:
   - Oral Dosage Forms such as: capsules, tablets, bolus, paste, powder for suspension, granules for suspensions, powder, suspension, solutions, syrups, emulsions;
   - Injectables such as: solutions, suspensions, powder for injections, granules for injections, parenterals;
   - External preparations such as: topical suspension, creams, ointments, lotions, aerosols, spray, pastes, gels, powders, medicated soaps and shampoo, solutions, medicated collars, and the like; and
   - Ophthalmic or otic creams, ointments, solutions, or suspensions.

b. Active pharmaceutical ingredients and excipients intended for use as a component in the manufacture of the products mentioned in letter a.

Licensing of Veterinary Establishments

The FDA shall regulate the licensing of manufacturers, traders, and/or distributors (importers, exporters, wholesalers) of the product classified in the registration of veterinary drugs and products.

Monitoring of Veterinary Drug and Products and Establishments

The FDA shall monitor the products and establishments identified in the registration and licensing, respectively, except veterinary drug outlets.

Import Permit for Raw Materials and/or Active Pharmaceutical Ingredient (API)

The FDA shall issue import permits for imported active pharmaceutical ingredients and other raw materials intended for use as a component in the manufacture of the products mentioned in the abovementioned registration.

Bureau of Animal Industry

Registration of Veterinary Drugs and Products

a. Pre-mixes, water soluble powder, and other preparations (but not limited to solution, suspension, granules, powder, emulsions) added to feeds or water, feed supplements, feed additives and other drinking/ dipping solutions intended for mass medication for terrestrial and aquatic animals;
b. Veterinary vaccines, diagnostic kits and reagents, veterinary medical devices, and other biological products;
c. Non-medicated soap and shampoo, toothpaste, colognes, conditioners, talc/ dusting powder, coat shine oil, breath freshener (dental sticks), plaque remover, mouth wash, coat deodorants (spray), beddings (e.g., disposable litter paper, adsorbents, etc.), and other grooming products;
d. Dips for animals and eggs;

e. Disinfectants that are intended for veterinary and aquaculture use including their environment or surrounding, facilities, and equipment; and
f. Probiotics that are intended for animal facilities and/or environment including pond or pond water or deodorizer, adsorbent, disinfectant, sanitizer, etc.
g. Active pharmaceutical ingredients and other raw materials intended for use as a component in the manufacture of the products mentioned in letters a to f exclusively intended for veterinary use.

Licensing of Veterinary Establishments
The BAI shall regulate the veterinary drug manufacturers, traders, importers, distributors, exporters, wholesalers, and outlets of the product classified in the registration of veterinary drugs and products.

Monitoring of Veterinary Drug and Products and Establishments
The BAI shall monitor the products identified in letters a to h and establishments mentioned above carrying the same. The BAI shall also be responsible for the regulation of veterinary outlets whether or not the same carries products classified as mentioned above.

Import Permit
The BAI shall issue import permits for all veterinary products classified as mentioned above and their respective API.

6.1.8. What is the procedure for the submission and issuance of the FDA Certification for animal feeds and feed products?
Please refer to FDA Circular No. 2014-017 for the procedure and this may be accessed through the link provided https://ww2.fda.gov.ph/index.php/issuances-2/pharml-1/pharml-fda-circular/175543-fda-circular-no-2014-017 under the **Issuance tab**.

6.1.9. How is the surcharge computed if we filed a renewal application a day after the expiration of the CPR?

As per Republic Act No. 9711, computation of surcharge is equivalent to twice the renewal fee plus an additional 10% per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (120) days or four (4) months (40%). Renewal applications filed after one hundred twenty (120) days from its expiration date shall be considered turned initial.

Please note that the surcharge will still be added to the renewal fee of the establishment plus 1% Legal Research Fund. Fees are based on AO No. 50 s. 2001 or the "Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs."

6.2. Monitored Release Registration and MR to Regular Initial Registration

IMPORTANT: Information in this section **does not** include those for Monitored Release registration of New Drugs/New Chemical Entities/New Molecules (refer to Section 3) and Biologicals/Large molecules and Vaccines (refer to Section 4.2).

6.2.1. What are the veterinary drugs that are Monitored Release (MR) Product and Requirements?

Products under Monitored Release are determine based if the product is a new chemical entity and not yet registered in the FDA Philippines and New Fixed-Dose combination product.

6.2.2. For applications of MR to Regular Initial registration of Veterinary drug products, is it required to submit both RMP and PSUR?

Yes. However, in some cases, foreign drug manufacturers/ product owners of veterinary drug products cannot comply with these requirements. Only PSUR is provided, and not RMP, due to its low-risk level in the country of origin.

7. RENEWAL REGISTRATION AND POST-APPROVAL CHANGE/ VARIATION

IMPORTANT:
1. Information in this section **does not** include those for Renewal Registration of Biologicals/Large molecules and Vaccines (refer to Section 4.3); and Post-Approval Change/Variation of Biologicals/Large Molecules and Vaccines (refer to Section 4.4).
2. *"Product Certificate"* in this Section refers to a Certificate of Product Registration (CPR), Principal CPR (PCPR), and Certificate of Listing of Identical Drug Product (CLIDP).

