VOLUME 5

SECTION 5

APPROVAL PROCESS FOR FOOD, DRUGS COSMETICS, MEDICAL DEVICES, PRECURSOR CHEMICALS AND NARCOTICS

The Responsibility of
the Ministry of Health
2-4 Kings Street
Kingston

TABLE OF CONTENT

CHAPTER 1

STANDARDS & REGULATION DIVISION OF THE MINISTRY OF HEALTH

1.0 BACKGROUND

The Standards & Regulation Division was established in March 1999 under the Health Reform process of the Ministry of Health. The role and functions of the Division are regulatory, legislative and administrative in nature and are executed through the following four sections:

i Standards and Regulation - Administration
ii Standards Research & Development
iii Investigation & Enforcement
iv Pharmaceutical & Regulatory Affairs

1.01 Mission Statement

To improve the quality of health care services in Jamaica through standards development and monitoring in consultation with public and private health care providers; to regulate healthcare facilities, pharmaceuticals and other designated products; and to facilitate the recognition of the rights of all clients.

1.1 SUB-DIVISIONS

The Pharmaceutical and Regulatory Affairs Department comprises three sub units:

- The Permit Approval Unit
- The Product Registration Unit
- The Institutions and Facilities Unit.

1.2 ADVISORY PANEL MECHANISM

An Advisory Panel Mechanism consisting of three Advisory Panels was created within the new framework in 2000. The purpose of the Advisory Mechanism is to provide a collaborative network supporting the Division in the development of systems and programmes, which will advance the quality of healthcare and provide

inputs for health policy formulation.

The Panels are:

- Professional Affairs
- Complementary/Alternative Medicine
- Ethics and Medico-Legal Affairs

1.3 ROLE AND FUNCTIONS OF THE STANDARDS DIVISION

1.3.1 Mandate

The mandate of The Standards and Regulation Division is to contribute to the achievement of the Ministry of Health's corporate goals and objectives by leading the process for quality improvement through standard setting and monitoring of the public and private health sectors. The core functions include:

i Policy Formulation;

ii Maintenance of an effective Regulatory framework supported by sound legislation for the regulation of healthcare facilities, pharmaceuticals, foods, cosmetics and other designated products;

iii Development of healthcare standards and guidelines;

iv Monitoring and enforcement of standards, regulations and guidelines;

v Resolution of complaints regarding health issues;

vi Maintenance of critical linkages locally, regionally and internationally;

1.3.2 Functions

The functions are critical, ensuring conformance with legislation, standards and guidelines resulting in:

i Access to safe, effective products of acceptable quality including narcotics, psychotropics, herbal products and other drugs, cosmetics, foods and medical devices

ii The importation for sale/distribution to the public of products,

which have prior approval by the Ministry. Those designated by law are food, drugs, cosmetics, medical devices and precursor chemicals. The importation of all chemicals is also regulated through the Pharmaceutical and Regulatory Affairs Department

iii Improved healthcare delivery by health professionals

iv The implementation of appropriate health standards & guidelines

v The provision of quality service in Health Institutions

1.3.3 Regulatory Functions

The regulatory oversight of the Division is national and therefore spans both public and private health domains.

CHAPTER 2

LEGISLATIVE FRAMEWORK

2.0 LAWS AND REGULATIONS

The following Laws and Regulations primarily govern the functions of the Division:

- The Food & Drugs Act, 1964
- The Food & Drugs Regulation, 1975
- The Dangerous Drugs Act, 1948
- Precursor Chemicals Act, 1999
- The Nursing Homes Registration Act, 1934

2.1 FOOD AND DRUGS ACT

The Food and Drugs Act and Regulations authorise the regulation of foods, drugs, cosmetics and medical devices. The scope of authority includes domestically manufactured, as well as imported products. Under the Act and Regulations, local manufacturing sites should possess current manufacturing licences, renewable annually and should comply with Good Manufacturing Practice standards. The registration and licensing, importation, sale and distribution of the designated products are also covered. Under the Act similar standards for quality, safety and efficacy are applicable for both imported and locally manufactured products.

2.2 DANGEROUS DRUGS ACT

The Dangerous Drugs Act allows for the monitoring and control against the illicit use of specific narcotic drugs such as cocaine and morphine and psychotropic substances such as ganja (marijuana).

2.3 PRECURSOR CHEMICALS ACT

The Precursor Chemicals Act provides for the monitoring and control of precursor chemicals and other chemical substances used or capable of being used in any form of illicit operations involving narcotic drugs and psychotropic substances or other substances having a similar effect.

2.4 NURSING HOME ACT

The Nursing Home Act ensures registration and the proper operation of nursing homes and other facilities named in the Act such as maternity homes. The Act defines a nursing home as any premises used or intended to be used to provide nursing for individuals affected by any sickness, injury or infirmity but does not include hospitals or other premises operated or controlled by a government department.

2.5 BREACHES AND PENALTIES

The laws specify the breaches and penalties or fines applicable for contravention. They are amended from time to time so as to keep pace with current needs. They are available from the Jamaica Printing Service, Duke Street, Kingston, or may be accessed from the Ministry 's website at www.moh.gov.jm

CHAPTER 3

STRUCTURE AND FUNCTIONS OF THE STANDARDS DIVISION

3.0 STAFFING

A team of technical experts comprising various skills executes the day-to-day activities of the Standards and Regulation Division and a Director guides each section. An Administrator, five secretaries and a clerk provide administrative and clerical support. Technical positions include:

i Five Drug Inspectors
ii One Chief Drugs Inspector
iii One Chief Dangerous Drugs Inspector
iv Two Scientific Officers
v Two Senior Investigators
vi A Registrar for Institutions and Facilities
vii One Monitoring Officer
viii One Quality Assurance Coordinator

3.1 PRINCIPAL SECTIONS AND THEIR FUNCTIONS

The principal functions of the sections are summarized hereunder:

3.1.1 Standards & Regulation - Administration

This section:

i Maintains an effective regulatory framework within which to operate

ii Maintains an efficient client satisfaction mechanism

iii Identifies gaps /weaknesses in existing legislation and seek amendment to be in keeping with current needs

iv Monitors health care standards

v Establishes and maintain consultative mechanisms

vi Ensures effective functioning of the Advisory Panels

vii Maintains critical links with the Regional Health Authorities to ensure quality service delivery.

3.1.2 Investigation & Enforcement

This section:

i Maintains an efficient client satisfaction mechanism
ii Conducts investigations and carry out health related audits
iii Plans systems to impose fines and penalties
iv Develops framework for confidentiality
v Educates clients and service delivery personnel
vi Coordinates functioning of Medico-Legal Advisory Panel
vii Monitors complaints with a view to timely resolution

3.1.3 Pharmaceutical & Regulatory Affairs

This section

i Ensures the safety, efficacy and quality of products available on the Jamaican market through effective drug registration and import permit approval systems.

ii Maintains an efficient system for the registration/approval for drugs and other designated products

iii Monitors critical drugs and other medical supplies to ensure their availability in support of an efficient pharmaceutical service in the health system.

iv Promotes Rational Drug Use in hospitals and other health institutions

v Maintains an efficient system of Registration for Nursing Homes and other health facilities

vi Monitors Nursing Homes and other health facilities for compliance with standards and guidelines

vii Monitors pharmaceuticals already on the market through post market surveillance

viii Maintains an effective mechanism for collaboration with the

Customs Department and other relevant government agencies for the proper monitoring and control of the designated products imported for use by the Jamaican public.

3.1.4 Standards Research and Development

This section carries out the following activities:

i Standards Development
ii Reviews and update existing Standards
iii Researches/develops new standards and audit instruments as needed;
iv Coordinates activities of Complementary/Alternate Medicine Advisory Panel
v Maintains effective Quality Assurance systems

CHAPTER 4

DRUG REGISTRATION CENTRE

4.0 REGULATORY FUNCTIONS

The Registration of drugs is a major regulatory function executed through the Pharmaceutical & Regulatory Affairs Department. It involves in-depth scientific evaluation of the technical documentation submitted in support of the registration of a drug or other related product. It is one of the primary mechanisms through which the quality, safety and efficacy of drugs, and other products mentioned in the Food and Drugs Act and Regulations are ensured.

4.1 DRUG DEFINITION

'Drug' refers to any substance that conforms to the definition prescribed by the Act. Such substances generally require registration and include drugs, herbal preparations and some vitamins. Registration may also be required for any cosmetic, food or device making therapeutic claims.

