Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Dear / pharmaceutical companies

Dear / agents of pharmaceutical companies

Greetings,,,

Reference to Council of Ministers' royal decree number No. M/6 dated 25/01/1428 AH concerning the permission of the Saudi Food and Drug Authority, which includes ensuring the quality and safety of biological products that requires releasing of each lot (Lot Release) for human vaccines and blood derivatives products. We would like to inform you that you must provide the following documents upon submitting the samples to the National Control Laboratory:

Vaccines:

- National Regulatory authority (NRA) certificate.
- Lot Summary Protocol document.
- Finished product Certificate of analysis (COA).
- Diluent or solvent Certificate of analysis (COA).

Blood Products:

- National Regulatory authority (NRA) certificate.
- Lot Summary Protocol document.
- Finished product Certificate of analysis (COA).
- Diluent or solvent Certificate of analysis (COA).
- Summary Flow chart.
- NRA certificate(s) of approval for plasma pools.

Biotech. Medicine:

- Finished product Certificate of analysis (COA).
- Diluent or solvent Certificate of analysis (COA).

- Submit the above requirements in two electronic copies (CDs), clearly labeled with the following information:
  - Trade name
  - Batch number
- Alternatively, submit the requirements electronically to the following email addresses, according to product type:
  - Vaccines: Vaccine.LD@sfda.gov.sa
  - Blood products: Bloodproducts.LD@sfda.gov.sa
  - Biotech. Medicine: Biotherapeutics.LD@sfda.gov.sa

Filling the samples delivery form for biological products (attached)

Please note if the above requirements are not submitted the sample will not be accepted and the Lot Release certificate/final report will not be issued.

Accept our sincere greetings and appreciation,

Assistant CEO of Research and Laboratories Sector
Abrar Almusharraf

National Control Laboratories
Samples and Documents of Biological Products

1. Information on submitted product lot:

Product	Company/agent comments	NCL comments
Type of biological products	**Vaccine □** **Blood product □** **Biotech. Medicine □** **Others:**	
Trade name		
Registration number at SFDA		
Lot number		
Quantity imported to KSA and Numbers of Doses		
Number of submitted samples to the NCL		

2. Information on submitted diluent or solvent lots:

Diluent or solvent	Company/agent comments	NCL comments
Diluent lot number		

Quantity imported to KSA and Numbers of Doses		
Number of submitted Diluent(s) samples to NCL		

3. Information on submitted Documents:

Documents	Company/agent comments	NCL comments
Lot Summary Protocol (for vaccine and blood product)	**Yes** □ **No** □ **Comment:**	
National Regulatory Authority certificate (for vaccine and blood product)	**Yes** □ **No** □ **Comment:**	
Finished Product Certificate of Analysis	**Yes** □ **No** □ **Comment:**	
Diluent(s) Certificate of Analysis	**Yes** □ **No** □ **Comment:**	

I declare that all the submitted documents and information regarding the above mentioned Lot are correct.

Lot Submission	**Date:**
	Time:
Company Name	
Contact person	**Name:**
	Phone No.:
	E-mail:
	Signature: