DATE: 12TH OCTOBER, 2017

WAIVERS FOR CURRENT GOOD MANUFACTURING PRACTICES (cGMP) INSPECTIONS FOR PHARMACEUTICAL PRODUCTS, INNOVATOR VACCINES AND BIOLOGICAL PRODUCTS

In respect of the above, the Food and Drugs Authority has instituted the following measures;

Companies from the following regions and under the underlisted regulatory bodies can have a waiver of on-site verification audit by the Officers of the Food and Drugs Authority Ghana if they can provide the underlisted documents to the FDA Ghana for assessment towards registration of products

INTERNATIONAL REGULATORY BODIES	COUNTRY	REQUIRED DOCUMENTS
ICH members	USA Japan EMA	• GMP certificate from the manufacturing country's regulatory Authority • Inspection report from the regulatory Authority
ICH observers	Australia Iceland Liechtenstein Norway	

ICH: International Council on Harmonization

***ICH Observer**: *a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement (as may be updated from time to time).* Other waiver may be on case by case basis