In instances where products are deemed safe enough to be placed on the market without formal registration, the Ministry of Health grants a written approval. Once registered or approved, products are allowed importation by way of permits granted by the Ministry through the department.

4.2 REGISTRATION PROCESS

The registration process may be summarized as follows:

i Submission of the dossier for review
ii Review and approval/refusal
iii Issuance of a Licence/Letter of refusal

4.3 REQUIREMENTS FOR REGISTRATION

The requirements for registration are outlined in the Food & Drugs Regulations. The method for the submission of the requisite documentation and subsequent assessment and evaluation is as follows:

i A Dossier in the English Language (or authenticated translation) bound in hard cover and correctly indexed, containing information for assessment purposes should be prepared for submission (see list of requirements at Appendix 1). The Dossier may comprise one or more volumes.

ii All items in the list of requirements including fees should be submitted at the same time to the Pharmaceutical and Regulatory Affairs Department. Completed documentation only is accepted. Separate lists exist for:

- New drug registration (See Appendix 1)
- Herbal product registration (See Appendix 2)

iii An appointment should be made with a Scientific Officer in the Pharmaceutical & Regulatory Affairs Department for the initial dossier review.

iv Once accepted, dossiers are further subject to scientific evaluation by the Product Registration Committee. The Committee consists of a wide cross-section of scientists and officially meets once every month.

v Official Registration Lead Times are as follows:

- New drugs – One Hundred and Twenty Days (120)
- Generic drugs, drug line extensions, herbal products and registerable vitamins – Ninety Days (90)
- Drugs used in the treatment of life threatening illnesses such as Cancer and HIV/AIDS – Sixty Days (60)
- Me – Too's – Sixty Days (60)
- Products for literature review only (registration not required) – Thirty Days (30)

vi During the evaluative process the committee may recommend that:

- A product be referred for expert clinical consults;
- The client be requested to provide additional information in support of claims made or to facilitate complete evaluation;
- The product is sent for testing at relevant laboratories to

further validate data submitted.

In instances such as those indicated above lead times may be affected.

vii Following the review clients are advised in writing whether registration has been approved or refused. If refused, reasons for refusal are stated.

viii The Standards and Regulation Division issues a Pharmaceutical Product Licence for all registered products.

ix An official Letter of Approval is issued within thirty (30) days for products for which registration as a drug is not required but for which assessment is necessary.

CHAPTER 5

PERMIT APPROVAL CENTRE

5.0 IMPORTATION OF FOODS, DRUGS AND OTHER DESIGNATED PRODUCTS

The permit approval system allows for the importation of products regulated under the Food & Drugs Act and Regulations, the Dangerous Drugs Act and the Precursor Chemicals Act. Such products include:

i All registered drugs including narcotics and other controlled drugs
ii Vitamins and herbal preparations
iii Approved cosmetics, Medical devices & Diagnostics
iv Approved Precursor and Essential chemicals
v Food additives, preservatives and foods which make therapeutic claims
vi Any other product including cosmetic or food for which the Scientific Officer deems a permit necessary for importation following assessment.

5.1 APPLICATION FORM

The prescribed application forms for importation are available from the Ministry of Health's Pharmaceutical and Regulatory Affairs Division or may be downloaded from the Ministry's website at www.moh.gov.jm. Sample forms are at Appendix 2.

For ease of access, the forms are also available from Custom Brokers and the The Chief Pharmacist at the Cornwall Regional Hospital in Montego Bay.

5.2 VALIDITY OF PERMIT

Once approved, permits for controlled substances remain valid for six (6) months from the date stamped on the form. Permits for all other products have a validity of twelve (12) months, during which partial shipments (often referred to as P.I.P or Part-in-Part) may be transacted. Partial shipments are not allowed for controlled substances. For these items the permit becomes unusable once a shipment transaction takes place.

5.3 CONTROLLED SUBSTANCES

For controlled substances, upon arrival of the goods in the island, the invoice must be presented to the Chief Dangerous Drugs Inspector at the Ministry of Health

for assessment. The Inspector returns the stamped invoice to the importer within twenty-four hours. The stamped invoice is then presented to the customs officer in order to effect clearance from the port of entry. An unprocessed invoice will result in delay, as without it, clearance of the item will not be allowed.

