DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1825]

Investigational COVID-19 Convalescent Plasma; Guidance for Industry; Withdrawal of Guidance

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of a final guidance for industry entitled “Investigational COVID-19 Convalescent Plasma,” which was issued in April 2020 and updated in May 2020. FDA is withdrawing the guidance because the Agency is issuing a new guidance for industry of the same title.

DATES: The withdrawal is applicable [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: FDA is withdrawing the guidance for industry entitled “Investigational COVID-19 Convalescent Plasma” (May 2020 guidance) dated April 2020 and updated May 2020. The availability of this guidance was announced in the Federal Register of May 26, 2020, (85 FR 31513) and was posted on FDA’s website on May 1, 2020.

On August 23, 2020, the Agency issued an emergency use authorization (EUA) (available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-
regulatory-and-policy-framework/emergency-use-authorization#coviddrugs) for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19. Given the issuance of this EUA, FDA is issuing a new guidance of the same title that provides recommendations and additional information related to the EUA for the use of COVID-19 convalescent plasma to treat hospitalized patients with COVID-19. The new guidance supersedes the May 2020 guidance. Elsewhere in this issue of the Federal Register, FDA is announcing the availability of the new guidance.


Lauren K. Roth,

Associate Commissioner for Policy.

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