



EUA Amendment Review Memorandum Addendum

Date: November 19, 2022

To: The File

From: Peter Marks, MD, PhD (CBER/OD)

EUA Application Number: 27073

Product: Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (mRNA-1273.222)

Subject: Addendum #8 (DP batch044H22-2A) to the September 20, 2022 memorandum entitled “Assessment of certain Moderna COVID-19 Vaccine, Bivalent Batches”

The purpose of this addendum is to document the Agency’s determination regarding the disposition of Moderna COVID-19 Vaccine, Bivalent DP batch 044H22-2A.

Disposition of Moderna COVID-19 Vaccine, Bivalent DP batch 044H22-2A

In light of concerns about potential supply limitations, Moderna requested that FDA review and authorize under the EUA certain batches of Moderna bivalent final DP produced at the Catalent facility. Although FDA does not intend to determine whether to add Catalent as an authorized manufacturing facility for the Moderna COVID-19 Vaccine, Bivalent until the Agency’s evaluation of the recent inspection is complete, in the interim, FDA can authorize batches of Moderna bivalent DP produced at this facility provided that FDA has sufficient data and information to conclude these batches are suitable for use.

Moderna submitted data and information supporting the quality of one bivalent booster final DP batch—044H22-2A—manufactured at the Catalent facility. Specifically, Moderna provided the results of its comprehensive batch review, which included, for example, data and analysis covering, environmental monitoring, media fills, and particle characterization. OVRR has carefully reviewed this information and determined that all applicable specifications were met for this batch. Thus, OVRR does not have safety, effectiveness, or quality concerns with this batch, and has concluded that the batch is suitable for use.

Further, ORA informed CBER that it has no direct evidence or information indicating that the vaccine batch was manufactured in a manner that would impact their safety, efficacy, or quality.

Accordingly, regardless of any assessment FDA makes regarding the Catalent facility’s cGMP compliance at the time this batch was manufactured, Moderna has provided sufficient data and information for FDA to determine that this batch is suitable for use and that the known and potential benefits outweigh the known and potential risks for the use described in the Moderna COVID-19 EUA for bivalent boosters. Thus, the Agency has determined it is appropriate to amend the EUA for the Moderna COVID-19 Vaccine, Bivalent to include Moderna bivalent DP batch 044H22-2A. Additionally, in the event that FDA ultimately



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determines that the Catalent facility was not operating in compliance with cGMP requirements at the time this batch was manufactured, Condition I in the Moderna COVID-19 Vaccine Letter of Authorization will be waived as to this batch.