

the Eastern District of Texas.¹ 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.² 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.³ 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.⁴ 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.⁵ 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

Persons with access to the internet may obtain an electronic version of the guidance at <https://www.regulations.gov>, <https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance>, and <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

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, and 100 mcg/hr, held by Wayne 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,

¹ *R.J. Reynolds Tobacco Co. et al. v. United States Food and Drug Administration et al.*, No. 6:20–cv–00176 (E.D. Tex. filed April 3, 2020).

² *R.J. Reynolds Tobacco Co. et al.*, No. 6:20–cv–00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

³ *R.J. Reynolds Tobacco Co. et al.*, No. 6:20–cv–00176 (E.D. Tex. December 2, 2020) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 80.

⁴ *R.J. Reynolds Tobacco Co. et al.*, No. 6:20–cv–00176 (E.D. Tex. March 2, 2021) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 89.

⁵ *R.J. Reynolds Tobacco Co. et al.*, No. 6:20–cv–00176 (E.D. Tex. May 21, 2021) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 91.

Maryland 20852. Phone: 240-453-6173; email: COVID19HETF@hhs.gov.

SUPPLEMENTARY INFORMATION:

Background: The COVID-19 Health Equity Task Force (Task Force) was established by Executive Order 13995, dated January 21, 2021. The Task Force is tasked with providing specific recommendations to the President, through the Coordinator of the COVID-19 Response and Counselor to the President (COVID-19 Response Coordinator), for mitigating the health inequities caused or exacerbated by the COVID-19 pandemic and for preventing such inequities in the future. The Task Force shall submit a final report to the COVID-19 Response Coordinator addressing any ongoing health inequities faced by COVID-19 survivors that may merit a public health response, describing the factors that contributed to disparities in COVID-19 outcomes, and recommending actions to combat such disparities in future pandemic responses.

The meeting is open to the public and will be live-streamed at www.hhs.gov/live. No registration is required. A public comment session will be held during the meeting. Pre-registration is required to provide public comment during the meeting. To pre-register, please send an email to COVID19HETF@hhs.gov and include your name, title, and organization by close of business on Friday, July 23, 2021. Comments will be limited to no more than three minutes per speaker

and should be pertinent to the meeting discussion. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute-taking purposes. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing COVID19HETF@hhs.gov no later than close of business on Thursday, August 5, 2021. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact: COVID19HETF@hhs.gov and reference this meeting. Requests for special accommodations should be made at least 10 business days prior to the meeting.

Dated: July 6, 2021.

Samuel Wu,

Designated Federal Officer, COVID-19 Health Equity Task Force.

[FR Doc. 2021-14703 Filed 7-9-21; 8:45 am]

BILLING CODE 4150-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Oligonucleotides Analogues Targeting Human LMNA "lamin A" Gene

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Human Genome Research Institute (NHGRI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive, Sublicensable Patent License to consolidate co-owned rights to the inventions and the Patents and Patent Applications listed in the Supplementary Information section of this notice to The Progeria Research Foundation ("PRF"), having a place of business in 200 Lake Street, Unit 102, Peabody, MA 01960.

DATES: Only written comments and/or applications for a license that are received by the NHGRI Office of Technology Transfer Office on or before July 27, 2021 will be considered.

ADDRESSES: Requests for a copy of the patent application(s), inquiries, and comments relating to the contemplated license should be directed to: Eggerton Campbell, License and Patent Manager, NHGRI Technology Transfer Office, Telephone: 301-402-1648; email: eggerton.campbell@nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement:

Country	Title	Application No.	Patent No.
United States	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-US-01.	61/568,590.	
WIPO	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-PCT-03.	PCT/US12/068609 WO 2013/086444.	
United Kingdom	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-GB-12.	12806796.4	2788488
United States	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-US-02.	13/708,709	9,326,992
United States	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-US-06.	15/084,255	9,833,468
United States	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-US-07.	15/727,483 CON ..	10,398,721
Europe	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-EP-04.	12806796.4	2788488
Japan	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-JP-15.	2019-109410.	
France	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-FR-11.	12806796.4	2788488
Germany	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-DE-10.	12806796.4	2788488
Ireland	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-IE-13.	12806796.4	2788488
Japan	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-JP-05.	2014-546152	6132849
Japan	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-JP-08.	2017-41744.	
Netherlands	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-NL-14.	12806796.4	2788488
Switzerland	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-CH-09.	12806796.4	2788488
United States	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-US-01	62/330,027.	
WIPO	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-PCT-02	PCT/US17/30174 WO 2017/190041.	