7.1. General Procedures

7.1.1. What are the requirements for Automatic Renewal?

As per Bureau Circular No. 2006-005, below is the list of requirements:

a. Duly signed and notarized IAF
b. Copy of Certifications issued as a result of post-approval change/s (if there is any)
c. Labeling materials (i.e., actual and commercial labeling materials) based on RA No. 6675, AO No. 2016-0008
d. Copy of latest CPR
e. Copy of LTO
f. For oral solid dosage forms, proof of interchangeability (i.e., Bioequivalence study or Biowaiver, whichever is applicable) based on Republic Act 9502, AO No. 67 s. 1989, and FDA Circular No. 2016-019
g. Actual commercial samples (with Certificates of Analysis) upon request of the FDA
h. Proof of payment

7.1.2. What are the requirements for Regular Renewal?

As per Bureau Circular No. 5 s. 1997, below is the list of requirements:

a. Application Letter
b. Copy of latest CPR
c. Unit Dose and Batch Formulation
d. Technical Specifications of Finished Product
e. Certificate of Analysis of Finished Product
f. Details of the assay and other test procedures for finished product including data analysis
g. Detailed report of stability studies to justify claimed shelf-life (at least 3 batches)
h. Labeling materials
i. Notarized IAF
j. Copy of LTO
k. Copy of GMP
l. Proof of Payment
m. Biowaiver/ BE Report (whichever is applicable), as per FDA Circular No. 2016-019
n. Annex A and/or C clearly stating the current and the proposed change/s

7.1.3. What is the turnaround time (TAT) for renewal and variation evaluation and issuance?

Type of Application	TAT
Regular Renewal	68 calendar days
Automatic Renewal	33 calendar days
CLIDP	31 calendar days
Post-Approval Change/ Variation	52 calendar days

7.1.4. What is the validity of a renewed product certificate?

The validity of a renewed CPR is five (5) years.

7.1.5. When should I renew my product certificates?

Product certificates may be renewed within three (3) months or ninety (90) days from its validity date.

7.1.6. Can we add documents after filing our application?

No. As per RA No. 9711, applicants should submit the documents and the applications be paid on the exact day of the schedule given to them. Thus, companies must make sure that the documents they will submit are complete. However, there are some circumstances that an evaluator needs some clarification regarding an application. Hence, some companies receive emails containing specific instructions, such as submission of additional documents or letter of explanation.

7.1.7. What are the requirements for withdrawing a product certificate?

The MAH may choose not to renew their product certificate until its expiration date. Another option is to submit a letter explaining the reason for withdrawal together with the original certificate (CPR/ PCPR/ CLIDP), and the inventory of the existing product for exhaustion or recall, or refer to the Frequently Asked Questions of the PRSDD under Cancellation of Marketing Authorization.

7.2. Renewal Registration

7.2.1. Why is my product certificate only given two (2) or three (3) years validity?

The MAH must check the letter included because it means that the application was only given a "conditional" certificate and the company needs to submit a specific requirement. Please use the same Document Tracking Number (DTN) when submitting the compliance, together with the issued certificate (CPR/ PCPR/ CLIDP) and the letter. The compliance should be done before the expiration of the conditional certificate.

7.2.2. What if my product certificate has only two (2) or three (3) years validity, then I applied for renewal application before the expiration?

This is going to be disapproved on the grounds that it is a wrong type of application. Note that the previous application was issued with a product certificate and the letter K condition was marked on the second page, stating that "subject to satisfactory compliance to the post-approval commitments detailed in the letter accompanying this CPR." Furthermore, in the post-approval commitment letter, the last paragraph states: "Failure to comply with any of the aforementioned requirement/s shall mean revocation/ cancellation/ non-revalidation of

the CPR with subsequent withdrawal of the subject product from the market and other appropriate regulatory action/s."

7.2.3. My latest product certificate is Monitored Release (MR), should I apply for renewal application?

No. The next type of application for MR **should be INITIAL** and not renewal. If the company applied for renewal, it shall result to disapproval due to wrong type of application.

7.2.4. What if I filed my renewal application after its validity?

The client needs to pay an additional fee for the surcharge as per FDA Circular No. 2011-004.

Branded	
1 day to 1 month	₱ 31,100.00
1 month, 1 day to 2 months	₱ 32,100.00
2 months, 1 day to 3 months	₱ 33,100.00
3 months, 1 day to 4 months	₱ 34,100.00
Unbranded	
1 day to 1 month	₱ 23,325.00
1 month, 1 day to 2 months	₱ 24,075.00
2 months, 1 day to 3 months	₱ 24,825.00
3 months, 1 day to 4 months	₱ 25,575.00

7.2.5. How is the surcharge computed if we filed a renewal application a day after the expiration of the product certificate?

As per FDA Circular No. 2011-004, an application for renewal received after its date of expiration shall be subject to a surcharge or penalty equivalent to twice the renewal registration fee and an additional 10% per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (120) days.

Example computation if renewal (branded) is filed a day after the LTO validity:
= (10,000 x 2) + (10,000 x 10%) + 10,000 + (10,000 x 1%)
= 20,000 + 1,000 + 10,000 + 100
= ₱ 31,100.00

7.2.6. What if my product certificate has been expired for more than one hundred twenty (120) days? Should I still apply for Renewal type of application?

No. This should be filed as **INITIAL** (**Turned Initial**). As per Department Circular No. 2011-0101, any application for renewal registration filed after one hundred twenty (120) days shall be considered expired and the application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee and the application shall undergo the initial filing and evaluation procedure. If filed as renewal, this shall result to disapproval due to wrong type of application. The fee for the branded, turned initial application is ₱ 39,150.00 and the unbranded, turned initial application is ₱ 28,100.00 as per FDA Circular No. 2011-004.

