''Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention.'' This final guidance addresses nonclinical development, key study design considerations for animal efficacy studies to support potential new drug application (NDA) submissions under the Animal Rule, and considerations for obtaining a human safety database. This guidance finalizes the draft guidance of the same name issued on July 11, 2018 (83 FR 32136). Changes in this final guidance compared with the previous draft version are:

- Clarification of the assessment of immunologically naïve status in animals used in the animal studies
- Minor editorial changes

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention.'' 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

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collection of information in 21 CFR part 312 (investigational new drug applications) has been approved under OMB control number 0910–0014. The collection of information in 21 CFR part 314 (NDAs) has been approved under OMB control number 0910–0001. The collection of information resulting from special protocol assessments has been approved under OMB control number 0910–0470. The collection of information resulting from emergency use authorization of medical products has been approved under OMB control number 0910–0595. The collection of information resulting from individual patient expanded access applications has been approved under OMB control number 0910–0814. The collection of information resulting from good laboratory practices has been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: November 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24916 Filed 11–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4693]

Mayne Pharma Group Limited and Actavis Laboratories UT, Inc.; Withdrawal of Approval of Abbreviated New Drug Applications for Fentanyl Transdermal Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing the approval of abbreviated new drug application (ANDA) 077062 for the fentanyl transdermal system held by Mayne Pharma Group Ltd. (Mayne) and ANDA 076709 for the fentanyl transdermal system held by Actavis Laboratories UT, Inc. (Actavis), an indirect wholly owned subsidiary of Teva Pharmaceuticals USA, Inc. (Teva). These drug products are both transdermal systems designed with a liquid reservoir. Mayne and Actavis have both requested withdrawal of their respective applications and have waived their opportunity for a hearing.

DATES: Approval is withdrawn as of November 18, 2019.

FOR FURTHER INFORMATION CONTACT: Bronwen Blass, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: On August 20, 2007, FDA approved Actavis South Atlantic LLC Inc.'s (Actavis South) ANDA 077062, and Watson Pharmaceuticals' (Watson) ANDA 076709 for fentanyl transdermal systems with liquid reservoirs. Both ANDAs 077062 and 076709 are indicated for use in the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Both ANDAs 077062 and 076709 fentanyl transdermal systems were approved for the following strengths: 25 micrograms (mcg)/hour (hr), 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr.

ANDA 077062, previously held by Actavis South, is now held by Mayne [1] and ANDA 076709 is now held by Actavis as an indirect wholly owned subsidiary of Teva.[2] However, after ANDAs 077062 and 076709 were approved, FDA became aware of new information related to problems with the manufacturing, design, and quality control of fentanyl transdermal systems with a liquid reservoir design, leading to potential leakage, unintended opioid exposure, and potentially life-threatening adverse events.

In June 2019, Mayne requested withdrawal of ANDA 077062 under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing, and in July 2019, Actavis requested withdrawal of ANDA 076709 under § 314.150(d) and waived its opportunity for a hearing. In its letter requesting withdrawal of approval, Actavis stated that it voluntarily discontinued manufacture and sale of products under ANDA 076709 in 2018 for commercial reasons and has agreed to withdrawal of the application for those reasons only.

For the reasons discussed above, and pursuant to Mayne's and Actavis' requests, approval of ANDAs 077062 and 076709, and all amendments and supplements thereto, is withdrawn under § 314.150(d).

Distribution of Mayne's fentanyl transdermal system (25 mcg/hr, 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr) or Actavis's fentanyl transdermal system (25 mcg/hr, 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr) into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: November 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24922 Filed 11–15–19; 8:45 am]

BILLING CODE 4164–01–P

[1] At the time of original approval, ANDA 077062 was held by Actavis South. In 2012, Actavis South divested ANDA 077062 to Par Pharmaceutical, Inc. In 2017, Par Pharmaceutical, Inc., divested ANDA 077062 to Mayne.

[2] At the time of original approval, ANDA 076709 was held by Watson. In 2015, Watson became a wholly owned subsidiary of Actavis, and thus, the application transferred to Actavis. In 2017, Actavis became an indirect wholly owned subsidiary of Teva. Thus, ANDA 076709 is currently held by Actavis as a subsidiary of Teva.