TITLE: APPLICATION FORM FOR LOT RELEASE OF VACCINES AND/OR OTHER BIOLOGICAL PRODUCTS

THIS APPLICATION FORM SHOULD BE COMPLETED AND SUBMITTED TO THE FOOD AND DRUGS AUTHORITY (FDA) WITH ALL OTHER DOCUMENTATION FOR LOT RELEASE.

Cover letter addressed to:
THE CHIEF EXECUTIVE
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS-ACCRA
GHANA.

SECTION A:

1	APPLICATION CATEGORY	
	Application type (tick as applicable options)	☐ Routine release ☐ Exceptional case Justify (if exceptional case is applicable):_____

SECTION B:

1.0	APPLICANT INFORMATION	
1.1	Name & address of Marketing Authorization Holder/Applicant	
1.2	Name & Address of Importer (consignee)	
1.3	Name and Address of Exporter (Consignor)	
1.4	Name & Address of storage/Warehouse including GPRS	
1.5	Contact Person	
1.6	Contact phone number.	

1.7	Email Address	
1.8	Details of local agent	• Name of company: • Address: • Contact person: • Phone number: • E-mail:
2.0	**MANUFACTURER(S) (IF DIFFERENT FROM MAH) (*please provide list of all manufacturers involved)***	
2.1	Name & Address (including units and blocks as applicable)	
2.2	Contact Person	
2.3	Contact phone number	
2.4	Email Address	
2.5	Details of other manufacturer(If any)	
3.0	**VACCINES AND/OR OTHER BIOLOGICAL PRODUCT INFORMATION**	
3.1	Product type	☐ Vaccine ☐ Other Biological product: please specify_____
3.2	Full Name of Product (proprietary name) as registered by the FDA	
3.3	International Non-Proprietary Name (INN)	
3.4	Ghana FDA registration number	
3.5	Lot Number(s) of Product	
	Bulk number / Component number	
3.6	Date of Manufacture	
	Date of start of period of validity	
3.7	Date of Expiry	
3.8	Country of Origin	

3.9	Name of Shipper in the Country of Origin (if different from consignor	
3.10	Storage Conditions: (*e.g.* Between 2° C and 8°C. Refrigerate. Do not freeze)	

3.11	Type of final container for Product	☐ Vial ☐ Ampoule ☐ Prefilled syringe ☐ Others; please specify_____
	Volume per container (Content volume per container)	
4.0	**DILUENT INFORMATION (IF APPLICABLE)**	
4.1	Name of Diluent	
4.2	Lot Number(s) of Diluent	
4.3	Date of Manufacture	
4.4	Date of Expiry	
4.5	Storage Condition(s)	
	Name & address of manufacturer	
4.6	Type of Final Container for Diluent	☐ Vial ☐ Ampoule ☐ Prefilled syringe

		☐ Others; please specify_____
	Volume per container (Content volume per container)	
5.0	**IMPORTATION DETAILS**	
5.1	Date of Importation *(dd/mm/yr)*	
5.2	Commercial invoice	
5.3	Quantity in Primary Packaging	
5.4	Quantity in Secondary Packaging	
5.5	Total no. of Units per Consignment (Specify total no. of doses of vaccine/plasma, sera consignment)	
5.6	Dosage Form	☐ Liquid/Solution/suspension ☐ Freeze Dried/Lyophilized
6.0	**DESCRIPTION OF CONSIGNMENT PACKAGING & TRANSPORTATION**	
6.1	Arrival Date	
6.2	Transit Point (s) (if any)	
6.3	Route of Transportation	☐ By air ☐ By sea
7.0	**STORAGE STABILITY DETAILS; SHELF-LIFE**	
7.1	The Shelf-Life from the Date of Manufacture.	
7.2	Remaining Shelf-life from the Proposed Date of Shipment ***(Note: Vaccine and biological products should have at least 60%-80% of its shelf-life remaining before arrival in-country except in a pandemic***	

	situation)		
8.0	**TEMPERATURE MONITORING DEVICE** *(Note: Only calibrated Temperature Monitoring Devices for transportation and shipping of cold chain products are allowed for use by manufacturers. http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue)*		
8.1	Name/Type of Temp. Logger		
8.2	Number of Temp. Loggers		
8.3	Description of Temperature Logger reading		
9.0	APPLICANT DECLARATION (		
	I hereby certify that the above information given are true and correct as to the best of my knowledge. I understand that I may be held liable if any of the above information is found to be false or misleading, and this application will be rejected, and any payments made will not be refunded.		
	REMARKS / EXPLANATION NOTES		
	NAME (Regulatory Affairs Manager)	SIGNATURE	DATE

For Official Use only:

1.	Lot summary protocol received	□ Yes	□ No	
2.	Lot release certificate from NRA of exporting country received (in case of imported products)	□ Yes	□No	Exemption Certificate
3.	Batch production record received (for locally manufactured products).	□ Yes	□ No	
4.	Copy of the registration letter received.	□ Yes	□ No	
5.	Copy of the endorsed paid bank receipt received.	□ Yes	□ No	
6.	Copy of endorsed invoice received	□ Yes	□ No	

Reception date _____ Received by (sign) _____

Application accepted □ Yes Name _____

If rejected (reason) _____ Designation _____

Assessment required □ Summary protocol review □ Laboratory Access

Assigned reviewer _____

Deadline for assessment _____

_____