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National Agency for Food & Drug Administration & Control (NAFDAC)

Drug Evaluation & Research Directorate

GUIDELINES FOR IMPORTATION OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)

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1.0 GENERAL

1.1 This document is intended to provide guidance on the process for obtaining PERMIT for Active Pharmaceutical Ingredients (APIs) by Importers, Distributors, Brokers, Marketing Authorization Holders (MAH) who import or act as site for physical importation of APIs for own use or distribution, re-labellers, re-packers and other end users (e.g. educational, health and research institutions) in Nigeria

1.2 This document is also intended to provide guidance for the control of APIs locally manufactured and distributed or exported out of the country.

1.3 API should not be imported into Nigeria unless the Finished Pharmaceutical Products (FPP) manufacturers, marketers, re-labelers, re-packers and other end users (e.g. Educational, health and research institutions) has been duly issued a Permit or Authorization to do so.

2.0 DEFINITIONS AND ABBREVIATIONS

2.1 API(s) - Active Pharmaceutical Ingredient(s)
2.2 CTD - Common Technical Document
2.3 DS - Drug Substance
2.4 ASMF (DMF) - Active Substance Master File (Drug Master File)
2.5 LOA - Letter of Access / Authorization
2.6 FPP - Finished Pharmaceutical Product
2.7 MA - Marketing Authorization
2.8 MAH - Marketing Authorization Holder

2.9 Active Pharmaceutical Ingredient (API) or Drug Substance (DS)
A substance used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.

2.10 Drug Master File (DMF)/Active Substance Master File (ASMF)
A document containing complete information of an Active Pharmaceutical Ingredient or finished drug dosage form. The drug manufacturer must include adequate information or data to demonstrate that the drug substance used for particular drug of interest will not in any way affect the safety and efficacy of the drug. The DMF contains complete and factual information on drug product chemistry, manufacture, stability, purity, impurity profile, packaging and the GMP of any human drug product. Drug Master Files consist of two parts namely open and closed parts.

3.0 SCOPE

These guidelines apply to the following:

3.1 All Drug Substances (DS) or Active Pharmaceutical Ingredients (APIs) that fall within the definition of APIs as given in this document whether manufactured locally, imported, exported, marketed, repackaged, relabeled, distributed, sold or used in the manufacture of drug products, for new products or generics in Nigeria except those materials indicated under exemption from this guidelines.

3.2 Local manufacturers of Finished Pharmaceutical Products (FPPs) in Nigeria authorized by the Agency and intending to import APIs for manufacture of their products.

3.3 Applicants who import APIs solely for the purpose of sale and distribution.

3.4 Applicants who hold wholesale authorization for distribution and sale of APIs but are not direct importers of APIs (DMF not required).

3.5 Applicants who are manufacturers of APIs (local or foreign) that export, distribute or import APIs into the Nigeria.

3.6 Applicants or Institutions who import APIs for the purpose of Research and Development (R&D).

3.7 Brokers who import APIs for clients.

4.0 APPLICABILITY

4.1 Applicants regarded as API manufacturers, FPP manufacturers, MAHs, Importers, Brokers, Exporters, Educational, Research or Health institutions; should submit DMF or equivalent documentation for API(s) for which permit is sought either for the purpose of distribution or to be used in the manufacture of or research into;

4.1.1 Investigational medicinal product

4.1.2 New drug application

4.1.3 Abbreviated new drug application

4.1.4 Variation, Supplements or amendments to any of the above

4.2 **Exemptions to this guidance**

4.2.1 The requirements of these guidelines do not cover the following groups of materials:

a. Biotechnology or biological active substances
b. Immunological active substances
c. Intermediates from process of APIs manufacturing
d. Starting materials for APIs.

5.0 Procedure

The procedure for the control and issuance of permit for APIs is based on the following principles:

5.1 Understanding of the production and quality control for the manufacturer of the API
5.2 Assessment of API data and information including changes and variation submitted by the API manufacturer/Applicant
5.3 Assessment of manufacturing site(s) for compliance with GMP requirements for APIs
5.4 Post marketing surveillance through randomized sampling and testing of APIs
5.5 Handling complaints and recalls
5.6 Local and external monitoring of co-agencies on complaints

6.0 Documentation for Importation of API(s)

6.1 All applications for API import permit should be made through the Federal Government Single Trade Portal at https://app.trade.gov.ng/elicense or trade.gov.ng

6.2 The following documents to support the application should be submitted through the Federal Government Single Trade E-Portal:

6.2.1 An application for permit to import drug substance(s) or Active Pharmaceutical Ingredient(s) should be made on the company's letter-headed paper, signed by the Managing Director of the company or designated technical officer and addressed to: The Director-General, National Agency for Food and Drug Administration and Control (NAFDAC)

ATTENTION: Director, Drug Evaluation & Research Directorate,

NAFDAC Office Complex, Apapa-Oshodi Expressway.

