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FDA Statement

Coronavirus (COVID-19) Update: FDA Recommends Inclusion of Omicron BA.4/5 Component for COVID-19 Vaccine Booster Doses

The following is attributed Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research

For Immediate Release: June 30, 2022
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On Tuesday, the U.S. Food and Drug Administration's independent experts on the Vaccines and Related Biological Products Advisory Committee met to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccines for booster doses is necessary for the 2022 fall and winter seasons.

The COVID-19 vaccines that the FDA has approved and authorized for emergency use have made a tremendous difference to public health and have saved countless lives in the U.S. and globally. However, SARS-CoV-2, the virus that causes COVID-19, has evolved significantly, with recent surges around the world associated with the rapid spread of highly transmissible variants such as omicron.

Currently available vaccines have helped reduce the most serious outcomes (hospitalization and death) caused by COVID-19, but results from post-authorization observational studies have shown that effectiveness of primary vaccination wanes over time against certain variants, including omicron. And while initial booster doses have helped restore protection against severe disease and hospitalization associated with omicron, studies have also indicated waning effectiveness of first booster doses over time.

The American public can be assured that any COVID-19 vaccine authorized or approved by the FDA meets our standards for safety and effectiveness. We encourage those who are currently eligible for a booster to get one.

As we move into the fall and winter, it is critical that we have safe and effective vaccine boosters that can provide protection against circulating and emerging variants to prevent the most severe consequences of COVID-19. Following a thorough discussion on June 28, 2022, an overwhelming majority of the advisory committee voted in favor of including a SARS-CoV-2 omicron component in COVID-19 vaccines that would be used for boosters in the U.S. beginning in fall 2022.

Following the vote, and striving to use the best available scientific evidence, we have advised manufacturers seeking to update their COVID-19 vaccines that they should develop modified vaccines that add an omicron BA.4/5 spike protein component to the current vaccine composition to create a two component (bivalent) booster vaccine, so that the modified vaccines can potentially be used starting in early to mid-fall 2022.

As we expect this coming year to be a transitional period when this modified booster vaccine may be introduced, we have not advised manufacturers to change the vaccine for primary vaccination, since a primary series with the FDA-authorized and approved COVID-19 vaccines provides a base of protection against serious outcomes of COVID-19 caused by circulating strains of SARS-CoV-2.

Vaccine manufacturers have already reported data from clinical trials with modified vaccines containing an omicron BA.1 component and we have advised them that they should submit these data to the FDA for our evaluation prior to any potential authorization of a modified vaccine containing an omicron BA.4/5 component. Manufacturers will also be asked to begin clinical trials with modified

vaccines containing an omicron BA.4/5 component, as these data will be of use as the pandemic further evolves.

The FDA has been planning for the possibility that vaccines would need to be modified to address circulating variants and previously provided guidance to industry on how to do so efficiently. As has been the case with all COVID-19 vaccines throughout the pandemic, the agency will evaluate all relevant data to inform the safety, effectiveness and manufacturing quality of modified vaccines under consideration for authorization or approval to ensure that they meet the FDA's standards.

In keeping with our commitment to transparency, the FDA will communicate future plans pertaining to the potential authorization or approval of COVID-19 vaccine booster doses with an omicron component.

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.