# FOOD AND DRUGS AUTHORITY

# GUIDELINES FOR REGISTRATION OF AN ORPHAN DRUG

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## 1.0. INTRODUCTION

The Food and Drugs Authority recognizes the need for granting special status to a drug to treat a rare disease or condition upon request of an applicant.

### 1.1. SCOPE

These guidelines apply to category of products classified as orphan drugs, documentation to be submitted and timelines.

## 2.0. GLOSSARY

**An Orphan drug is:**

(a) A pharmaceutical product which remains commercially undeveloped due to low commercial returns, or

(b) A drug intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders, or

(c) Drugs intended to treat rare diseases that the sponsors are reluctant to develop them under usual marketing conditions.

**"A Rare Disease"** means a disease condition which occurs in a small percentage of the population

## 3.0. REQUIREMENTS FOR REGISTRATION

The following should be submitted for the registration of Orphan Drugs

1. A covering letter from the local representative

2. A completed FDA application form for the registration of allopathic medicines (please refer to the FDA website www.fdaghana.gov.gh).

3. Samples of the product as per the FDA's sample schedule.

4. Pay the requisite application fee (Please refer to the FDA website www.fdaghana.gov.gh)

## 4.0. CRITERIA FOR ORPHAN DRUG CLASSIFICATION

1. The drug should fall under conditions in the above definition.

2. If a product is registered through the normal registration, application for orphan drug status by another applicant will be considered if applicant is able to prove nonavailability and meet orphan drug criteria.

## 5.0. TIMELINES FOR REGISTRATION

Applications under this category shall have a decision made within three (3) months of submission.