7.3. Post-Approval Change/ Variation

7.3.1. General Procedures

7.3.1.1. What do we consider in determining the type of variation that we need to apply?

Guide questions for the applicant:

a. What is/are the involved/ proposed change/s? To what product/s?
b. What specific section/s is/are affected?
c. Do the conditions (AVG and national guidelines) satisfy the proposed change/s?
d. Does the change affect other sections of the dossier? If so, what are those?
e. Is/are the proposed change/s classified under Initial (new registration)? Variation-turned-Initial?

Addition or Change of Batch Size	
MaV-7	DP, sterile
MaV-8	DP, non-sterile (>10x)
MiV-PA13	DP, non-sterile (<10x)
MiV-PA5	DS without CEP
MiV-PA12	DS with CEP

Addition or Change of Manufacturing Site of Drug Substance	
MaV-3	Without European Pharmacopoeial Certificate of Suitability (CEP)
MiV-PA4	With European Pharmacopoeial Certificate of Suitability (CEP)

Addition or Change of Supplier	
MiV-PH-N4	DS/ Excipient
MiV-PH-N5	Packaging Materials

Analytical Procedure	
MiV-PA9	DS without European Pharmacopoeial Certificate of Suitability (CEP)
MiV-PA12	DS with European Pharmacopoeial Certificate of Suitability (CEP)
MiV-PA22	Excipient
MiV-PA27	DP

Change in Tablet Coating, Size of Capsule Shell	
MaV-11	Modified release
MiV-PA16	Immediate release

Change of Product Labeling	
MaV-1	Indication/ Dosing Regimen/ Population/ Usage
MaV-2	Label other than MaV-1
MaV-PH1	Addition of Route of Administration (Parenteral only)
MiV-PA2	Label other than MaV-2 (in accordance to AO No. 2016-0008)
MiV-PH-N1	Label other than MiV-PA2 (layout/ pictures, logos, barcode outer box, sticker and insert dimension, texts without implication to another indication)

Change of Site of Drug Product	
MaV-4	Manufacturing site
MaV-PH2	Manufacturing site (same subsidiary)
MaV-5	Primary Packaging Site
MiV-PA3	Batch Release Site
MiV-PA29	Secondary Packaging Site
MiV-PH-N2	QC/ Stability Testing Site/s

Note: The inclusion of an additional site is not acceptable (except for MiV-PH-N2), as there can only be one manufacturing-distribution chain per product registration (one line of production only).

Change of Specifications	
MaV-6	DS (without CEP) & DP – widen/ addition
MiV-PA8	DS (without CEP) – tighten/ addition
MiV-PA21	Excipient – tighten/ addition
MiV-PA24	DP – tighten/ addition
MiV-PA12	DS (with CEP) – tighten/ addition

Diluent or Solvent	
MaV-14	Inclusion/ Replacement
MiV-PA18	Deletion

Dosage Form	
MiV-PH1	Capsule color
MiV-PA17	Flavorant/ colorant
MiV-PA25	Imprint/ marking/ bossing/ printing of capsule or tablets
MiV-PA26	Dimension/ shape of tablets, capsules, suppository or pessaries without change in composition and mean mass
MiV-PA23	Hard capsule source

Drug Substance Quality Attributes	
MiV-PA5	Batch Size
MiV-PA6	In-process controls
MiV-PA7	Manufacturing process
MiV-PA8	DS Specifications
MiV-PA9	Test Procedure
MiV-PA10	Shelf-life/ re-test period
MiV-PA11	Storage condition
MiV-PA12	With European Pharmacopoeial Certificate of Suitability (CEP)

In-Process Controls	
MiV-PA6	DS without CEP
MiV-PA12	DS with CEP
MiV-PA19	DP

Manufacturing Process	
MaV-9	Major, sterile DP
MiV-PA20	Minor, non-sterile DP
MiV-PA7	DS without European Pharmacopoeial Certificate of Suitability (CEP)
MiV-PA12	DS with European Pharmacopoeial Certificate of Suitability (CEP)

Marketing Authorization Holder	
MiV-PH3	Change of MAH
MiV-N1	Change in name and/or address
MiV-PH-N3	Change/ inclusion/ deletion of distributor for PCPR
MiV-PH-N6	Changes affecting entities other than the MAH

Measuring Device	
MiV-PA33	Addition/ replacement

Name	
MiV-PA1	Product Name
MiV-PH2	Brand Name (inclusion/ replacement/ change)

Overages	
MiV-PA14	Reduction/ removal

Note: Addition of overage (apply for initial registration)

Packaging Material/Pack Size	
MaV-12	Sterile primary packaging material, including thickness
MiV-PA28	Non-sterile primary packaging material, including thickness
MaV-13	Sterile pack size/ fill volume/ shape or dimension of container
MiV-PA30	Non-sterile pack size/ fill volume/ shape or dimension of container
MiV-PA31	Change in outer carton pack size
MiV-PH-N7	Addition of pack size (non-sterile)
MiV-N10	Deletion of pack size
MiV-PA32	Other packaging material aside from primary packaging (not in contact with DP)

Qualitative or Quantitative Change of Excipient	
MaV-10	Immediate release (SUPAC level 2 & 3), modified release, other critical dosage forms (e.g., sterile)
MiV-PA15	Immediate release (SUPAC level 1), other non-critical dosage forms (e.g., oral liquid, external prep)

Reclassification	
MiV-PH4	Rx to OTC
MiV-PH5	OTC to HR

Shelf-life of Drug Product	
MaV-15	Extension
MiV-PA34	Reduction

Storage Condition of Drug Product	
MaV-16	Lowering/ less stringent
MiV-PA35	Increasing/ more stringent

