Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
Maine Center for Disease Control and Prevention
11 State House Station
286 Water Street
Augusta, Maine 04333-0011
Tel; (207) 287-8016; Fax (207) 287-9058
TTY: Dial 711 (Maine Relay)

To: Maine Immunization Program Providers
From: Maine Immunization Program
Subject: Update on Pfizer COVID-19 Vaccine for Children 6 months – 4 years of age
Date: February 11, 2021

FDA Postpones Meeting to Discuss Request for Authorization of Pfizer-BioNTech COVID-19 Vaccine for Children 6 Months Through 4 Years of Age

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

The U.S. Food and Drug Administration has been notified by Pfizer that new data have recently emerged regarding its emergency use authorization request for the use of the Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age. As part of its rolling submission, the company recently notified the agency of additional findings from its ongoing clinical trial. Based on the agency's preliminary assessment, and to allow more time to evaluate additional data, we believe additional information regarding the ongoing evaluation of a third dose should be considered as part of our decision-making for potential authorization.

Therefore, the FDA is postponing the Vaccines and Related Biological Products Advisory Committee meeting originally scheduled for Feb. 15. This will give the agency time to consider the additional data, allowing for a transparent public discussion as part of our usual scientific and regulatory processes for COVID-19 vaccines. We will provide an update on timing for the advisory committee meeting once we receive additional data on a third dose in this age group from the company's ongoing clinical trial and have an opportunity to complete an updated evaluation.

Since the early days of the pandemic, we have always followed the science in this ever-changing situation. Given the recent omicron surge and the notable increase in hospitalizations in the youngest children to their highest levels during the pandemic so far, we felt it was our responsibility as a public health agency to act with urgency and consider all available options, including requesting that the company provide us with initial data on two doses from its ongoing study. The goal was to understand if two doses would provide sufficient protection to move forward with authorizing the use of the vaccine in this age group. Our approach has always been to conduct a regulatory review that's responsive to the urgent public health needs created by the pandemic, while adhering to our rigorous standards for safety and effectiveness. Being able to begin evaluating initial data has been useful in our review of these vaccines, but at this time, we believe additional information regarding the ongoing evaluation of a third dose should be considered.

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The agency will ensure the data support effectiveness and safety before authorizing a COVID-19 vaccine for use in our youngest children. In the meantime, the best way to protect children, including when they are at school or daycare, is to practice social distancing and masking in accordance with public health recommendations, and for their family members and caregivers to get vaccinated or receive a booster dose when eligible.

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Vaccine Order Update:

With regards to orders that have already been placed with the Maine Immunization Program, no action is necessary at this time. We will send out additional information and guidance as soon as we receive it.