FOOD AND DRUGS AUTHORITY

8th January 2024
FDA/DNC/GDL - 06/02
Technical Advisory Committee on Safety of Medicines

Guideline on The Registration of Medicinal Products Classified for Fast Track Processing

Draft written by Drug and Herbal Medicines Directorate	N/A
Draft reviewed by QMS	N/A
Start of public consultation	N/A
Adopted by TAC	1st February 2013
Final Quality Assurance Review	11th December 2023
Approved by CEO	14th December 2023
Date of coming into effect	8th January 2024

No. 17 Indian Ocean Street, Nelson Mandela Avenue, Shiashie ● Greater Accra ● Ghana
P. O. Box CT 2783, Accra ● GPS: GA-237-7316 ● (+233) 302 233200 / 235100 ● fda@fda.gov.gh

Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
15th March 2019	01	Initial Issue
08th January 2024	02	General review of the Guideline in line with the current structure.

Table of Contents

Executive Summary

This guideline specifies the requirements for processing all allopathic drugs classified by the FDA for expedited processing for registration in accordance with section 118 of the Public Health Act 851, 2012.

1.0. Introduction

Who Prequalified Medicinal Products

- This guideline outlines the procedure for the application and registration of WHO prequalified allopathic drugs by the Food and Drugs Authority (FDA).
- This is based on a collaborative procedure between the WHO Prequalification of Medicines Programme (WHO/PQP) and the FDA in the assessment and accelerated registration of WHO prequalified allopathic drugs.
- Applicants with allopathic drugs that have been prequalified by the WHO/PQP can take advantage of this procedure for fast-track registration of their prequalified medicinal product by the FDA.

1.1 Legal Basis

This guideline applies to Marketing Authorisation Applications for human medicinal products submitted in accordance with Section 118 of the Public Health Act 851, 2012.

1.2 Scope

This guidelines convers the requirement and processing of all allopathic drugs classified by the FDA for expedited processing for registration. Currently, the following categories of applications are covered;

- World Health Organization (WHO) Prequalified Products
- Public health products (Anti-Retroviral Drugs, Anti-Malaria drugs, Drugs for Tuberculosis, Reproductive health products and Drugs for neglected health products).
- Product Registered by countries within the International Conference on Harmonization (ICH) region

2. Definition

In the context of this guideline, the following words/phrases are defined as follows:

Allopathic drug: Any product or substance other than a medical device, which is to be administered to one or more human beings or animals on its own, or as an ingredient in the preparation of a substance, for a medicinal purpose.

Medicinal purpose: means treating or preventing a disease, diagnosing or ascertaining the presence and extent of a physiological function, contraception, inducing anaesthesia, altering normal physiologic function permanently or temporarily in any way in humans.

Applicant: The product owner or licence holder. Representatives of licence holders

Drug, medicine or pharmaceutical product: means a substance or mixture of substances prepared, sold or represented for use in –

(a) Diagnosis, treatment, mitigation or prevention of disease, disorders or abnormal physical state or the symptoms of it in man or animal

(b) Restoring, correcting or modifying organic functions in man or animal.

Finished Pharmaceutical Product (FPP): A product that has undergone all stages of production, including packaging in its final container and labelling.

Manufacture (manufacturing): Means all operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products and the related controls.

Manufacturer: Means a person or firm that is engaged in the manufacture of product(s).

Variation: Means a change to any aspect of a pharmaceutical product, including but not limited to a change to formulation, method and site of manufacture, specifications for the finished product and ingredients, container and container labelling and product information.

3. Requirements

3.1 Application Steps

1. Applicant should submit the product dossier for a WHO-prequalified pharmaceutical product to the Food and Drugs Authority (FDA). The dossier submitted to the FDA should be the same as submitted to the WHO-PQP during the initial prequalification procedure, and subsequent variation documentation where applicable; The application should include;

    a) A completed application form for the registration of allopathic drug by the FDA, including the same technical information as that submitted to WHO/PQP. The technical part of the dossier should be identical to the current version of the WHO/PQP dossier.

    b) The following country specific documentation;
        i) Executed batch manufacturing records of one production batch.
        ii) Where applicable, long-term stability studies protocol and report conducted at Zone IVB conditions
        iii) Copy of the current version of Quality Information Summary (QIS) submitted to the WHO.

c) Pay the required application fees for the registration of allopathic drugs as per the fee schedule of the FDA. (access a copy of the fee schedule at www.fdaghana.gov.gh)

2. In situations where the applicant wishes to apply the Procedure to an application which is already pending with FDA, the applicant should first update the dossier to ensure that the technical part of the information is the same as that submitted to WHO.

3. Complete and submit an expression of interest form (Part A of Appendix 3) to the FDA through the WHO-PQ collaborative procedure focal person of the FDA.

4. The FDA shall communicate its consent to apply the procedure to the application for registration of the product and to request the WHO-PQ to share product-specific information by completing and signing Part B of Appendix 3.

5. Applicant shall then complete and submit an expression of interest form (Part A of Appendix 3) to WHO-PQP directing the PQP to provide full access to the information on the prequalified product to the FDA.

3.2 Processing

The FDA shall process the application and communicate its decision on the product to the applicant and WHO within 90 calendar days.

3.3 Post Approval

All post-prequalification variations submitted to WHO shall be submitted simultaneously to the FDA after the product has been registered by the FDA.

4 Specific Requirements

4.1 Program Drugs

1. Medicinal product that listed under the any of the following Ministry of Health Programs shall be classified as fast track applications;
    i. Anti-Retroviral Drugs
    ii. Anti-Malaria drugs
    iii. Drugs for Tuberculosis
    iv. Reproductive health products
    v. Drugs for neglected tropical diseases

2. Submission of application; Applicant for the registration of medicinal product under this category shall

i. submit full application as per the FDAs requirement for the registration of medicinal product.
ii. pay the requisite application fees
iii. submit the required number of samples of the product

3. include a cover letter for the submission

4. Processing steps – applications shall be processed through the normal registration processing steps and include;
    i. Acknowledgement of applications
    ii. Evaluation of dossiers and samples (Full review as per standard applicable depth of evaluation)
    iii. Presentation of evaluation comments to the Product Registration Committee
    iv. Final communication to the application

5. Timelines – applications under this category shall be processed within 90 calendar days.

4.2 SRA Registered Drugs

1. Medicinal products applications with valid marketing authorization from a country or region considered by the FDA as stringent. This will include countries that were members of the ICH prior to 2015.

2. Submission of application; Applicant for the registration of medicinal product under this category shall
    i. Submit full application as per the FDAs requirement for the registration of medicinal product.
    ii. pay the requisite application fees
    iii. submit the required number of samples of the product
    iv. include a cover letter for the submission.

3. Processing steps: applications shall be processed through the normal registration processing steps and include;
    i. Acknowledgement of applications
    ii. Evaluation of dossiers and samples (Limited review based on risk-based approach)
    iii. Presentation of evaluation comments to the Product Registration Committee
    iv. Final communication to the application

4. Timelines: applications classified under this category shall be processed within 90 days.