7.3.1.2. What are the variation guidelines we need to follow?

The references for variations are:

a. ASEAN Variation Guideline for Pharmaceutical Products
b. FDA Circular No. 2014-008 (Application and Requirements for Post-Approval Changes of Pharmaceutical Products)
c. FDA Circular No. 2016-017 (Additional Post-Approval Changes for Pharmaceutical Products)

7.3.1.3. How much are the fees for post-approval changes?

POST APPROVAL CHANGES	
MaV-15	₱ 1,000.00 + LRF
MiV-PA34	₱ 1,000.00 + LRF
MiV-PA1	₱ 3,000.00 + LRF
MiV-PH2	₱ 3,000.00 + LRF
MiV-PH4	₱ 3,000.00 + LRF
MiV-PH5	₱ 3,000.00 + LRF
Others (except for PACs equivalent to initial fees)	₱ 500.00 + LRF
TURNED INITIAL APPLICATION	
For Unbranded	₱ 10,000.00 + LRF
For Branded	₱ 15,000.00 + LRF
For Monitored Release Status	₱ 40,400.00 + LRF

Note: Payment computation is per change basis. Thus, there would be additional payment per variation regardless if one (1) or more variation type is classified as "**turned initial**".

7.3.1.4. What are the post-approval changes that are equivalent to Initial Registration schedule of fees?

MaV-1	Change and/or additional indication/ dosing regimen/ patient population/ inclusion of clinical information extending the usage of the product
MaV-4	Addition or replacement of the manufacturing site of the drug product
MaV-10	Qualitative or quantitative change of excipient a. For immediate release oral dosage forms (as per Level 2 and 3, Part III Components and Composition, SUPAC guideline) b. For modified release oral dosage forms c. For other critical dosage forms such as sterile preparations
MaV-11	Quantitative change in the coating weight of tablets or weight and/or size of capsule shell for modified release oral dosage form
MaV-12	Change in primary packaging material for sterile product a. Qualitative and quantitative composition and/or b. Type of container and/or c. Inclusion of primary packaging material

MaV-13	Change or addition of pack size/ fill volume and/or change of shape or dimension of container or closure for sterile solid and liquid drug product (unless the change is dimension, i.e., wide-mouth bottles vs. narrow-mouth bottles)
MiV-PA15	Qualitative or quantitative change of excipient a. For immediate release oral dosage forms (as per Level 1, Part III Components and Composition, SUPAC guideline) b. For other non-critical dosage forms (e.g., oral liquid, external preparation)
MiV-PA16	Quantitative change in coating weight of tablets or weight and/or size of capsule shell for immediate release oral dosage form
MiV-PA17	Change of the colouring/ flavouring agent of the product [addition, deletion or replacement of colourant(s)/ flavour(s)]
MiV-PA28	Change in primary packaging material for non-sterile product a. Qualitative and quantitative composition and/or b. Type of container and/or c. Inclusion of primary packaging material
MaV-PH1	Additional route of administration (parenteral only)
MaV-PH2	Change of Manufacturing Site (Same Subsidiary) of drug product

7.3.1.5. What are the changes that may lead to new product registration or needed to be applied as initial registration?

a. Changes to the API
b. Change of the API to a diff. API including change in salt/ isomer form
c. Inclusion of an additional API to a single component/ multicomponent product
d. Removal of one (1) API from a multicomponent product
e. Change in the strength of one (1) or more APIs
f. Changes to the pharmaceutical form/ dosage form
g. Changes in the route of administration (except parenteral route)
h. Change or replacement or inclusion of delivery system of the drug product
i. Addition and/or removal of excipient
j. Increase in overage
k. Change in the manufacturing site of the drug product (bulk packaging + release)
l. Change from a currently approved contract manufacturer or own plant to another contract manufacturer
m. Addition of a new manufacturer/ primary packaging/ secondary packaging site to the currently approved site
n. Deletion of "for export only" in CPR for products intended to be marketed locally

7.3.2. Product Labeling

7.3.2.1. What is the difference between MaV-2, MiV-PA2 and MiV-PH-N1?

MaV-2	**MiV-PA2** (In compliance to AO No. 2016-0008)	**MiV-PH-N1** (Notification)

• Change of content of product labeling • Change in text	• Change in text, layout, logo/s, barcode, artwork	• Change in layout, logo/s, barcode, artwork • Strictly no change in text

7.3.2.2. What is the classification for change in instructions for reconstitution?

The appropriate PAC is MaV-2 or change of content of product labeling.

7.3.2.3. What are the approved reference regulatory agencies?

North America
1. Food and Drug Administration (FDA) – United States of America
2. Health Canada (HC) – Canada
Europe
3. European Medicines Agency (EMA) – European Union
4. Medicines and Healthcare Products Regulatory Agency (MHRA) – United Kingdom
5. Swiss Agency for Therapeutic Products (SwissMedic) – Switzerland
6. Federal Ministry of Health (BMG) – Germany
7. National Drug and Health Products Safety Agency (ANSM) – France
8. Italian Medicines Agency (AIFA) – Italy
Asia-Pacific
9. Therapeutics Goods Administration (TGA) – Australia

7.3.2.4. What are the information to be included in the product insert in compliance to FDA Advisory 2019-128 or "Safety Information: Fluoroquinolones and risk of aortic aneurysm and dissection"?

Information on the labeling materials in compliance to the said advisory shall be based on the product information, e.g., Summary of Product Characteristics (SPC), of the innovator counterpart.

7.3.2.5. What type of post-approval change should we apply for the change of product labeling (including addition/ strengthening of warnings, precautions, contraindications, and/or adverse events/ effects to the approved product labeling)?

