GUIDANCE DOCUMENT FOR CARRYING OUT CRIA SERVICES BY CRIA AGENTS

This is a summary of procedures and requirements for the issuance of CRIA reports to Exporters/Manufacturers. CRIA Agents are required to strictly abide by the set requirements as issued by NAFDAC. Please note that activities would be monitored from our end in Nigeria. On no occasion should you ignore NAFDAC laid down requirements and Guidelines for processing of CRIA. Where there are any challenges or need for clarification, kindly ensure you contact NAFDAC and obtain approval before processing CRIA or otherwise. Any defaulting CRIA Consultant would be sanctioned if discovered that the CRIA guidelines was not followed during the processing of CRIA for shipments.

Find below a summary of conduct and requirements for processing requests for CRIA services on behalf of NAFDAC.

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 license would be issued by NAFDAC for the change in Nigerian Importer. This e-license must be provided by importer before processing the CRIA.
2. "Treasury Receipt" is NOT to be considered as proof of product registration. You are required to request for a valid NAFDAC certificate or Import Permit and accompanying e-license.
3. **A copy of the CRIA Report issued to any exporter MUST be attached on PIDCARMS as part of documents provided for CRIA issuance.**
4. **All Remittances accruable to NAFDAC must be remitted to NAFDAC on quarterly basis and as when due.**

5. 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.)**
6. All product primary and 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.
7. Stickering of Product NAFDAC Registration Number, Manufacturer's Name with Address, Name and address of the Nigerian Marketing Authorization holder is strictly not allowed.
8. 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).
9. The packing of products (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 the Exporter/Manufacturer is required to also provide Pack Size Extension Letter issued by NAFDAC.
10. Packaging Material on drums / bags / large containers etc should be pre-printed with stencil and should be permanent in nature. Where labels are pasted on the Packaging Material (Drums / bags / large containers etc.), the labels should be made of PVC or any other such material that is water resistant and cannot be torn or the indicated details washed off.
11. The details mandatory to be indicated on these Packaging Material (drums/bags/ containers etc.) / Labels are :

    - Product Name:
    - Batch Number:
    - Manufacturing Date:
    - Expiry Date:
    - Manufacturer's name:
    - Manufacturer's full location address:
    - Package No: ___ of ____

12. You must also request the manufacturing license of the manufacturers to confirm that they are duly licensed manufacturers in your country.
13. Product(s) with special approvals as issued by NAFDAC should clearly mention the name & address of the manufacturer in India.
14. 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.
15. All Finished Pharmaceutical Products being shipped to Nigeria shall come with a sample of the Active Pharmaceutical Ingredients (API) which will be tested along with the Finished Pharmaceutical Products at NAFDAC's approved labs by the CRIA agent.
16. Where there are multiple APIs in a particular product, you are required to sample a maximum of two APIs in that particular product.
17. 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.
18. 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.
19. Certificates of Pharmaceutical Product (COPP) should be submitted by Exporter/Manufacturer for issuance of CRIA for every inspected Pharmaceutical Finished Formulation product to be exported to Nigeria.
20. Copy of FORM M is to be provided as part of documentation to be provided by Exporter.
21. Copy of Electronic licenses is required for all regulated products no matter the type of approval.
22. DO NOT provide CRIA services to clients without confirmation of the e-license submitted by Exporter/ Manufacturer on PIDCARMS. Where an e-license is not found on PIDCARMS, you are required to seek confirmation/update of such e-license on PIDCARMS. This also applies to any incidences of missing items.

23. **All documents submitted on PIDCARMS must be in English language and where in any other language, an interpretation is to be provided.**
24. CRIA agents **MUST** ensure that all reports issued are immediately uploaded on PIDCARMS. Issuance of CRIA Reports without uploading same on PIDCARMS is not acceptable.
25. Testing of products must entail all parameters claimed in Product COA (or as per Pharmacopeia claimed) unless the NAFDAC approved Laboratory does not have facility to test any particular parameter. Where this occurs, the CRIA agent **MUST** contact NAFDAC for approval to use another laboratory.
26. Where any of the three (3) laboratories that you have chosen does not have capacity to conduct particular tests, you are allowed to choose from the other NAFDAC approved laboratories but you must seek approval from NAFDAC before engaging any laboratory outside the three (3) you had submitted for approval. Where any of the approved laboratories cannot conduct a test, approval must be sought from NAFDAC before engaging any other laboratory. **For no reason should any CRIA Agent patronize any laboratory that is not approved for that CRIA agent without seeking clear approval from NAFDAC.**
27. Where there is an incidence of unsatisfactory laboratory report on any consignment of regulated products, **you are required to immediately report the failure to NAFDAC within 24 hours of notification by the Approved CRIA laboratory**.
28. Where an Exporter/Manufacturer contests the outcome of a failed laboratory evaluation, NAFDAC should be contacted for directives on the next line of action within 24 hours of complaint by the Exporter/Manufacturer. Where NAFDAC approves that samples are sent to a designated laboratory, you should within three (3) working days send all batches of the product to another CRIA laboratory after payment for the new service by the Manufacturer/Exporter.
29. You must ensure that you do not process CRIA for any consignment with Pictorial representation of Prescription Only Medicines and you are advised to contact NAFDAC where you are not clear about the status of the packaging of any regulated product.
30. Photographs of the sample products and the container for shipping have to be taken as part of documents to be submitted on PIDCARMS.

31. You must conduct Container Stuffing Inspection of all consignments exported to Nigeria and **provide Names and Photograph of the Inspector(s)** who conducted the Inspection as part of the Inspection Report submitted on PIDCARMS.
32. CRIA Reports uploaded on PIDCARMS must have the following list of documents:
    a) Bill of Laden
    b) Form M (Governments and United Nation Agencies shipments are exempted from this)
    c) Inspection Report
    d) Invoice
    e) Laboratory Analysis Report (Certificate(s) of Analysis)
    f) Packing List
    g) Photo-Container Exterior
    h) Photo-Container Interior
    i) Photo-Product Label

    It is now mandatory that you include these documents as atttachments on PIDCARMS
33. Kindly note that you are not allowed to form any alliance with any **delisted CRIA Agent or Laboratory** in the course of performing CRIA services for NAFDAC.
34. No CRIA Agents is allowed to engage in unethical competition with other CRIA Agents.
35. Any manufacturer and importer that presents request for CRIA with all necessary documents but did not complete the process as a result of an issued query by any CRIA Agent must be reported to NAFDAC within the shortest possible time via the official email of the Director (Ports Inspection, NAFDAC), the Secretary of the CRIA committee and CRIA email (cria@nafdac.gov.ng). The report to NAFDAC should contain available details of the shipment and documents presented.
36. All CRIA Agents are required to abide by the above requirements and other extant rules in the Consultancy Agreement signed with NAFDAC and accompanying CRIA Guidelines.
37. Note that this document would be updated from time to time whenever the need arises.

Thank you.

Signed:
NAFDAC Management