FOOD AND DRUGS AUTHORITY

GUIDELINES FOR FAST TRACK REGISTRATION OF WHO PREQUALIFIED MEDICINAL PRODUCTS

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GUIDELINES FOR THE FAST TRACK REGISTRATION OF WHO PREQUALIFIED MEDICINAL PRODUCTS.

Introduction;

This guideline outlines the procedure for the application and registration of WHO prequalified medicinal products 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 medicinal products.

Applicants with medicinal products 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.

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.

Processing

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

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.