the Eastern District of Texas. On May 8, 2020, the Court granted a joint motion to govern proceedings in that case and postpone the effective date of the final rule by 120 days. On December 2, 2020, the same Court granted a new motion by Plaintiffs in the same case to postpone the effective date of the final rule by an additional 90 days. On March 2, 2021, the same Court granted a new motion by Plaintiffs in the same case to postpone the effective date of the final rule by an additional 90 days. On May 21, 2021, the same Court granted a new motion by Plaintiffs in the same case to postpone the effective date of the final rule by an additional 90 days. The new effective date of the final rule is July 13, 2022. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date of the final rule is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date. As such, this revised guidance strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event, by September 13, 2021.

FDA is issuing this guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA regarding the submission of plans for cigarette packages and cigarette advertisements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 1141.10 have been approved under 0910–0877.

III. Electronic Access


Dated: June 24, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14674 Filed 7–9–21; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4590]

Morton Grove Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 21 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of December 2, 2019. The document announced the withdrawal of approval of 21 abbreviated new drug applications (ANDAs) from multiple applicants, effective January 2, 2020. The document erroneously included ANDA 076709 for Fentanyl Extended-Release Film, 25 micrograms (mcg)/hour (hr), 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, held by Actavis Laboratories UT, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 577 Chipeta Way, Salt Lake City, UT 84108, and ANDA 077062 for Fentanyl Extended-Release Film, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, held by Mayne Pharma LLC, 1240 Sugg Parkway, Greenville, NC 27834. This correction is being made because FDA previously withdrew the approval of ANDAs 076709 and 077062 in the Federal Register of November 18, 2019. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of Monday, December 2, 2019, 84 FR 65986, appearing on page 65986 in FR Doc. 2019–25946, the following correction is made:

On page 65986, in the table, the entries for ANDAs 076709 and 077062 are removed.

Dated: July 6, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14717 Filed 7–9–21; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the COVID–19 Health Equity Task Force

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As required by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the COVID–19 Health Equity Task Force (Task Force) will hold a virtual meeting on July 30, 2021. The purpose of this meeting is to consider interim recommendations addressing future pandemic preparedness, mitigation, and resilience needed to ensure equitable response and recovery in communities of color and other underserved populations. This meeting is open to the public and will be live-streamed at www.hhs.gov/live. Information about the meeting will be posted on the HHS Office of Minority Health website: www.minorityhealth.hhs.gov/healthequitytaskforce/ prior to the meeting.

DATES: The Task Force meeting will be held on Friday, July 30, 2021, from 2 p.m. to approximately 6 p.m. ET (date and time are tentative and subject to change). The confirmed time and agenda will be posted on the COVID–19 Health Equity Task Force web page: www.minorityhealth.hhs.gov/healthequitytaskforce/ when this information becomes available.

FOR FURTHER INFORMATION CONTACT: Samuel Wu, Designated Federal Officer for the Task Force; Office of Minority Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville,