TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.2, Requests for Samples and Protocols; Official Release	72	82.972	5,974	3	17,922
660.6(b), Protocols	3	4	12	5	60
660.36(a)(2) and (b), Samples and Protocols	1	1	1	6	6
660.46(b), Protocols	1	1	1	5	5
Total	77		5,988		17,993

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall decrease of 1,463 hours and a corresponding decrease of 491 responses. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05367 Filed 3–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1127]

Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice entitled ''Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments'' that appeared in the **Federal Register** of June 1, 2020. The notice announced the establishment of a docket to solicit comments on the listing of patent information in the FDA publication ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (commonly known as the ''Orange Book''). The Agency is taking this action in response to the recently enacted Orange Book Transparency Act of 2020, which was signed into law on January 5, 2021.

DATES: FDA is reopening the comment period for the notice published on June 1, 2020 (85 FR 33169). Submit either electronic or written comments by April 15, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 15, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 15, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2020–N–1127 for ''Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments; Reopening of Comment Period.'' 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, 240–402–7500.

- 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 the 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Nicole Park, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7764.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 1, 2020 (85 FR 33169), FDA published a notice with a 90-day comment period to solicit comments on the listing of patent information in the FDA publication ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (commonly known as the ''Orange Book''), including comments on the types of patent information that should be included in the Orange Book. In the **Federal Register** of October 16, 2020 (85 FR 65819), FDA reopened the comment period for the public docket for an additional 30 days in response to a request for an extension to allow interested persons additional time to submit comments.

On January 5, 2021, the President signed into law the Orange Book Transparency Act of 2020 (Pub. L. 116–290). Section 2(e) of the Orange Book Transparency Act of 2020 requires the Agency to solicit public comment regarding the types of patent information that should be included on, or removed from, the Orange Book and to transmit to Congress a summary of such comments and actions the Agency is considering taking, if any, in response to such public comment by January 5, 2022.

In accordance with section 2(e) of the Orange Book Transparency Act of 2020, FDA is reopening the comment period for the public docket for 30 days, until April 15, 2021, to allow interested persons time to submit any additional comments regarding the types of patent information that should be included on, or removed from, the Orange Book. The Agency believes that an additional 30 days will allow adequate time for interested persons to submit comments.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05327 Filed 3–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–1678]

Determination That NIPRIDE RTU (Sodium Nitroprusside), 10 Milligrams/50 Milliliters (0.2 Milligrams/Milliliters), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that NIPRIDE RTU (sodium nitroprusside), 10 milligrams (mg)/50 milliliters (mL) (0.2 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for sodium nitroprusside, 10 mg/50 mL (0.2 mg/mL), if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Michael Bernstein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6240, Silver Spring, MD 20993–0002, 301–796–3478, *michael.bernstein@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), is the subject of NDA 209387, held by Exela Pharma Sciences, LLC, and initially approved on March 8, 2017. NIPRIDE RTU is indicated for immediate reduction of blood pressure of adult and pediatric patients in hypertensive crises; induction and maintenance of controlled hypotension in adults and children during surgery, to reduce bleeding; and treatment of acute heart failure to reduce left ventricular end-diastolic pressure, pulmonary capillary wedge pressure, peripheral vascular resistance, and mean arterial blood pressure.

NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Cardinal Health Regulatory Sciences submitted a citizen petition dated July 15, 2020 (Docket No. FDA–2020–P–1678), under 21 CFR 10.30, requesting that the Agency determine whether NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NIPRIDE RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other