NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

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Your Ref: ..... *Our Ref:* ..... *Date:* March 23, 2020

ADHERENCE TO CRIA REQUIREMENTS AND GUIDELINES

Find a summary of requirements for processing of CRIA and attached Guidelines.

1. Product / Brands **can only be exported to the company holding** the Product Brand Name (Marketing Authorization) or to the Company mentioned in the NAFDAC

Registration Certificate. In case of any deviation an electronic approval would be issued by NAFDAC for the change in Nigerian Importer. This e-approval must be provided by importer before processing the CRIA.

2. "Treasury Receipt" is NOT to be considered as product registration proof. We require NAFDAC certificate or Valid Import Permit.
3. All primary & secondary packing material should bear the name of manufacturer with address and the name of Nigerian Marketing Authorization holder only as indicated in the NAFDAC Product Registration Certificate. **(No other importer name is to be printed on the packing material apart from the market authorization holder.)**
4. All product primary & secondary packing material (as the case may be) to be exported and provided for inspection should clearly bear the respective NAFDAC Product Registration Number as indicated on the NAFDAC Product Registration Certificate.
5. Stickering of Product NAFDAC Registration Number, Manufacturer's Name with Address, Name & address of the Nigerian Marketing Authorization holder is strictly **"NO"**.
6. Different design packing for same Brand Name and Strength is not allowed (e.g. Packing Diclofenac Tablets in different color packs and different color tablets with same NAFDAC Registration No. printed on the packing material is not allowed).
7. The packing of the product (pack size) should be same as mentioned in the NAFDAC certificate. If the product is being packed in different packing (pack size) other then what is mentioned in NAFDAC certificate then kindly also provide Pack Size Extension Letter issued by NAFDAC competent authority;
8. Product(s) with special "Import Permit" issued by the competent authority at Nigeria should clearly mention the name & address of the manufacturer in India.

9. Clean Report of Inspection and Analysis (CRIA) Consultants are required to sample every product imported but should randomly select twenty percent (20%) of total batches of products to be exported.
10. All Finished Pharmaceutical Products being shipped to Nigeria shall come with a sample of the API which will be tested along with the Finished Pharmaceutical Products at NAFDAC's approved labs by the CRIA agent.
11. All bulk Active Pharmaceutical Ingredients being shipped into Nigeria must come with Dug Master File (DMF) as posted on NAFDAC's website under "Notes to the Industry". If manufacturer cannot give DMF to importer/Market Authorization Holder, it must be sent directly to DER.
12. If the DMF cannot be immediately provided, the importer will be given a "one off" grace for the API to be inspected and tested by the CRIA Agent pending when the DMF will be provided.
13. "Certificate of Pharmaceutical Product" (COPP) has to be provided as a hard copy for issuing the related CRIA for each inspected Pharmaceutical Finished Formulation product and for each inspection which would become part of CRIA Document for clearance of the said consignment at Nigeria.
14. Copy of FORM M is to be provided.
15. Copy of Electronic Registration Certificate is required for Pharmaceutical Finished Formulations.
16. Testing of product has to be done for all the parameters claimed in Product COA (or as per Pharmacopeia claimed) unless the NAFDAC approved Indian Laboratory does not have facility to test any particular parameter for which CRIA agent contact NAFDAC for approval to use another laboratory.

18. Photographs of the sample products have to be taken which is a part of CRIA.