Isolo, Lagos.

6.2.2 The application letter should indicate the applicant's address, location address of API source, the list of APIs and the purpose for which the API is required – importation, distribution, sale, manufacturing of FPP etc.

6.2.3 Separate application letters should be submitted for different sites or sources of APIs.

6.2.4 Applicants should duly complete an API request e-form on the portal under section of trader/client module to indicate the name of API and source of import (name and site address of API manufacturer), API grade e.g. USP or BP., size of unit pack e.g. 25kg bag, total amount requested in Kilogram (KG) per API, commodity code number as specified by the Nigeria Customs Service.

6.2.5 An API manufactured from different sites, or with different synthesis route or of different salts should be treated as separate item when entering the list of APIs in the request form.

6.2.6 The DMF (open and closed parts) or equivalent documentation (e.g. Common Technical Document modules 1 and 3) from the API Manufacturer(s) should be provided. This can be scanned and uploaded as an attachment to the application. File size limit for scanned documents is 2 MB but there is no limit for the total

size of all attachments. The file-size of an attachment can be reduced by scanning it in black and white instead of grayscale and with a scanning resolution of maximum of 300dpi.

NOTE: As a result of file size limitation for scanned document attachments, DMFs (labeled) can also be submitted in a USB flash drive to:
The Director, Drug Evaluation & Research Directorate
1st Floor, NAFDAC Office Complex,
Isolo, Lagos.

6.2.7 Current GMP Certificate or evidence of GMP compliance of the actual site of API manufacture and shipment to the applicant.

6.2.8 Certificates of Analysis of three (3) commercial scale batches of the API from the API manufacturer with the date of test release not exceeding six months from date of application submission.

6.2.9 Letter of Access (LOA) or Letter of Authorization from the API source for access to the closed part of the Company's DMFs.

6.2.10 Certificate of business registration or incorporation of the applicant company

6.2.11 Annual License to Practice of the Superintendent Pharmacist and Certificate of Premises Registration for the Company.

6.2.12 Evidence of payment for permit to import requested APIs following issuance of NAFDAC payment advice for API import permit

6.2.13 A written assurance that no significant changes in the manufacturing method or processing have taken place following the approval of the API and a declaration from the manufacturer that the local MAH and NAFDAC will be notified should there be any change in the API specifications that is likely to affect the product quality or safety. This declaration should include the product name, dosage form and strength including the name of the local MAH responsible for registration or information about the importer, vendor or Broker

7.0 Inspection

7.1 For FPP manufacturers and non-manufacturing importers, a risk-based approach is applied for GMP inspection of the FPP manufacturing site and importer's warehouse respectively, and this will be done following successful assessment of DMF or equivalent documentation and payment of inspection fee.

7.2 The modalities for inspection of the manufacturing site will be communicated to the applicant and a satisfactory report of such inspection or risk assessment in lieu of site inspection will be uploaded by DER inspectors on the e-portal for further processing of the application.

8.0 Approval

8.1 A permit which authorizes the applicant to import the API is issued after a satisfactory review of DMF or equivalent documentation, satisfactory inspection of the manufacturing plant/warehouse and payment of appropriate API import permit fee.

9.0 Application for Permit to Import API by Educational, Research or Health Institutions

9.1 The following documents are to be submitted online by other applicants (Educational, Research and Health Institutions) through the Federal Government Single Trade E-Portal:

- 9.1.1 Covering letter signed by head of institution
- 9.1.2 Duly completed online API application e-form
- 9.1.3 Certificate of Analysis of API from manufacturer
- 9.1.4 Evidence of payment for PI Import Permit
- 9.1.5 A letter of undertaking stating that the API is strictly for academic or research purposes

9.2 API importation by this set of applicants should not exceed 25kg per item

9.3 Importation of API by educational, research and health institution may not require site audit or ASMF assessment. However, applicants in this category must pay the appropriate fees.

10.0 API Brokers

10.1 This category of traders and importers are required to fulfil all requirements under sections 6.0 - 8.0.

10.2 API Brokers should in addition provide evidence of requests or Local Purchase Orders from their clients to justify any request for API Import Permit.

10.3 Where a broker delivers the ordered consignment of API(s) directly to the clients, the warehouse of the client's facility will be inspected and must meet all requirements for Good Storage Practice and Good Warehousing Practice.

10.4 Brokers operating own storage facilities for pickup of orders by clients will also have their warehouses inspected for compliance to Good storage, warehousing and distribution practices.

11.0 Disposal and Use

11.1 All categories of API importers and local manufacturers as enumerated under this guidance will be subject to track and trace of disposal, utilization, distribution or use of all API receipts for which they obtained import permits.

