for disclosures that contain PII. The DUA form also provides data requestors and custodians with a formal means to agree to the data protection and destruction statutory and regulatory requirements of CMS' PII data.

When entities, such as academic, federal or state agency researchers or CMS contractors request CMS PII/PHI data, they enter into a Data Use Agreement (DUA) with CMS. The DUA stipulates that the recipient of CMS data must properly protect the data according to all applicable data security standards and also provide for its appropriate destruction at the completion of the project/study or the expiration date of the DUA. The DUA form enables the data recipient and CMS to document the request and approval for release of CMS data. *Form Number:* CMS–R–235 (OMB control number: 0938–0734); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 9,200; *Total Annual Responses:* 9,200; *Total Annual Hours:* 2,900. (For policy questions regarding this collection contact Kari A Gaare at 410–786–8612.)

Dated: November 13, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–24929 Filed 11–15–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1835]

Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for treating or preventing smallpox (variola virus) infection. This guidance finalizes the draft guidance of the same name issued on July 11, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on November 18, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1835 for ''Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled

''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.