For other goods, the invoices are not required for clearance. However the Drug Inspector reserves the right to request that an invoice be provided in the event it is deemed necessary.

5.4 GUIDELINES FOR IMPORT PERMITS APPLICATION

The following are the guidelines to apply for import permits:

i Application for import permits should be made on the official colour coded application forms as follows:

- Blue - foods e.g. additives, preservatives and drugs
- Pink - cosmetics and essential chemicals
- Yellow – psychotropics substances, narcotics, precursor chemicals, and any other controlled substance

ii Once submitted applications are processed and can be retrieved from the Department within twenty-four hours of submission. If the product is found to be acceptable for importation and all the requirements are satisfied, a permit is issued which bears an official stamp of the Ministry of Health along with the signature of a Drugs Inspector. Permits for controlled substances are returned within seventy-two (72) hours of submission

iii The appropriate colour coded Form should be used as failure to comply will delay the approval process. Clients are advised to consult with the unit if they are unsure whether a product requires permit approval for importation or to confirm which is the appropriate Form to use.

iv Applications should be submitted and the approved permits bearing the Ministry's official stamp, obtained from the department before the goods are ordered from the supplier. This is to avoid breaches under the Food and Drugs Act and the Customs Act. **Submission of an application does not guarantee approval or automatic granting of the permit.**

v Importers are advised to factor into their time frame for submission, public holidays and weekends which could impact lead times when making applications for permits.

5.5 COMPLETING THE APPLICATION FORM FOR PROCESSING

The following are guidelines to complete the application form for processing:

i The names of the goods to be imported (brand, chemical/generic name) should be clearly stated in the space provided on the Form.

ii The amount of goods, package size, units of the goods should be declared.

iii The completed original permit application form along with the carbonized copy should be submitted to the import permit unit for processing.

iv A maximum of ten (10) items are allowed per application.

5.6 IMPORTATION THROUGH THE POST OFFICE

For products imported through the Post Office for which a permit was not granted, a drug inspector visits the Post Office and processes the Parcel Notice issued by the Post Office before the products can be released from the post office. The Parcel Notice should indicate the nature of the item(s) being imported. This is validated by checking the actual item(s) being held.

CHAPTER 6

REQUIREMENTS FOR IMPORTATION OF FOODS & DRUGS

6.0 DRUGS

Applicants are advised to use the Blue Forms (Sample form is at Appendix 3) and to note the following instructions.

i All drugs being imported should have a valid registration with the Ministry of Health. This means that drugs that have been withdrawn or recalled from the market may not be imported (see section- special permit)

ii The trade and/or generic names, concentration/strength and pack size should be clearly stated;

iii Importers of pharmaceuticals for trade purposes should be licensed by the Pharmacy Council of Jamaica;

iv The manufacturer and source country should be the same as indicated in the official registration records;

v A certificate from the Veterinary Division, Ministry of Agriculture should accompany application for importation of drugs for veterinary use.

vi All drugs being imported should have expiration dates of not less than twelve to eighteen months

6.1 FOODS

The Food & Drugs Act and Regulation provide the categories of foods for which import permits are applicable. These include food additives and preservatives, foods making therapeutic claims and those classified as dietary supplements such as some vitamins, and amino acids. These foods are subject to assessment and issuance of import permits prior to importation. A Blue Form is used to apply. The requirements for assessment include:

i A Certificate of analysis on the batch being imported from the manufacturer

ii The European Commission (EC) or Fragrances & Essential Manufacturers Association (FEMA) numbers where applicable.

iii Any other information on the product deemed necessary by the Drug Inspector to facilitate complete assessment.

CHAPTER 7

IMPORTATION OF CHEMICALS, RAW MATERIALS AND COSMETICS

7.0 GUIDELINES FOR IMPORTATION

Applicants should use the Pink Form and provide the following:

i The chemical names and brand names (where applicable) of the products should be clearly indicated. Clients are advised not to describe products using assigned product numbers e.g. European Commission or FEMA number.

ii Material safety data sheets or other technical information on the product should accompany the applications for chemicals for which permission for importation is being sought for the first time.

iii A Scientific Officer should assess cosmetics being imported for the first time before the permit application is made. For assessment the following are required:

- Five samples of the form in which the cosmetic is to be marketed
- Five labels in the finished form
- A Certificate of Analysis on a recent batch from the manufacturer
- A Free Sale Certificate from the Competent Authority in the country in which the cosmetic is made
- Any other documentation deemed necessary for assessment by the Scientific Officer
- A lead-time of fourteen to twenty working days should be allowed depending on the nature of the submission.

iv If the cosmetic is determined to be acceptable the permit application is made in the manner described above on the Pink Permit Form (Sample form is at Appendix 4).

