MINISTRY OF HEALTH & WELLNESS
DRUG REGISTRATION APPLICATION FORM

Completion of this form is necessary for consideration for drug registration.
Type or print legibly.

Application Date		Application No. *(for official use only)*	
Product Name		Product Registration No. *(for official use only)*	
Generic Name or International Non-proprietary (INN) name			

TYPE OF APPLICATION	
New	□
Renewal	□
Modification	□

PRODUCT LICENSEE INFORMATION			
Social Security No.			
Full name			
Date of Birth		Country of birth	
Permanent Address	Street	Town	District
Telephone number			
Email address			

COMPANY'S INFORMATION	
Business Name	
Trade License No.	
Date of issue	
Place of issue	

MANUFACTURER INFORMATION	
Name of Manufacturer	
Country of Manufacture	

DOCUMENTS TO BE SUBMITTED WITH APPLICATION FORM (FOR A DRUG NOT REGISTERED WITH A NATIONAL REGULATORY AUTHORITY)		
No.	**Document**	**Received *(for official use only)***
1	Ministry of Health & Wellness Pharmaceutical Wholesaler/Importer Licence	
2	Good Manufacturing Practice Certificate	
3	Manufacturer's Sanitary Licence	
4	Certificate of Pharmaceutical Product (when applicable)	
5	Free Sale Certificate (when applicable)	
6	Certificate of analysis	
7	Product sample	
8	Additional scientific technical information (optional)	

DOCUMENTS TO BE SUBMITTED WITH APPLICATION FORM (FOR A DRUG REGISTERED WITH A NATIONAL REGULATORY AUTHORITY)		
No.	**Document**	**Received** ***(for official use only)***
1	Registration documents from respective National Regulatory Authority	
2	Product Registration Number from respective National regulatory Authority	

AFFIDDAVIT		
I, _____ (licence holder) declare that the information detailed in this document is truthful and complies with the legal requirements; on the other hand, _____ (registered chemist and druggist) acting as the professional responsible for the product _____ (product name), declare under oath that the information concerning the name of the product, formulation and therapeutic indications are truthful and guarantee the good quality of the product. Consequently, we declare that this file meets the requirements for registration, so that the data contained in this application, are expression of truth and assume administrative and criminal liabilities.		
Name and signature of product licensee	Name and Signature of Chemist and Druggist	Date

FOR OFFICIAL USE ONLY	
Date received	
Receiving officer (Name and signature)	
Assessment officer (Name and signature)	
Notification sent	
Assessment comments	
Date approved/refused	
Approving Officer	
Ministry of Health & Wellness (stamp)	

LIST OF REQUIREMENTS FOR ASSESSMENT PURPOSES

The application form along with required documents should be submitted in a hard covered folder with ***Documents to be submitted in application form*** indexed in the same order as it appears in the form.

For a DRUG NOT REGISTERED WITH A NATIONAL REGULATORY AUTHORITY

1. A copy of Ministry of Health & Wellness Pharmaceutical Wholesaler/Importer Licence should be submitted.
2. A photocopy of a valid Good Manufacturing Practice Certificate
3. A photocopy of a valid Manufacturer's Sanitary Licence
4. A "Certificate of a Pharmaceutical Product" (original, not photocopy) bearing information as recommended by the World Health Organization 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.
5. Free Sales Certificate: if the country is not a member of the World Health Organization certification scheme this certificate must be submitted.
6. Original copy of the Certificate of Analysis of the product intended to be imported into Belize.
7. A product sample of the finished pharmaceutical form in which it is to be sold.
8. Additional scientific technical information upon request.
9. Official documents such as the Certificates of Pharmaceutical Product and Good Manufacturing Practice Certificate should be authenticated by the Belizean Embassy or Belizean Consulate in the country of origin and apostilled, respectively.
10. All documents submitted **must** be in the English Language or authenticated translation should be bound in a hard cover and correctly indexed in the order presented above for easy reference.
11. The registration fee for each product is one hundred dollars for new registration or fifty dollars for amended modification. This must be made payable to the Treasury Department and the original and a copy of payment should be presented with the application form:
    Cost Center – 19068
    Line Item – 11725
    Programme – 120
    Activity - 14

For a DRUG REGISTERED WITH A NATIONAL REGULATORY AUTHORITY

1. A copy of Ministry of Health & Wellness Pharmaceutical Wholesaler/Importer Licence should be submitted.
2. Registration documents from respective National Regulatory Authority (bearing product registration number); *see table below for a list of the accepted National Regulatory Authorities as legislated*
3. A product sample of the finished pharmaceutical form in which it is to be sold.
4. Additional scientific technical information upon request.
5. Official documents should be apostilled or authenticated by the Belizean Embassy or Belizean Consulate in the country of origin.
6. All documents submitted **must** be in the English Language or authenticated translation should be bound in a hard cover and correctly indexed in the order presented above for easy reference.
7. The registration fee for each product is five hundred dollars. This must be made payable to the Treasury Department and the original and a copy of payment should be presented with the application form:
    Cost Center – 19068
    Line Item – 11725
    Programme – 120
    Activity – 14

National Regulatory Authority

NRA Name	**Region/Country**
Therapeutic Goods Administration	Australia
The Brazilian Health regulatory Agency (ANVISA)	Brazil
Health Canada Drug and Health Products	Canada
Caribbean Regulatory System (CRS)	CARICOM
The Colombia National Food and Drug Surveillance Institute (INVIMA)	Colombia
National Directorate of Medicines of El Salvador (DNM)	El Salvadaor
European Medicines Agency database of manufacturing authorisations and of certificates of good manufacturing practice (EudraGMDP)	European Union
Central Drug Standard Control Organisation (CDSCO)	India
The Federal Commission for the Protection against Health risks (COFEPRIS)	Mexico
Medicines and Healthcare products Regulatory Authority (MHRA)	United Kingdom
The United States Food and Drug Administration	United States of America".

All the above requirements must be submitted as one package to the Drug Inspectorate Unit, Ministry of Health & Wellness. Incomplete submissions will be returned to the applicant.

Request for importation of orphan drug should be done directly to the Office of the Director of Health Services.