Page 11 – Invivyd, Inc.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2024.04.03 11:54:53 -04'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dated: May 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11640 Filed 5–24–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2245]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product; PAXLOVID

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that PAXLOVID (nirmatrelvir co-packaged with ritonavir) tablets, approved on May 25, 2023, manufactured by Pfizer, Inc., meets the criteria for a material threat MCM priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a) FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that PAXLOVID (nirmatrelvir co-packaged with ritonavir) tablets, manufactured by Pfizer, Inc., meets the criteria for a material threat MCM priority review voucher. PAXLOVID was approved on May 25, 2023, for the treatment of mild-to-moderate coronavirus disease 2019 (COVID–19) in adults who are at high risk for progression to severe COVID–19, including hospitalization or death.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions#prv.* For further information about PAXLOVID (nirmatrelvir co-packaged with ritonavir) tablets go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: May 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11643 Filed 5–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2219]

Progynon Associates, et al.; Proposal to Withdraw Approval of Four New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of four new drug applications (NDAs) and is announcing an opportunity for the NDA holders to request a hearing on this proposal. The basis for the proposal is that the NDA holders have repeatedly failed to file required annual reports for those NDAs.

DATES: The NDA holders may submit a request for a hearing by June 27, 2024. Submit all data, information, and analyses upon which the request for a hearing relies July 29, 2024. Submit electronic or written comments by July 29, 2024.

ADDRESSES: The request for a hearing may be submitted by the NDA holders by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to *https://www.regulations.gov,* including