FOOD AND DRUGS AUTHORITY

GUIDELINES FOR APPEAL AGAINST REGULATORY DECISIONS OF THE FDA

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1 INTRODUCTION

This guideline has been developed to provide guidance to applicants who are aggrieved by any regulatory decision of the Authority with regards to the services provided by the Food and Drugs Authority (FDA).

The Public Health Act 2012, Act 851 provides an avenue to clients to make representations in writing to the Minister of Health in the case of Clinical Trail Application (refer to section 156, subsection 3) or the Chief Executive Officer of the FDA in the case of registration and/or marketing authorization (refer to section 118 (6)) within sixty (60) days after the date of notification of the decision.

If any person is aggrieved by a regulatory decision of the FDA, it is the person's right to appeal against the decision in line with the provisions in the Public Health Act 2012, Act 851 and this guideline.

The purpose of this guideline is to provide guidance on the appeal process to applicants.

1.1 SCOPE

This guideline has been developed to give guidance to persons aggrieved by decisions of the authority in the following regulatory functions;

I. Marketing authorization or Registration
II. Inspection and Licensing of manufacturers, importers, exporters and wholesalers
III. Regulatory enforcement actions, such as:
    a. Detention and/or seizure medical products
    b. Recall and withdrawal of medical products
    c. Disposal of medical products
    d. Fines
IV. Control of clinical trials of medical products
V. Control of promotion and advertisement of medical products
VI. Laboratory testing of medical products
VII. Any other decision made by the authority

2 GLOSSORY

An Appeal: Is a formal request for a review of a regulatory decision and/or an outcome of an application.

3 REQUIREMENT

3.1 GENERAL

1. A person who is aggrieved by a regulatory decision made by the FDA may formally request in writing for FDA to reconsider/review the initial decision within 60 days after the date of notification of the decision.
2. All appeal request shall be made in writing, and addressed to:

   THE CHIEF EXECUTIVE OFFICER
   FOOD AND DRUGS AUTHORITY
   POST OFFICE BOX CT 2783
   CANTONMENTS
   ACCRA, GHANA
3. In case of regulatory decisions on clinical trials the appeal shall be made in writing to the Honorable Minister of Health within 60 days after the notification of the decision.
4. The aggrieved person shall ensure that the representation includes the following:
   - the appeal letter, dated and signed by the aggrieved person requesting for the review
   - a copy of the initial decision notification letter (or other evidence of notification) stating clearly the regulatory decision for which the appeal is requested
   - any information/documentation in support of the request, clearly labeled to correspond with (any or each of) the reasons why review is requested
   - a description of how the interests of the aggrieved person are affected by the regulatory decision (only applicable if the notification of an initial decision was not issued to the aggrieved person)
5. It is important to ensure that all information and documentation that you wish the FDA to consider is provided with the request to the FDA since the FDA shall not

consider any information provided after the submission of the request unless the information is provided in response to a request from the FDA.

6. In the event that the aggrieved person whose interests are affected is a third party (i.e. the applicant was not the person to whom the regulatory decision was issued by the FDA), the FDA shall also notify in writing, the person to whom the regulatory decision was issued (e.g. the Market Authorization Holder (MAH) of the product, Sponsor of a Clinical Trial, etc) advising that a request for review has been received by the FDA.
7. All appeals received by the FDA shall be acknowledged and adequately investigated by the responsible Division/Department with inputs from the Legal Service Department where applicable. The Head of the responsible Division/Department shall make representation to an Administrative Appeal Committee that shall be established to hear and determine appeals lodged by persons aggrieved by the decisions of the Authority. The committee shall consider new information submitted with the appeal application.

3.2 REVIEWING AN APPEAL APPLICATION

Upon review of the appeal application, the FDA shall give response in writing of the outcome of the appeal application, which shall include a statement of reasons (i.e. findings, references to evidence and reasons for the decision). The response shall be addressed to the aggrieved person **within 90 days after submitting an appeal application.**

If the initial decision is one of which is required to be published on the FDA's website (such as a decision to register a product or revoke/cancel/suspend a product registration, facility license, etc.), and the FDA upon revision of the regulatory decision decides to 'revoke and substitute' the regulatory decision, the particulars of the current decision shall be published on the FDA website.

An appeal of a regulatory decision will result in one of the under listed outcomes:

- **Endorse** the regulatory decision
- **Revoke** the regulatory decision
- **Revoke and substitute** the regulatory decision with a new decision

Endorsing the* regulatory *decision

Where upon review the FDA decides to uphold the regulatory decision, the regulatory decision shall remain unchanged.

It is however possible that upon review, the FDA may have come to the same conclusion as the regulatory decision but for different reasons. The committee may assess evidence in support of the regulatory decision differently or come to another conclusion on the basis of available evidence (which might be additional to what was available when making the regulatory decision).

Revoking the regulatory decision

Where upon review the FDA decides to overturn a regulatory decision, the regulatory decision is would be reversed as though the regulatory decision was never made.

Revoking and substituting the regulatory decision with a new decision

Where upon review the FDA decides to vary all or part of the regulatory decision, the regulatory decision would be partially or entirely replaced (substituted) by a new decision.

Upon review of the initial decision, the FDA may decide that a variation (to one or more specific aspects) of the initial decision is, under certain circumstances, the correct outcome. The FDA may assess the initial decision as being partially or entirely incorrect at the time it was made or as being partially or entirely incorrect in light of additional information made available to the FDA upon review of the initial decision.

The decision of the Administrative Appeals Committee is final.

3.3 WITHDRAWING AN APPEAL APPLICATION

An aggrieved person may withdraw their request at any time before the FDA convenes a committee to review the regulatory decision. Withdrawal of an appeal application should be notified in writing to the FDA within ten (10) working days of the initial appeal submission. Notification of the withdrawal of an appeal application should be addressed to the Chief Executive Officer (CEO).

Nonetheless, the committee shall work independently of the office associated with the appeal and the Chair of the committee shall document and maintain records of all engagements related to the appeal process.

The FDA shall suspend all routine evaluation activities related to the appeal pending the completion of the appeal review process and pending confirmation that the client wishes to proceed with the regulation.