CHAPTER 8

IMPORTATION OF CONTROLLED SUBSTANCES PSYCHOTROPIC SUBSTANCES, NARCOTICS, PRECURSOR AND ESSENTIAL CHEMICALS

8.0 General Information

Applicants should note the following information:

i Controlled substances include Narcotics, Psychotropic Substances, Precursor and Essential (dual purpose) Chemicals

ii The yellow form is used for applications for permits to import these substances (Sample form is at Appendix 5).

iii Applications for each controlled substance should be made on a separate application form.

iv Permits for Narcotic and Psychotropic Substances are issued within **72 hours** after receipt of the applications.

v Permits for controlled substances are valid for **six (6) months** only from the date of approval.

vi Part-In-Part (PIP) shipments of these goods are not permitted.

vii On arrival of the goods, the permit accompanied by the original invoice and a copy must be re-submitted for processing prior to submission at Customs for clearance.

8.1 Guidelines for the Importation of Narcotics

i A written request seeking permission to import the desired substance(s) should accompany the yellow application form. These are submitted to the Chief Dangerous Drugs Inspector - Pharmaceutical & Regulatory Affairs Department.

ii The written request should include the following:

- The name and address of the overseas manufacturer and supplier

- The name of product(s), concentration and desired quantities
- The signature of the company pharmacist/researcher.
- The purpose for which importation is required.

iii Import permits for these substances are accompanied by specific documents, namely Form A and Form C. These are prepared and issued by the Chief Dangerous Drugs Inspector, Pharmaceutical and Regulatory Affairs.Form A is to be sent to the overseas supplier and Form C should be presented to the Customs Department along with the permit on the Yellow form on arrival of the goods.

iv International Control

- **For the international control of narcotic substances, all such shipments MUST arrive in the importing country (e.g. Jamaica) before December 31. In view of this, submissions for the importation of Narcotic substances into Jamaica are not accommodated after the 30th of September each calendar year.**

- **All importers of the above substances must be authorised to conduct activities relating to the substances e.g. storage and handling.**

8.2 IMPORTATION OF NARCOTICS FOR PERSONAL USE

A special permit must be prepared for the Jamaican Customs. The following information is required for its preparation:

i A letter from the patient's physician stating the name of the patient and the treatment prescribed (name, strength, quantity to last for duration of stay)

ii Flight details (dates and times of arrival and departure, flight numbers, ports of disembarkation and embarkation

iii Address of the patient while in Jamaica

iv A contact number/facsimile number of the physician and/or patient.

8.3 PSYCHOTROPIC SUBSTANCES

A written request seeking permission to import the desired substance(s) should accompany the completed yellow application form. These are submitted to the Chief Dangerous Drugs Inspector - Pharmaceutical & Regulatory Affairs Department.

The request should include the following:

i the name and address of the overseas manufacturer and supplier
ii the name of product(s), concentration and desired quantities
iii the signature of the company pharmacist/researcher.

The letter of request for the psychotropic substances must clearly state that the items are for the local market and will not be re-exported.

8.3.1 Controlled Drug Permit

A Controlled Drug Permit is prepared and issued by the Chief Dangerous Drugs Inspector in conjunction with the permit on the yellow form. The Controlled Drug Permit when collected by the importer should be forwarded to the overseas supplier.

