REGISTRATION AND REGULATORY AFFAIRS DIRECTORATE

GUIDELINES FOR ADDITIONAL SOURCE AND/OR CHANGE OF SOURCE OF REGISTERED IMPORTED REGULATED PRODUCTS IN NIGERIA NAFDAC/RR/016/00

A. GENERAL

1. These guidelines are for the interest of the general public and in particular, industries in Nigeria that have registered NAFDAC regulated products.

2. It is necessary to emphasize that, no regulated product should be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of decree 19 of 1993 (as amended) and the accompanying guidelines.

3. Additional source refers to another manufacturing facility used for the manufacture of an already registered product (within or outside the original country of manufacture) without any change in the product formulation.

4. Change of source refers to change of manufacturer of an already registered product (within or outside the former country of manufacture) without any change in the product formulation.

5. The Product Registration Certificate shall be valid at time of application.

B. APPLICATIONS

1. (a) An application for change of source / additional source (as appropriate) of a registered regulated product should be made by the manufacturer / manufacturer's representative holding the Power of Attorney.

2. (a) The applicant should obtain and submit to the office of the Director (Registration and Regulatory Affairs) the prescribed application form which must be properly filled with all required information.

   (b) A separate application form shall be submitted for each regulated product.

C DOCUMENTATION

The following documents shall accompany the application;

1 Power of Attorney which should be:
   a) Notarized by a Notary public in the country of manufacture.

b) Issued by the manufacturer of the product.
c) Signed by the responsible officer of the Company, stating the names of the products to be registered. (This may not be required for same name corporations since such information is already with NAFDAC)

OR

Contract Manufacturing Agreement shall be
a) Notarized by a notary public in the country of manufacture.
b) Signed by both parties stating names and designations of the signatories with the names of all the products to be registered and other relevant clauses clearly explained in an unambiguous language.

2 Manufacturing Licence / Certificate shall be: (applicable only to drugs from India and China only)
a) Issued by a relevant health/regulatory body
b) Authenticated by the Nigerian Embassy in the country of origin. In countries where no Nigerian Embassy exists, British High Commission or any Commonwealth or ECOWAS country commission can authenticate.
c) Indicate the name and address of manufacturer and products to be registered.

3) Certificate of Pharmaceutical Products (COPP – WHO FORMAT) (drug products only)
a) Issued by the relevant health/regulatory body
b) Authenticated by the Nigerian Embassy in the country of origin. In countries where no Nigerian Embassy exists, British High Commission or any Commonwealth or ECOWAS country commission can authenticate

4 Current Good Manufacturing Practice (GMP) Certificate of the manufacturing facility.(as applicable)
a) Issued by the relevant health/regulatory body
b) Authenticated by the Nigerian Embassy in the country of origin. In countries where no Nigerian Embassy exists, British High Commission or any Commonwealth or ECOWAS country commission can authenticate.

5 Certificate of Registration of Brand Name (not necessary for same name corporation) with the trademark Registry in the Ministry of Commerce in Nigeria/ Evidence of Trademark approval from Federal Ministry of Commerce & Tourism Abuja. This should be done in the name of the owner of trademark as the case may be.

6 Comprehensive Certificate of Analysis issued by the manufacturer with analyst name and designation.

7 Current Annual Licence to Practice of the Superintendent Pharmacist issued by the Pharmacists Council of Nigeria. (Drug products only)

8 Current Certificate of Registration Retention of Premises issued by the Pharmacists Council of Nigeria. (Drug products only)

9 A letter of invitation to inspect the factory abroad which should state the full location address of the manufacturer, Name of contact person, e-mail address, current phone no. & fax no., guide map illustrating the shortest land/air route to the factory overseas.

10 Evidence of product registration by NAFDAC.

11 All documents must be found satisfactory for issuance of permit to import.

D LABELLING

Product formulation and labeling information should comply as previously registered.

E TARIFF

All payments to the Agency are in bank draft in favour of National Agency for Food and Drug Administration and Control.

1. Registration form per drug product is five hundred naira (₦500.00).
2. Registration form for other regulated products is two hundred and fifty naira only (₦ 250:00)

3	Change of source for drugs to different manufacturer	
	POM	₦ 250,000:00 + 5% VAT
	OTC	₦1, 000,000:00 + 5% VAT
4	Change of source for drugs to same name manufacturer	
	POM	₦150, 000:00 + 5% VAT
	OTC	₦ 250,000:00 + 5% VAT
5	Additional Source for food products:	₦ 250,000.00 + 5% VAT
6	Change of Source for food product:	₦ 450,000:00 + 5% VAT
7	Change of source for cosmetic products:	₦ 750,000:00 + 5% VAT
8	Change source for herbal products:	₦ 375, 000:00 + 5% VAT
9	Nutraceuticals	₦750, 000:00 + 5% VAT
10	Medical devices:	₦ 250, 000:00 + 5% VAT

Processing fee per regulated product for all additional sites belonging to same name corporation is one hundred and fifty thousand naira only plus 5% VAT (=N=150,000:00 + 5% VAT)

NOTE
Where the additional site belongs to another company even of the same management, the application should be treated as additional source, full fees shall apply.

F All correspondence and application should be addressed to:

The Director,
Registration & Regulatory Affairs
NAFDAC
Central Laboratory Complex
Oshodi, Lagos.
NAFDAC website: www.nafdac.gov.ng
e-mail address: registration@nafdac.gov.ng
Telephone numbers: +234-1-4772452, 1- 4772458, 1- 4748627, 1- 4772455