This should be applied under MaV-2 or change of content of product labeling.

7.3.3. Packaging Material/ Pack Size

7.3.3.1. What type of post-approval change should we apply for additional pack size specific for DOH products (for products with Notice of Award)?

The appropriate PAC is MiV-PH06 (Other Variations).

7.3.3.2. What type of post-approval change should we apply for change/ addition of pack size with change in packaging material?

For Sterile Product	For Non-Sterile Product
Apply for both MaV-12 & MaV-13	Apply for both MiV-PA28 & MiV-PA30

7.3.3.3. What is the difference among MaV-12, MaV-13, MiV-PA28, MiV-PA30, MiV-PA31, MIV-PA32 and MiV-PH-N7?

MaV-12	Primary packaging material (sterile)
MaV-13	Container/ closure/ secondary packaging (sterile)
MiV-PA28	Primary packaging material (non-sterile) • Example: Alu/PVC to Alu/Alu
MiV-PA30	Container/ closure/ secondary packaging (non-sterile) • Example: Blister Pack x 10's **TO** Blister Pack x 20's
MiV-PA31	Outer carton pack size • Example: Box of 30's **TO** Box of 100's
MiV-PA32	Part of the primary packaging not in contact with the finished product • Example: Color of flip-off seal
MiV-PH-N7	Addition of pack size (non-sterile) • Example: Physician's sample, Box of 30's + Box of 100's

7.3.4. Specifications of Drug Substance, Drug Product, and Excipients

7.3.4.1. What are the changes for the specification of drug product?

For Non-Compendial	
MaV-6	a. Specification limits are widened b. Deletion of test parameter and limits
MiV-PA24	a. Specification limits are tightened b. Addition of new test parameter and limits
For Compendial	
MiV-N9	Change of specifications following the updates in the compendium • Example: USP 36 to USP 40
MiV-PH6	Change of current compendium, e.g., USP, to another compendial references (e.g., BP, JP, etc.)

7.3.4.2. What are the changes for the specification of drug substance?

MiV-PA12	Where CEP is available/ with revision of CEP
For Non-Compendial	
MaV-6	Where CEP is not available a. Specification limits are widened b. Deletion of test parameter and limits
MiV-PA8	Where CEP is not available a. Specification limits are tightened b. Addition of new test parameter and limits
For Compendial	
MiV-N9	Change of specifications following the updates in the compendium • Example: USP 36 to USP 40
MiV-PH6	Change of current compendium, e.g., USP, to another compendial references (e.g., BP, JP, etc.)

7.3.4.3. What are the changes for the specification of excipient?

For Non-Compendial	
MiV-PA21	a. Specification limits are tightened b. Addition of new test parameter and limits
For Compendial	
MiV-N9	Change of specifications following the updates in the compendium • Example: USP 36 to USP 40
MiV-PH6	Change of current compendium, e.g., USP, to another compendial references (e.g., BP, JP, etc.)

7.3.5. Marketing Authorization Holders

7.3.5.1. What type of post-approval change should we apply for change of Marketing Authorization Holder (MAH)?

The appropriate PAC is MiV-PH03.

7.3.5.2. What type of post-approval change should we apply for change/ inclusion of distributor?

For PCPR	For CLIDP
MiV-PH-N3	MiV-PH-03
Both are classified as notification as per FDA Circular No. 2016-017.	

7.3.6. Others

7.3.6.1. How should we apply for the Addition or Replacement of the manufacturing site of the drug product?

CASE NO. 1 **Type of Application: Initial**	
Current	**Proposed**
Manufacturer A (Bulk, Packaging, Batch Release) e.g., Ants Pharmaceuticals UK	Manufacturer B (Bulk, Packaging, Batch Release) e.g., Shark Manufacturing Ltd. Indonesia
CASE NO. 2 **Type of Application: MaV-4**	
Current	**Proposed**
Manufacturer A (Bulk, Packaging) *Batch Release – remains the same	Manufacturer B (Bulk, Packaging) *Batch Release – remains the same
CASE NO. 3 **Type of Application: MaV-PH02**	
If Manufacturer A and Manufacturer B are sister companies (Bulk, Packaging) *Batch Release – remains the same e.g., Ants Pharmaceuticals UK to Ants Pharmaceuticals USA	
CASE NO. 4 **Type of Application: MaV-PH02 & MiV-PA3**	

If Manufacturer A and Manufacturer B are sister companies (Bulk, Packaging) *Batch Release – change e.g., Manufacture-Ants Pharmaceuticals Australia; Batch Release-Ants Pharmaceuticals Australia **TO** Manufacture-Ants Pharmaceuticals USA; Batch Release-Ants Pharmaceuticals Germany

7.3.6.2. How should we apply for the change and/or addition of alternative manufacturer/ site of the drug substance?

a. For Generics and Innovator: Complete ACTD sections of S1-S7 should be provided (including the closed part).
b. For OTC & Household Remedies: National Guidelines should be followed.
c. Specifications of drug substances should remain unchanged. If there are changes in the specification of drug substance/s, the applicant shall apply for MaV-6 or MiV-PA8 (whichever is applicable) together with this variation under a single DTN.

7.3.6.3. What type of post-approval change should we apply for change of manufacturing equipment?

The appropriate PAC is MaV-9 or MiV-PA20 (major or minor change in manufacturing process, whichever is applicable), since a validation of the manufacturing process using the new equipment is needed.

7.3.6.4. What type of post-approval change should we apply for change of batch size of non-sterile drug product/ sterile drug product/ drug substance?