8.4 PRECURSORS AND ESSENTIAL CHEMICALS

These chemicals are implicated in the manufacture of illicit drugs. The relevant substances are listed below:

Precursor Chemicals	Essential Chemicals
N-acetylanthranilic acid and its salts	Ammonia, Ammonium Hydroxide
Ergotamine	Acetic acid
Ergometrine	Acetic Anhydride
Ephedrine	Acetone
Isosafrole	Benzene
Safrole	Ethyl Ether
Lysergic acid (LSD)	Ethyl alcohol (Ethanol)
3,4-methylenedioxyphenyl-1,2-propanone	Hexane
Piperonal	Hydrochloric Acid
Piperidine	Isopropanol (IPA)
Pseudoephedrine	Methylene Chloride
Phenylpropanolamine	Methyl Ethyl Ketone (MEK)
1-Phenyl-2-propanone (PCP)	Methyl Isobutyl Ketone (MIBK)
	Potassium Carbonate
	Potassium Permanganate
	Phenyl Acetic acid and its salts
	Sulphuric Acid
	Sodium Hydroxide
	Sodium Carbonate
	Sodium Sulphate
	Toluene
	Xylene

NB. Each completed yellow form should have only one chemical.

8.5 RECORDS

The Chief Dangerous Drugs Inspector retains for inspection all records inclusive of invoices pertaining to sale/purchases as well as manufacturing records of controlled substances.

8.6 EXPLANATORY NOTES

These notes are included for emphasis in an effort to facilitate users.

8.6.1 Notices of Detention

The Customs Department issues Notices of Detention in instances where pharmaceuticals, food additives and chemicals or any other product regulated under the Acts and Regulations arrive in the island without the relevant permit in place. These notices are issued for goods intended for trading as well as for personal purposes.

They are to be presented to an Officer in the Pharmaceutical & Regulatory Affairs Department. If approved by the Department, the goods may be cleared from the port of entry on presentation to the Customs Officer. It is to be noted that approval for clearance from the ports is not automatic. Goods not approved may be seized for destruction or the importer may be allowed to return them to the Sender.

The type of Notice issued varies with the point of detention as follows:

- Airway Bill – Airport
- Parcel notice – Parcel Post Office
- Detention notice – Airport Or Seaport

8.6.2 Fees for service

There is a charge for the processing of each application of ten (10) items. This fee is instructed by the Food & Drug Regulations and may be amended from time to time as allowed by the legislation.

8.6.3 Validity of Permit Life

A period of one (1) year is allowed for the importation of goods approved on the Blue and Pink application forms. Six (6) months are allowed for

goods approved on the Yellow form

8.6.4 Pack Size:

This is the weight or volume of each unit of item being imported.

8.6.5 Unit

This is the total amount of each item being imported / e.g. 500ml; 2kg; 16oz; 5 gallon.

8.6.6 Name of Item on Permit

This should include, (where applicable) the chemical nomenclature, class or category of the item.

8.6.7 Special Permits

Drugs that are not registered but are required for optimal patient care (human/animal) may be imported on a special permit. This is issued on the submission of the application along with a letter and prescription from the attending Practitioner. The letter should indicate the name of the patient, the medical condition(s), and the desired therapy. It should be forwarded to the Director, Pharmaceutical & Regulatory Affairs Department (PRAD).

8.6.8 Amendment to Permits

An importer may wish to amend the permit application after it has been submitted approved and returned. The request for change may be allowed based on the circumstance.

In such instances the following documents should be submitted:

i Letter from the importer stating the problem.
ii The original permit.
iii Invoices of current shipment and for quantities already imported (if it is part of a shipment)

8.7 CONTACT INFORMATION

For further information please contact:

The Director
Standards & Regulation Division
Ministry of Health
2-4 Kings Street Kingston
Tel: (876) 967-1100-06, 948-4206
Fax: (876) 967-1629
website: www.moh.gov.jm

Appendix I

MINISTRY OF HEALTH
STANDARDS & REGULATION DIVISION
PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT
JAMAICA, WEST INDIES
REGISTRATION OF NEW DRUGS
FOOD AND DRUGS ACT 1964

Product Particulars:

1. NAME OF DRUG:
.....

2. GENERIC NAME OR NON-PROPRIETARY DESIGNATION OF DRUG:

.....

3. NAME AND ADDRESS OF MANUFACTURER:.....

.....

4. NAME AND ADDRESS OF APPLICANT:.....

.....

5. NAME & ADDRESS OF LOCAL REPRESENTATIVE (If different from above): -

.....

LIST OF REQUIREMENTS FOR ASSESSMENT PURPOSES:

1. Three copies of a summarized statement (not package insert) giving the information on:

   a. All ingredients present in the formulation;
   b. Dose, Dose Schedule, Route of administration;
   c. Therapeutic/diagnostic claims;
   d. Description of dosage form being registered;
   e. Contraindication/precautions;
   f. Side effects;
   g. Toxic effects, and protocol for treating toxicity or where applicable, antidote.

