FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE REGISTRATION OF PARALLEL IMPORTED COSMETICS AND HOUSEHOLD CHEMICAL SUBSTANCES

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1.0 SCOPE

In pursuance of section 122 of the Public Health Act 2012, Act 851 of this guideline is hereby made to provide guidance on the procedure for registering parallel imported cosmetics and household chemical substances. Applicants are encouraged to familiarize themselves with this document and the above law before completing the registration form.

2.0 DEFINITION OF TERMS

Parallel importation:
means importing a cosmetic and/or household chemical substance without authorization of the product registration holder from another country where it is legitimately placed.
The Food and Drugs Authority may in the public interest authorize parallel importation of cosmetics and/or household chemical substances in pursuant to section 122 subsection 2 of the Public Health Act, 2012.

In this document '**Product**' means a Cosmetic and Household chemical substance.

3.0 OBJECTIVES

The main objective of the Food and Drugs Authority's consideration for parallel import registration is to establish whether the required identity exists between the cosmetics and/or household chemical substances already registered and cosmetics or household chemical substances for which an application for a parallel import registration has been submitted.

It also include products not registered but which an application for a parallel import registration has been submitted from the grey market.

4.0 REQUIREMENTS AND CONDITIONS FOR PARALLEL IMPORTATION

4.1 Conditions for Parallel Import

The following requirements must be met in order for the Food and Drugs Authority to issue registration for a parallel importation of cosmetics and household chemical substance(s):

1. The parallel imported product can be imported from any country of the world.
2. There must not be any differences in product indication between the parallel imported product and the registered product.
3. The parallel imported product must conform to the registration requirements and the guidelines of the Authority
4. An application must be submitted for registration of parallel import from each individual exporting country.
5. It is the responsibility of the parallel importer to notify the registration license holder of the registered product about their intention of parallel importation of the product in question.
6. The Authority will not register or allow the importation of any product when the license holder is known to the Authority as having the sole agency or have power of attorney for the importation of the product
7. The license holder who possess the sole right for the importation of a product may allow variants or products in a similar category to be imported into the country with the permission or approval of the Authority
8. Parallel imported products of the from the same product category can be imported into the country from the grey market by more than one importer if registration requirements are satisfied by the importers
9. Importers importing into the country products of the same brand and product category are to ensure that adequate product documentation and information (ie. BL, pdt source, BN any other relevant info) is provided to the Authority to ensure proper identification of products with specific importers
10. All applications submitted for parallel imported products should have certificate of analysis from a public analyst

4.2 Cosmetics and Household Chemical substances

Due to the risk associated with some chemical substances used in the formulation of some product categories e.g. insecticides, the Authority may not register products from this product category unless adequate documentation has been submitted on the toxicological profile and product safety.

Furthermore it is a requirement that all parallel importer must ensure traceability of the product and submit records to the Authority when the need arises.

4.3 Scope of Parallel Import Registration

Parallel import registration shall be valid for 3years from the time when the first registration for the parallel imported product is issued. Renewal applications must be submitted not later than 3months before the registration expires for all of the products, dosage forms and strengths under the same name.

4.4 Withdrawal of Registration for a Parallel imported Product

If the registration of a product is withdrawn for safety reasons, any parallel import registration will be withdrawn at the same time.

If the registration of a product is withdrawn for reasons not related to safety, the parallel import registration will not be withdrawn unless for reasons of protecting public health.

4.5 Changes to a Parallel Imported Product

The parallel importer is obliged to keep the Food and Drugs Authority updated on any changes to the parallel imported product. Changes to the parallel imported product composition, appearance, primary packing, manufacturer, registration license holder in the exporting country etc. in relation to what was applied for at the time parallel importation registration was issued must be approved by the FDA before permit to import the product can be allowed.

The parallel importer must ensure that records of minor changes to the approved product is communicated to the FDA to aid in the Authority’s programme of controlling substandard, spurious , falsely labeled, falsified, counterfeit products.

4.6 Company Authorization

A parallel importer must have a license to import products. Parallel importers who wish to engage in additional labeling or repackaging etc. must in addition to having an importers license also hold a manufacturing license.

Parallel importers must observe current good distribution and good manufacturing practices for all regulated products.

4.7 Fees

Registration fees for parallel imported products shall be the same as the registration fees for the product relative to which parallel import is granted as stated in the Authority's fee schedule.

4.8 Product Name

Parallel imported products can be marketed under the same name as the registered product in relation to which the parallel imported product is being registered.

If parallel importers wish to change the name of a parallel imported product after issuance of their registration, they can apply for another name by submitting a variation application.

4.9 Labeling and Package Leaflets

Labeling and package leaflets of parallel imported products must not deviate from that of the product in relation to which the parallel import is granted. Parallel imported products labeling and package leaflets must conform to the FDA labeling guidelines.

4.10 Reporting of Adverse Reactions

Parallel importers are subject to the same condition on reporting of adverse reactions as importers of the products in relation to which the parallel import is granted as explained in the FDA guideline on safety monitoring based on section 125 of the Public Health Act, 2012.