Change of Batch Size of Non-Sterile Drug Product	
MaV-8	Change of batch size more than 10-fold compared to the currently registered batch size
MiV-PA13	Change of batch size up to 10-fold compared to the currently registered batch size
MaV-7	Change of batch size of sterile drug product
Change of Batch Size of Drug Substance	
MiV-PA5	Change of batch size of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]

7.3.6.5. What is the minimum time period covered by the data at the submission of the stability of the drug product?

Complete stability data up to the proposed shelf-life must be submitted for variations classified under MaV-15 and MaV-16. For other variations, the ASEAN Guideline on Stability Study for the minimum data should be followed upon submission.

8. OTHER AUTHORIZATIONS, CLEARANCE, PERMITS, AND CERTIFICATIONS

8.1. Principal Certificate of Product Registration and Certificate of Listing of Identical Drug Product (PCPR and CLIDP)

8.1.1. What are the requirements for PCPR conversion application?

Below is the list of requirements as per Administrative Order 31 s. 2005, Bureau Circular No. 11 s. 2006, and FDA Circular No. 2014-003:

a. Signed and notarized IAF
b. Valid License to Operate
    - Principal CPR applicant
    - Toll Mfg. (if applicable)
c. Original and Valid CPR
d. Proof of Payment

8.1.2. What are the requirements for CLIDP application?

Below is the list of requirements as per Administrative Order 31 s. 2005 and Bureau Circular No. 11 s. 2006:

a. Signed and notarized IAF
b. Proof of payment
c. Copy of the current and valid PCPR
d. Authenticated copy of the duly notarized Distributorship Agreement, License Agreement, or other written contract between the principal CPR holder and the identical drug applicant
e. Facsimile of Labeling Materials (Compliant to AO No. 2016-0008)
f. For foreign/ imported products: fGMP Clearance
g. Copy of valid License to Operate
    - Identical Drug Applicant
    - Principal CPR owner/ holder

8.1.3. How much is the payment for CLIDP application?

As per Administrative Order No. 50 s. 2001 and Bureau Circular No. 11 s. 2006, the payment shall be based on the remaining PCPR validity:

Unbranded	Branded
₱ 2,000.00/year + 1% LRF	₱ 3,000.00/year + 1% LRF (Plus ₱ 500.00 per proposed brand name + 1% LRF)

8.2. Certificate of Pharmaceutical Product and Certificate of Free Sale (CPP and CFS)

8.2.1. What are the requirements for CPP and CFS?

CPP

a. Signed IAF
b. Letter of Intent (Importing Country)
c. Valid CPR
d. Valid LTO and GMP of the MAH
e. Labeling Materials (Immediate and Secondary Labeling materials)
f. Approved Post-Approval Changes/ Variations (if any)
g. Unit Dose Formulation
h. Proof of payment

CFS

a. Signed IAF
b. Letter of Intent (Importing Country)
c. Valid CPR
d. Valid LTO and GMP of the MAH
e. Proof of payment

8.2.2. What is the validity of CPP and CFS?

The validity of each CPP and CFS is one (1) year.

8.2.3. What is the turnaround time in the processing of CPP and CFS?

CPP	CFS
20 working days	7 working days

8.2.4. Can I apply more than one exporting country in one CPP or CFS application or DTN?

No. Only one (1) exporting country per one application is allowed per DTN.

8.2.5. We changed our manufacturing site, e.g., from Australia to Canada, can I use my CPP which reflects the previous site?

No. The current/ new manufacturing site must be reflected in the CPP, and hence, a new application must be lodged for the current/ new site.

8.2.6. What is the reference of the CPP format?

The reference of the CPP format is based from the WHO.

8.3. Sales Promo Permit (SPP)

8.3.1. What is the right time for filing a promo application to the FDAC?

This should be done at least thirty (30) days before the actual commencement of the promotional activity.

8.3.2. What are the requirements for the Sales Promo Permit?

For initial application

a. Accomplished IAF;
b. Letter of intent for application of Sales Promo Permit;
c. Information Sheet and Mechanics of the Sales Promotion;
d. List of participating products in Excel format (Sheet 3 of Information Sheet);
e. Copy of the valid Certificate of Product Registration/ Certificate of Listing of Identical Drug Product/ Notification/ Exemption;
f. Layout of promo materials;
g. Proof of payment; and
h. Self-Assessment Form for Sales Promo Permit.

For amendment application

a. Accomplished IAF;
b. Letter of intent specifying the type of amendment;
c. Copy of previously issued valid promo permit;
d. Supporting documents for the requested amendment;
e. Proof of payment; and
f. Self-Assessment Form for Sales Promo Permit.

8.3.3. Where can you download the Info Sheet on the FDA website?

The soft copy of the Information Sheet can be downloaded on the FDA website at the following: Drugs > Downloadables > Information Sheet and Mechanics of the Sales Promotion or through this link: https://www.fda.gov.ph/cdrr-downloadables/.