Appendix I

2. Details of the tests conducted to control the potency, purity, and stability.

3. Summary of:

   a. Clinical Pharmacology: pharmacodynamics; pharmacokinetics; bioavailability; bioequivalence;

   b. Efficacy: controlled studies; uncontrolled studies;

   c. Safety: adverse drug reactions in volunteers and where a new chemical moiety has been marketed for less than five (5) years, adverse drug reactions in patients.

4. A Certificate of Analysis (original, not photocopy) or a certified report containing: -
   a. Assay report on a recent batch of the product analysed;
   b. The method of analysis used.

5. Five (5) copies of a draft of every label bearing the address of the manufacturer proposed to be used in connection with the product, a batch/lot number and expiry date of the product.

6. Five (5) samples of the new drug in the finished pharmaceutical form in which it is to be sold along with adequate amounts of appropriate chemical and/ or biological reference standards of active ingredients necessary to perform analysises described in three (b).

7. A "**Certificate of a Pharmaceutical Product**" (original, not photocopy) bearing information as recommended by W.H.O. from the competent health authority in the country of manufacturer certifying that the drug is approved for use and registered in that country and the conditions under which it may be sold in that country.

8. A statement showing:

   a. The countries in which the product is approved for sale other than the country in which it is manufactured.

   b. Any country in which the product has been refused registration and the reasons for refusal.

9. Any other relevant information.

10. Official documents such as the Certificates of Pharmaceutical Product should be authenticated by the Jamaican Embassy or Jamaican Consulate in the country, and in cases where none of these is present by the British High Commission or British Embassy.

Appendix I

11. The document submitted **must** be in the English Language or authenticated translation should be bound in a hard cover with dimensions of approximately 9" x 11 ½ " and correctly indexed in the order presented above for easy reference.

12. The registration fee for each presentation is five thousand dollars (J$5,000.00). Cheques **must** be made payable to the Permanent Secretary, Ministry of Health.

13. All the above requirements must be submitted at the same time to the **PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT.**

NB. GENERIC COMPANIES ARE REQUIRED TO INDICATE THE EXPIRY DATE OF THE PATENT ON THE PRODUCT BEING SUBMITTED FOR REGISTRATION.

ACCEPTANCE OF REGISTRATION DOCUMENTS BY THE PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT IS NOT AN INDICATION THAT REGISTRATION IS AUTOMATIC.

FOR OFFICE USE ONLY

DATE RECEIVED:……..

NOTIFICATION SENT:……

ASSESSMENT COMMENTS:……

DATE APPROVED/REFUSED:……

M.H.F.D. 13 Revised December 1999.

Appendix 2

MINISTRY OF HEALTH
STANDARDS & REGULATION BRANCH
PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT
JAMAICA, WEST INDIES

REGISTRATION OF HERBAL PRODUCTS
FOOD AND DRUGS ACT 1964

PRODUCT PARTICULARS:

1. **NAME OF PRODUCT:**

.....

2. **GENERIC NAME OR NON-PROPRIETARY DESIGNATION OF PRODUCT:**

.....

3. **NAME & ADDRESS OF MANUFACTURER:** .....

.....

4. **NAME &ADDRESS OF APPLICANT**: .....

.....

LIST OF REQUIREMENTS FOR ASSESSMENT PURPOSES:

1. Three copies of a summarised statement (not package insert) giving the information on:

   a. All ingredients present in the formulation;
   b. Dose, Dose Schedule, Route of administration;
   c. Therapeutic/diagnostic claims;
   d. Description of dosage form being registered;
   e. Contraindication/precautions;
   f. Side effects;

Appendix 2

2. Details of the tests conducted to control the potency, purity, and stability.

3. A Certificate of Analysis (original, not photocopy) containing:-

   a. Assay report on a recent batch of the product analysed;
   b. The method of analysis used.

4. Five (5) copies of a draft of every label bearing the address of the manufacturer proposed to be used in connection with the product, a batch/lot number and expiry date of the product.

5. Five (5) samples of the product in the finished form in which it is to be sold along with adequate amounts of appropriate chemical and /or biological reference standards of active ingredients necessary to perform analyses described in two (2).

