EUA 111

EMERGENCY USE AUTHORIZATION-
REVISED FACT SHEETS

Eli Lilly and Company
Attention: Jennifer Riddle Camp
Associate Director-Global Regulatory Affairs-North America
Lilly Corporate Center Drop Code 2543
Indianapolis, IN 46285

Dear Ms. Riddle Camp:

Please refer to your Emergency Use Authorization (EUA) for bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults and pediatric patients who are at high-risk for progression to severe COVID-19, including hospitalization or death.

We refer to the action dated March 25, 2022 incorporating the following changes to the Fact Sheet for Health Care Providers (HCPs):

- Changes to Section 2.3 Dosage and Administration to include the required administration materials based on questions from HCPs regarding the need for the extension sets
- Updates to Table 4 in Section 12.4 Microbiology to include Omicron [+R346K] BA.1.1 and P.1 authentic virus data.

We also refer to your communication dated March 30, 2022 noting that the March 25, 2022 authorized HCP factsheet contained an inadvertent error omitting a footnote to Table 3.

The updated Fact Sheet for Health Care Providers is attached to this correspondence for your reference with March 30, 2022 as the new revised date.

By submitting these amendments for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the February 11, 2022, letter authorizing the emergency use of bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults and pediatric patients who are at high-risk for progression to severe COVID-19, including hospitalization or death.

Sincerely,

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Alicia Moruf, PharmD, MPH, RAC-US
Regulatory Project Manager
Antivirals Group
Division of Regulatory Operations for Infectious Diseases
Office of Regulatory Operations
Center for Drug Evaluation and Research

ENCLOSURE(S):

- EUA Fact Sheets
    - Fact Sheet for Health Care Providers