GOVERNMENT ANALYST- FOOD & DRUG DEPARTMENT INSPECTORATE
DRUG SUBMISSION APPLICATION
FOOD AND DRUGS ACT)
(CHAPTER 34:03)

Application #:_____

THIS FORM IS TO BE COMPLETED FOR ALL SUBMISSION TYPES
ONLY ONE FORMULATION SHOULD BE INCLUDED PER COPY OF THIS FORM.

1. Name of Agent/Importer: _____
2. Physical Address: _____
3. Telephone, Fax, Email, Website: _____
4. Mailing Address if different from 2: _____

   _____
5. Name and Address of Manufacturer: _____

   _____
6. Name of Contact Person: _____
7. Telephone, Fax, Email: _____
8. Type of Submission

   ☐ Prescription Only (POM) ☐ Non-prescription (OTC)

   ☐ Veterinary (POM / OTC) ☐ Biologicals
9. Brand Name: _____
10. International Non Proprietary Name : _____
11. Medicinal Ingredients :

Ingredient	Standard	Strength	Dosage Form	Route of Administration

12. Therapeutic Classification: _____
13. Indications, Contra-Indications and side effects _____

    _____

    _____
14. Proposed Expiry / Shelf Life : _____
15. Storage Requirements:_____
16. Finished Product Specifications and Limits, and description of the methods of analysis

    _____

    _____
17. Is the Drug presently marketed in Guyana? If yes, date of first introduction _____
18. Is the Drug registered in the country of manufacture.? If NO give reasons _____

    _____

20 Is the Drug approved for use in Canada, USA, UK or Australia as certified by the respective Regulatory Authorities? _____

If yes, attach a copy of Certificate of Registration

Address: IAST Building, University of Guyana Compound, Turkeyen, Georgetown, Guyana , P.O. BOX 1019
Telephone: 592-222-8857-61 Fax: 592-222-8855 Email: gafddgy@gmail.com

21 Are the following necessary documents / materials enclosed?

(i) A product dossier with the necessary information in accordance with the requirements for the Registration of a new drug (see attached sheet) □ Yes □ No

(ii) Product monograph. □ Yes □ No

(iii) Specifications for packaging materials in direct contact with the drug □ Yes □ No

(iv) A certified copy of a Certificate of the Pharmaceutical Product □ Yes □ No

(v) Drafts of inner and outer labels, package insert and product brochure □ Yes □ No

(vi) A batch certificate of the pharmaceutical product □ Yes □ No

(vii) Samples of the drug in the finished pharmaceutical form in which it is proposed to be sold □ Yes □ No

(viii) Reference standards of the active ingredients. □ Yes □ No

(ix) A certified copy of the WHO approval letter for biologicals □ Yes □ No

22 **For veterinary products only**

- Species recommend for use :_____
- Used for treatment of food producing animals: □ Yes □ No
- Withdrawal time:_____

Species	Days	Hours

23. Full Name of Authorized Signing Official: _____

_____

22. Official Designation: _____

_____ _____

Signature Date

Registration fee is twenty thousand dollars ($20,000.00) per dosage form. All cheques should be made payable to the Permanent Secretary, Ministry of Public Health.

FOR OFFICIAL USE ONLY

Date received: _____ - _____ - _____ Received by: _____

Receipt No.:_____ Date: _____ - _____ - _____

Licence #: _____ Expiry Date: _____ - _____ - _____

GOVERNMENT ANALYST FOOD AND DRUG DEPARTMENT INSPECTORATE SUBCONTRACTOR NOTIFICATION

The Government Analyst Food and Drug Department wishes to inform you that all or part of the inspection service may be subcontracted to an approved subcontractor. Notwithstanding, the final outcome of this inspection activity rests with the Food and Drug Department.

All Persons acting on behalf of the Government Analyst Food and Drug Department are required to do so with fairness and honesty.

Subcontractors are obligated to keep confidential all information obtained or created during the performance of their duties.

Any breach of these requirements will result in the appropriate disciplinary action being taken by the Director.

Director
Government Analyst Food and Drug Department

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