6. A **"CERTIFICATE OF FREE SALE"** (original, not photocopy)

7. A statement showing:

   a. The countries in which the product is approved for sale other than the country in which it is manufactured.

   a. Any country in which the product has been refused registration and the reasons for refusal.

8. Any other relevant information.

9. Official documents such as Certificates of Free Sale should be authenticated by the Jamaican Embassy or Jamaica Consulate in that country, and in cases where none of these is present by the British High Commission or British Embassy.

10. The document submitted **must** be in English Language or authenticated translation should be bound in a hard cover will dimensions of approximately 9" x 11 ½ " and correctly indexed in the order presented above for easy reference.

11. The registration fee for each presentation is five thousand dollars (J$5,000.00). Cheques **must** be made payable to the Permanent Secretary, Ministry of Health.

Appendix 2

12. All the above requirements must be submitted at the same time to the **PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT**.

N.B. ACCEPTANCE OF REGISTRATION DOCUMENTS BY THE PHARMACEUTICAL & REGULATORY AFFAIRS DEPARTMENT IS NOT AN INDICATION THAT REGISTRATION IS AUTOMATIC.

FOR OFFICE USE ONLY

DATE RECEIVED: .....

NOTIFICATION SENT: .....

ASSESSMENT COMMENTS: .....

DATE APPROVED/REFUSED: .....

M.H.F.D.13 Revised December, 1999

Appendix 3

MINISTRY OF HEALTH

STANDARDS AND REGULATION BRANCH
PHARMACEUTICAL AND REGULATORY AFFAIRS UNIT
FOOD AND DRUGS ACT 1964

PERMIT APPLICATION FOR FOOD AND DRUGS

FORMS SHOULD BE TYPEWRITTEN OR COMPLETED IN BLOCK CAPITALS

DATE .....

NAME AND ADDRESS OF IMPORTER

.....
.....
.....
.....

NAME AND ADDRESS OF SUPPLIER

.....
.....
.....
.....

This is to advise that permission is granted to Import the following Food/Drugs from the firm above

QUANTITY (Unit x Pack Size)	NAME OF ITEM(S)	NAME AND ADDRESS OF MANUFACTURER

CONDITIONS

As soon as the invoices are received you should return two (2) copies for the necessary processing.
These items should be imported before .....

M.H.F.D. 19.

Appendix 4

MINISTRY OF HEALTH

STANDARDS AND REGULATION BRANCH
PHARMACEUTICAL AND REGULATORY AFFAIRS UNIT
FOOD AND DRUGS ACT 1964

PERMIT APPLICATION FOR COSMETICS AND CHEMICALS

FORMS SHOULD BE TYPEWRITTEN OR COMPLETED IN BLOCK CAPITALS

DATE .....

NAME AND ADDRESS OF IMPORTER

.....
.....
.....
.....

NAME AND ADDRESS OF SUPPLIER

.....
.....
.....
.....

This is to advise that permission is granted to Import the following Cosmetics/Chemicals from the firm above.

QUANTITY (Unit x Pack Size)	NAME OF ITEM(S)	NAME AND ADDRESS OF MANUFACTURER

CONDITIONS

As soon as the invoices are received you should return two (2) copies for the necessary processing.
These items should be imported before .....

M.H.F.D. 19.

Appendix 5

MINISTRY OF HEALTH

STANDARDS AND REGULATION BRANCH
PHARMACEUTICAL AND REGULATORY AFFAIRS UNIT
FOOD AND DRUGS ACT 1964

PERMIT APPLICATION FOR PSYCHOTROPICS, NARCOTICS AND PRECURSORS

FORMS SHOULD BE TYPEWRITTEN OR COMPLETED IN BLOCK CAPITALS

DATE .....

NAME AND ADDRESS OF IMPORTER

.....
.....
.....
.....

NAME AND ADDRESS OF SUPPLIER

.....
.....
.....
.....

This is to advise that permission is granted to Import the following Psychotropics/Narcotics/ Precursors from the firm above.

QUANTITY (Unit x Pack Size)	NAME OF ITEM(S)	NAME AND ADDRESS OF MANUFACTURER

CONDITIONS

As soon as the invoices are received you should return two (2) copies for the necessary processing.
These items should be imported before .....

M.H.F.D. 19.