8.3.4. What is the hierarchy for the application of promo for combined product categories?

A sales promo application shall be submitted to any of the following Center depending on the participating products:

i. Drugs, Food, Cosmetics, Device and HHS – CDRR
ii. Food, Cosmetics, Device and HHS – CDRRHR
iii. Food, Cosmetics and HHS – CFRR
iv. Cosmetics and HHS – CCRR

8.3.5. How much is the payment for sales promo application?

The amount of fees for sales promotions (except for discount scheme type of promotion) which includes variables covered by blanket approval [covering a period of one (1) year as prescribed by the Consumer Act] shall be in accordance with geographical areas or with the amount of freebies/ prizes, whichever is higher, as per Joint Administrative Order DTI-DOH No. 1 s. 2000:

Coverage: (Fees)

a. NCR only or in several regions in NCR and Nationwide: ₱ 1,000.00 + 1% LRF
b. More than one (1) region in NCR and Nationwide: ₱ 750.00 + 1% LRF
c. Several provinces/ cities/ municipalities within a single region: ₱ 500.00 + 1% LRF
d. Single province/ city/ municipality: ₱ 250.00 + 1% LRF

Amount of Freebies/ Prizes: (Fees)

a. Up to ₱ 50,000: ₱ 250.00 + 1% LRF
b. ₱ 50,000 to ₱ 150,000: ₱ 500.00 + 1% LRF
c. ₱ 150,001 to below ₱ 300,000: ₱ 1,000.00 + 1% LRF
d. ₱ 300, 001 to ₱ 500,000: ₱ 2,000.00 + 1% LRF
e. ₱ 500,001 to ₱ 1,000,000: ₱ 3,000.00 + 1% LRF
f. Above ₱ 1,000,000: ₱ 5,000.00 + 1% LRF

8.3.6. What are the issuances/ legal bases for the Sales Promo Permit?

a. FDA Memorandum Circular No. 2013-028
b. AO No. 65 s. 1989
c. AO No. 2016-0008
d. Joint Administrative Order DTI-DOH No. 1 s. 2000
e. IRR of RA No. 7394
f. AO No. 2015-0053

8.3.7. Can a sales promo permit be applied for Rx or ethical drugs of any dosage form (e.g., topical, oral, etc.)?

No, any pharmaceutical product classified as a prescription or ethical drug shall not be advertised or promoted in any form of mass media, except through medical journals, publications, and/or literature solely intended for medical and allied professions.

8.3.8. What is the turnaround time for the application?

The turnaround time is fourteen (14) calendar days**.**

8.3.9. Is it possible to have multiple products in one promo permit?

Yes, provided that they have the same scheme.

8.3.10. What is the duration of the promo permit?

Premium Item/ Free Item Scheme: Maximum of one (1) year and can be extended only once for an additional six (6) months.

Price reduction/ discounts: Maximum of three (3) months. There is no granted extension.

8.3.11. What should be done if there are proposed changes in an approved permit, e.g., addition or removal of a product, free item, mechanics, etc.?

Any proposed change must be applied as an amendment.

8.3.12. Can the promo title of an approved promo permit be changed?

No. Once the promo permit is approved, the promo title cannot be changed.

8.3.13. What is the allowable coverage in selling promotional products?

The coverage is only limited to licensed establishments, such as Drugstores and RONPDs.

8.3.14. What are the things to be considered in promo collaterals?

For promo collaterals, the generic name shall be the prominently printed element on the advertising and other promotional materials.

Collateral labels must always follow the FDA-approved collaterals. No alteration should be done. Push Girls or uniforms of the Brand Ambassador/s should also be submitted.

8.3.15. What are the things to be considered in adding claims for the product?

a. No claim in the advertisement, promotion, sponsorship, and other marketing activities shall be made other than those contained in the approved label or packaging of the health product, or as duly approved by the FDA;
b. No claims, either therapeutic or scientific, shall be made without due approval by the FDA; and
c. Misleading claims shall be subjected to grounds for disapproval.

8.3.16. Can a discount scheme be added in an ongoing free item scheme as additional mechanics?

No. Note that the premium item scheme and the discount scheme are separate schemes. Only one scheme per application is allowed by the FDA.

8.3.17. How many days should the FDA be notified on a request for an FDA representative for the attestation/ supervision of a raffle?

This should be requested at least seven (7) working days before the actual activity.

8.3.18. Is the electronic selection of winners considered as a raffle scheme?

Yes. Tally count of likes, votes or electronic selection is still considered a raffle and must be attested by an FDA representative.

8.3.19. What is a sampling activity and do we need to secure a permit for such activity?

Sampling activity is when free samples are given to consumers and yes, you need to secure a permit for this.

8.3.20. What is flyering?

This is the handing out of flyers to consumers as part of a promotional activity. A flyer may or may not contain a participating product.

8.3.21. If the mechanics is only flyering (no free sample or selling), should this still be applied for a promo permit?

Yes, since the additional value that consumers will get from the flyering is product knowledge.

8.3.22. What is the approved coverage in flyering/ sampling?

There is no limit in the coverage of a flyering/ sampling activity as long as there will be no selling of a participating product.

8.4. Brand Name Clearance (BNC)

8.4.1. What is the corresponding fee for Brand Name Clearance?

The fee for BNC is ₱ 510.00 per proposed brand name.

8.4.2. What is the timeline for processing of BNC application?

The timeline for processing is one (1) to three (3) days per application.

8.4.3. My BNC application was denied for the reason that the proposed brand name was approved to another company. If I provide a certificate from IPO that I have an existing property right over the brand name pending registration, will it suffice for the approval my BNC application?

No, it does not apply. AO No 16 s. 2005 provides that intellectual property matters are beyond the legal mandate of the BFAD (now FDA) and that their proper recourse should be from the Intellectual Property Office of the Philippines or the appropriate courts of competent jurisdiction.

8.4.4. We have a proposed brand name but that brand name was already approved to other company. The MAH now allows us to use their brand name. What should I do now?

Together with your Brand Name Clearance application, attach a Deed of Transfer or Assignment stating that the MAH is transferring their rights to your company as the new owner or Marketing Authorization Holder of the subject brand name.

