



August 16, 2022

Attn: John Beigel, M.D.
Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases (NIAID)
31 Center Dr # 7A03
Bethesda, MD 20892

Re: EUA 28801 - Emergency Use Authorization of Jynneos, Issued on August 9, 2022, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3); To Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine

Dear Dr. Beigel:

This letter is to notify you that we have reviewed data to support changes to the Authorized Fact Sheet for Healthcare Providers Administering Vaccine, and we have granted the following changes to the authorized Fact Sheet:

2.2 Preparation and Administration

- Allow the vaccine to thaw and reach room temperature before use. Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks. Do not refreeze.

16.2 Storage Conditions

Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks.

Sincerely,

Peter Marks, M.D., Ph.D.
Acting Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research