p.HD DRUGS AUT//

FOOD AND DRUGS AUTHORITY

Wondershare™

GUIDELINES FOR IMPORTATION OF CONTROLLED SUBSTANCES

DOCUMENT NO.:	FDA/DRI/TSA/GL-ICS /2013/02
DATE OF FIRST ADOPTION:	18 FEBRUARY 2013
DATE OF ISSUE:	18 MAY 2018
VERSION NO.:	02

TABLE OF CONTENT

1.0	INTRODUCTION	1
2.0	DEFINmON OF TERMS	1
3.0	REQUIREMENTS	3
	3.1 General Requirements	3
	3.2 Inspections on controlled substances	3
	3.3 Allocation of Controlled Substances	3
4.0	ISSUING OF CONTROLLED SUBSTANCES IMPORT PERMR"	3
	4.1 Application for a Controlled Substance Import Permit	3
	4.2 Final Import Permit	4
	4.3 Rejection of Import permit application	4
	4.4 Schedule for samples	4
5.0	SUBMISSION OF REPORTING DOCUMENTS	5
	5.1 Advice of Receipt	5
	5.2 Returns	5
	5.2.1 Completion of Returns Form	6

Wondershare™

GUIDELINES FOR IMPORTATION OF CONTROLLED SUBSTANCES

1.0. INTRODUCTION

In pursuance of Section 126 of the Public Health Act, 2012 (ACT 851), the Food and Drugs Authority shall regulate the narcotics, psychotropic substances and precursor chemicals in accordance with the underlisted multilateral conventions which are currently in force:

a. The Single Convention on Narcotic Drugs of 1961 **(1961 Convention),** as amended by the 1972 Protocol;

b. The Convention on Psychotropic Substances of 1971 **(1971 Convention)** and, adopted in 1988,

c. The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances **(1988 Convention).**

The above mentioned Conventions and other related resolutions of the Economic and Social Council provides the framework for international cooperation in preventing the diversion of narcotic drugs, psychotropic substances and precursors. They contain special provisions relating to the international trade of controlled substances and impose a general obligation on States parties to cooperate in limiting the use of controlled substances to medical and scientific purposes, whilst preventing their diversion to illicit trade and abuse.

2.0. DEFINITION OF TERIVIS

In these Guidelines, unless the context otherwise states:

a) **"FDA"** means Food and Drugs Authority.

b) **"Controlled Substances"** means a Narcotic drug. Psychotropic substance or Precursor chemical.

c) **"Narcotic drugs"** means substances listed in Schedules I and II of the 1961 Convention. The esters and ethers and the salts of esters and ethers of the narcotic drugs in Schedule I are also subject to control.

d) **"Psychotropic substance"** means those natural or synthetic substances or any natural material listed in the four Schedules of the 1971 Convention. The salts of those substances, where they exist, as well as preparations containing those substances, are subject to the same control requirements as the base substance.

e) **"Precursor chemical"** means those substances listed in Tables I and II of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (1988 Convention) frequently used in the illicit manufacture of narcotic drugs and psychotropic substances under the international control.

f) **"Importer"** means a licensed pharmaceutical company registered with the FDA to import drugs into Ghana.

g) **"Permit for the Importation of Narcotics and Psychotropic Substances"** is a valid document issued by tine FDA to an importer for tine importation of controlled substances.

h) **"Advice of Receipt"** is a document submitted by an importer to show that a product covered by a controlled substance import permit has been duly imported into Ghana.

i) **"Returns"** is a document submitted by an importer to show the utilization and distribution records of a controlled substance that has been duly imported into Ghana.

j) **"GIVIP"** means Good manufacturing practices.

3.0. REQUIREIVIENTS

3.1 General Requirements

(a) The company shall be registered as an importer or manufacturer with the FDA *[refer to guidelines for licensing of manufacturing industries (drugs, cosmetics, household chemical substances and medical devices)].*

(b) For importers of finished products

- The company shall register the finished products containing controlled substance with the FDA.(refer *to Guidelines for the registration of allopathic drugs)*

(c) For Local manufacturers

- The company shall have a License to manufacture *[refer to Guidelines for licensing of manufacturing industries (drugs, cosmetics, household chemical substances and medical devices)].*

- The company shall register pharmaceutical preparations containing the controlled substance, *{refer to Guidelines for the registration of allopathic drugs)*

(d) Local manufacturers who have intentions to manufacture finished products (medicines) with controlled substances are expected to have been manufacturing other allopathic drugs for at least five (5) years.

(e) Controlled substance (Raw materials) imported into the country cannot be sold or transferred to another manufacturer or person.

3.2 Conducting Inspections on controlled substances

(a) Inspections shall be conducted on controlled substances imported into the country

(b) The inspection shall either be announced or unannounced however, for announced inspections, FDA shall issue a letter communicating to the entity/company the scheduled date for the inspection.

(c) Companies/entities which may fail to be available for the scheduled date of inspection shall fill and complete an inspection re-scheduling form indicating reason(s) for re-scheduling and may attract a re-scheduling fee as defined by the Authority.

3.3 Allocation of Controlled Substances

- The importer shall submit a letter requesting for an allocation of a controlled substance for the following year to the FDA. Based on previous utilization and distribution records received, FDA shall allot to the company the needed quantities.
- New Importers shall formally request for an allocation of a controlled substance after satisfying the general requirements.
- Increase in allocation or addition of controlled substances to Ghana's legitimate requirements shall be justified.

4.0. ISSUING OF CONTROLLED SUBSTANCE IMPORT PERMIT

4.1 Application for a Controlled Substance Import Permit

(a) The company shall apply for a controlled substance permit through the Ghana Community Network (GCNet) electronic permit system.

(b) The company shall enter the following details on the import permit application:

- Name, full postal address and telephone numbers of the importing company
- Name, full postal address and telephone numbers of the exporting company
- The purpose of import
- Item details – the following shall be stated
  - > the full name of the controlled substance,
  - > total quantity shall be stated in dosage unit. (For example, 2000 ampoules, capsules or tablets etc.)
- Transport details (NB. This section which includes the Mode of transport, Mode of Transport Description, Shipment date. Carrier, Port of Arrival, Port of Departure, Customs Office and Freight Station shall be fully stated).

Thank you for using Wondershare PDF Converter Pro 4.1.0.

You can only convert up to 5 pages in the trial version.

To get the full version, please purchase the program here:

http://cbs.wondershare.com/go.php?pid=970&m=db