8.4.5. What if an MAH of a certain brand name no longer uses it because the CPR was already expired and they have no plan to renew their CPR. Can we use their brand name?

Yes, but the concerned MAH need to submit first an application for deletion of the subject brand name.

9. ABBREVIATIONS

ACTD	ASEAN Common Technical Dossier
ACTR	ASEAN Common Technical Requirements
AO	Administrative Order
API	Active Pharmaceutical Ingredient
APIMF	Active Pharmaceutical Ingredient Master File
ASEAN	Association of Southeast Asian Nations
AVG	ASEAN Variation Guideline
BAI	Bureau of Animal Industry
BCS	Biopharmaceutics Classification System
BE	Bioequivalence
BFAD	Bureau of Food and Drugs
BP	British Pharmacopoeia
CCRR	Center for Cosmetic Regulation and Research
CDRR	Center for Drug Regulation and Research
CDRRHR	Center for Device Regulation, Radiation Health, and Research
CFRR	Center for Food Regulation and Research
CEP	Certificate of Suitability to the monographs of the European Pharmacopoeia
CFS	Certificate of Free Sale
CGMP	Current Good Manufacturing Practice
CLIDP	Certificate of Listing of Identical Drug Products
CoPP/CPP	Certificate of Pharmaceutical Product
CPR	Certificate of Product Registration
CTD	Common Technical Documents
DC	Department Circular
DMF	Drug Master File
DP	Drug Product
DS	Drug Substance
DOH	Department of Health
DTI	Department of Trade and Industry
DTN	Document Tracking Number
EDQM	European Directorate for the Quality of Medicines and Healthcare
EMA	European Medicines Agency
FDA	Food and Drug Administration
FDAC	Food and Drug Action Center
FDC	Fixed-Dose Combination
FGMP	Foreign Good Manufacturing Practice
FGMPC	Foreign Good Manufacturing Practice Clearance
FPP	Finished Pharmaceutical Product
GCP	Good Clinical Practice
GLP	Good Laboratory Practice

GMP	Good Manufacturing Practice
GRAS	General Recognized As Safe
HHS	Household/Urban Hazardous Substances
HR	Household Remedies
IAF	Integrated Application Form
ICH-CTD	International Council of Harmonization – Common Technical Requirements
INN	International Nonproprietary Name
IPO	Intellectual Property Office
JP	Japanese Pharmacopoeia
LOQ	Limit of Quantification
LRF	Legal and Research Fund
LTO	License to Operate
MAH	Marketing Authorization Holder
MaV	Major Variation
MiV	Minor Variation
MiV-N	Minor Variation – Notification (by AVG)
MiV-PA	Minor Variation – Prior Approval (by AVG)
MiV-PH	Minor Variation – Prior Approval (Philippine-specific)
MiV-PH-N	Minor Variation – Notification (Philippine-specific)
MR	Monitored Release
NCE	New Chemical Entities
NCR	National Capital Region
NRA	National Regulatory Authority
OR	Official Receipt
OTC	Over-the-Counter
PA	Prior Approval
PCPR	Principal Certificate of Product Registration
PDRI	Philippine Dietary Reference Intakes
Ph. Eur.	European Pharmacopoeia
Ph. Int.	International Pharmacopoeia
PP	Philippine Pharmacopoeia
PSUR	Periodic Safety Update Report
QPIRA	Qualified Personnel in Industry Regulatory Affairs
RA	Republic Act
RONPD	Retail Outlet for Non-Prescription Drugs
RBP	Reference Biotherapeutic Product
RENI	Recommended Energy and Nutrient Intakes
RMP	Risk Management Plan
Rx	Prescription/ethical drugs
SAF	Self-Assessment Form
SBP	Similar Biotherapeutic Product
SPC	Summary of Product Characteristics
SPP	Sales Promo Permit

SRA	Stringent Regulatory Authority
TAT	Turn-around Time
TRS	Technical Reports Series
UNICEF	United Nations Children's Fund
USB	Universal Series Bus
USP	United States Pharmacopoeia
USP-NF	United States Pharmacopoeia – National Formulary
WHO	World Health Organization
WHO-ATC	World Health Organization – Anatomical Therapeutic Chemical Classification

REVISION HISTORY

Date	Version	Changes
13 February 2020	1.0	N/A
19 February 2020	2.0	Changed the size of the FDA logo in the header; Fixed the formatting of page number; change the formatting of "Table of Contents" to Times New Roman; Changed symbol of currency from "Php" to "₱"; Added "DP" and "DS" in Abbreviations section
		5.3.1: Changed answer from "In accordance with AO 2016-0008, the name specified in the product labeling must be the International Nonproprietary Name (INN). It should be Ascorbic Acid, not Sodium Ascorbate." **to** "In accordance with AO 2016-0008, the generic name specified in the product labeling must be the active moiety based on the International Nonproprietary Name (INN) and consistent with the dosage strength indicated. It should be Ascorbic Acid, not Sodium Ascorbate. *For prodrugs, the generic name shall be the INN of the prodrug itself and not its active chemical (metabolite) form. (e.g., where Enalapril is the prodrug and Enalaprilat is the active metabolite, Enalapril shall be indicated in the generic name)"; 7.3.6.1: Changed "Pfizer" to "Ants Pharmaceuticals"; Changed "Abbott" to "Shark Manufacturing Ltd"
21 October 2020	3.0	1.1.3 Removal of pair@fda.gov.ph; 1.1.4 Changed "youtube" to "YouTube"; Changed AO to AO No., D.C. to DC, cdrr@fda.gov.ph to cdrr.od@fda.gov.ph Update of processes, requirements, and formatting.