11.2 All records of API receipts, use, sale, distribution, rejects, sub-orders etc. are expected to be maintained for the purpose of verification by NAFDAC

12.0 Exemptions from DMF/Equivalent Submission

12.1 DMF may not be required for common inorganic salts (sodium chloride salts, common electrolyte used as APIs in injection / infusions/dialysis, naturally occurring organic acids and their salts e.g. ascorbic acid, sodium citrate, simple mono and disaccharides- glucose and sucrose but evidence must be submitted by the MAH for FPP that these substances are obtainable from reliable sources and that they consistently comply with pharmacopeia specifications

13.0 Details of E-Processing of Applications for Permit to Import API

13.1 **Applicant's module**

13.1.1 Applicants should log in to Federal Government Single trade portal at trade.gov.ng to make a formal request or application for API Import Permit.

13.1.2 Applicants should complete all online information required for the processing of the type or category of API Import permit desired e.g. for marketer, broker, institution, manufacture of FPP.

13.1.3 Applicants should upload scanned copies of original documents indicated in sections 6.0 – 10.4 of these guidelines which are required for the category of API import permit desired i.e. FPP manufacturer, marketers and distributors, Brokers and institutional organization as may be applicable.

13.1.4 The applicant on completion of the e-application module and upload of scanned copies of all documents required online should click the submit button on the API window to submit application.

13.1.5 Where the file size of DMFs/ASMFs exceed the permitted size for uploading on the e-portal, the applicant should be submitted the documents in a USB flash drive to the office of the Director, Drug Evaluation and Research (DER), NAFDAC, Isolo, Lagos.

13.2 **Documentation module**

13.2.1 Submitted applications with accompanying documents will be screened by designated officers in DER Directorate for completeness, adequacy and correctness.

13.2.2 Unsatisfactory submissions will be queried and returned to applicants to make required amendment, inclusion, corrections and resubmit or effect cancellation.

13.2.3 Satisfactory submissions will be validated to the inspection module for further processing.

13.3 **Inspection module**

13.3.1 Appropriate assessment of the applicant's manufacturing/storage facility will be conducted through either risk -based evaluation or onsite inspection to determine compliance and suitability for purpose.

13.3.2 Only satisfactory report of facility assessment will be endorsed and forwarded to vetting stage for further processing.

13.4 **Vetting Module**

13.4.1 All applications will be reviewed at vetting stage for completeness and appropriateness regarding all information and documents uploaded by applicants. This will include outcome of inspection of applicant's facility or warehouse, list of requested APIs (grade and quantities) and summary of DMF/ASMF review.

13.4.2 All satisfactorily vetted applications will be costed or assessed according to approved NAFDAC tariff for the respective applicant category.

13.4.3 Satisfactorily vetted applications will be endorsed and forwarded to the Finance & Accounts Directorate for payment while a payment advice notification is also automatically sent to the applicant.

13.4.4 Applicants will be required to pay the statutory fees on receipt of the payment advice notification through the Treasury Single Account (TSA) and submit evidence of payment to NAFDAC Finance & Accounts Directorate to obtain a receipt.

13.4.5 The Finance & Accounts Directorate will verify the payment of the fee for Permit to Import API before issuing a receipt; uploading the payment information unto the e-portal and endorsing the application back to the Vetting Module.

13.4.6 The endorsed application from Finance & Accounts Directorate will be vetted to confirm payment information. Necessary adjustment on quantities of APIs requested may be made where necessary and the application will be recommended for approval.

13.4.7 Where the outcome of vetting of the application is unsatisfactory, a query will be raised to the applicant for any shortfall observed during the vetting or the application is returned to the Inspection Module for necessary action.

13.5 **Approval module**

13.5.1 The Director, DER will give approval for any application transmitted from the vetting module that has been satisfactory reviewed and found to comply with all requirements for the issuance of Permit to Import API.

13.5.2 Any application adjudged to be deficient would be queried accordingly and returned for further review.

13.5.3 Approved applications are automatically transmitted to the applicants on the e-portal and the applicants are required to print out the permit for their use.

13.6 **Post approval Request**

13.6.1 Upon an initial approval, an applicant may request for additional APIs or additional quantities of approved items by following all the steps enumerated for processing a new application.

13.6.2 DMF/ASMF submission will be required for additional items but not for additional quantities of approved items.

NOTE

All approved API import permits must be utilized within the same calendar year of issuance.

14.0 TARIFF

14.1 Please to refer to the appropriate section in the NAFDAC Approved Tariffs available at www.nafdac.gov.ng.

Note: fees will be charged per product and site (All fees attract 7.5% VAT)

15.0 CORRESPONDENCE

All correspondence should be addressed to:
The Director-General (NAFDAC)
Attn: The Director,
Drug Evaluation & Research Directorate
1st Floor, NAFDAC Office Complex,
Isolo Industrial Estate, Oshodi-Apapa Expressway
Isolo, Lagos State.
NAFDAC website: www.nafdac.gov.ng
E-mail address: der.headquarters@nafdac.gov.ng