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COVID 19 VACCINES ARE OF GOOD QUALITY, SAFE AND EFFICACIOUS

The Food and Drugs Authority (FDA) like other national regulatory authorities globally, uses the Emergency Use Authorization (EUA) pathway to ensure timely access to quality and safe medical products including vaccines during pandemics.

Although time is of essence during pandemics, the EUA pathway subjects all medical product applications to rigorous quality, safety and efficacy assessments prior to approvals.

To date, the FDA has authorized the importation, distribution and use of the three Covid-19 vaccines listed below:

1. Sputnik V
2. Covishield
3. Johnson & Johnson

It is important to note that, all these vaccines have been authorized for use in several countries around the world, for instance, Sputnik V has been authorized in 71 countries, Covishield in 170 countries and Johnson & Johnson in 74 countries.

On arrival of consignments, the FDA inspects each batch for compliance with the manufacturer's instructions on product handling and storage to ensure that the integrity of the cold chain has been maintained during transportation. Furthermore, samples are also taken for analysis, to ensure that critical quality attributes comply with the approved release specifications from the manufacturer. All these processes are completed before vaccines, including vaccines from the COVAX Facility, donation from MTN and the recently imported Sputnik V, are formally released to the Ministry of Health.

The FDA takes notice of recent remarks by some commentators which seek to suggest that the vaccines being deployed by the Ghana Health Service are not efficacious. It is instructive to note that the FDA runs an ISO17025: 2017 Quality Control Laboratory and operates a robust regulatory system which is designated by the World Health Organisation as Maturity Level of 3 (ML3), comparable to stringent regulatory agencies in the developed world. The ML3 means that the FDA has a stable, well-functioning and integrated system of regulatory oversight for medicines and vaccines. In addition, staff of the FDA routinely participate in the assessment of medicines and vaccines undergoing

World Health Organisation's Prequalification, European Medicines Agency (Article 58) and African Vaccine Regulatory Forum assessments.

The FDA, therefore wishes to assure the general public that all approved medical products are of the right quality, safe and efficacious and encourages the public to reach out to the Authority for credible and current information on the products that it regulates.

The Authority remains committed to safeguarding the health and safety of the public as mandated by the Public Health Act, 2012 (Act 851).

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FDA, Your Well-being, Our Priority.

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