

number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15676 Filed 7–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1252]

Panray Corp. Sub Ormont Drug and Chemical Co., Inc., et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new drug applications (NDAs) from multiple holders of those NDAs. The basis for the withdrawal is that these NDA holders have repeatedly failed to file required annual reports for the identified NDAs.

DATES: Approval is withdrawn as of July 22, 2022.

FOR FURTHER INFORMATION CONTACT:

Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–

796–3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of December 27, 2021 (86 FR 73296), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of three NDAs because the holders of those NDAs had repeatedly failed to submit the required annual reports for those NDAs. The holders of those NDAs did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by those holders of the NDAs not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their NDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the three applications listed in table 1 of this document.

TABLE 1—APPROVED NDAs FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	NDA holder
NDA 008284	Cortisone Acetate Tablets, 5 milligrams (mg) and 25 mg	Panray Corp. Sub Ormont Drug and Chemical Co., Inc., 520 South Dean St., Englewood, NJ 07631.
NDA 009659	Hydrocortisone Tablets, 10 mg and 20 mg	Do.
NDA 019503	Triamcinolone Acetonide Suspension, 3 mg/milliliters (mL)	Parnell Pharmaceuticals Inc., 111 Francisco Blvd., San Rafael, CA 94901.

FDA finds that the holders of the NDAs listed in table 1 have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, FDA finds that the holders of the NDAs have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the NDAs listed in table 1 and all amendments and supplements thereto is hereby withdrawn as of July 22, 2022.

Dated: July 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15629 Filed 7–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0414]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the

collection of information by August 22, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0601. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Manufactured Food Regulatory Program Standards

OMB Control Number 0910–0601—Revision

This information collection supports the FDA’s “Manufactured Food Regulatory Program Standards” (2019) (<https://www.fda.gov/media/131392/download>). We recommend that States use these program standards as the framework to design and manage their manufactured food programs. There are 44 State programs enrolled in the Manufactured Food Regulatory Program Standards (MFRPS or the program standards) under cooperative agreements.

The goal of the MFRPS is to implement a nationally integrated, risk-based, food safety system focused on protecting public health. The MFRPS establish a uniform basis for measuring and improving the performance of prevention, intervention, and response activities of manufactured food regulatory programs in the United States. The development and implementation of the standards will help Federal and State programs better direct their regulatory activities toward reducing foodborne illness. For more information, and to access the program standards, we invite you to visit our

website at: <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/regulatory-program-standards/manufactured-food-regulatory-program-standards-mfrps>.

FDA recommends that a State program enrolled in the MFRPS use the worksheets and forms contained in the standards; however, alternate forms that are equivalent may be used. The State program maintains documentation (guidance, procedures, documents, and forms) required by the 10 standards, which must be current and fit for use. In the first year of implementing the program standards, the State program conducts a baseline self-assessment of the documentation to determine if it meets the elements of each standard. The State program must participate in additional verification audits in subsequent years. After 5 years, FDA will conduct a comprehensive program audit of the documentation. As part of the program audit, the auditor reviews the records and supporting documents required by the criteria in each standard to determine if the self-assessment and improvement plan accurately reflect the State program’s level of conformance with each of the standards. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) the individual element of documentation requirement of the standard that was not met, (2) improvements needed to meet the

program element or documentation requirement of the standard, and (3) projected completion dates for each task.

In the **Federal Register** of January 13, 2022 (87 FR 2162), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Subsequent to the publication of the 60-day notice, in collaboration with the State Governments, FDA completed a revision of the program standards. In an effort to improve program effectiveness, understanding and clarity, changes include those to program definitions, inspection procedures, appendices and assessment worksheets that may be used by the States who have adopted the MFRPS. A copy of the revised program standards is available in the docket.

The revised program standards are the result of external collaboration and coordination between FDA and the Association of Food and Drug Officials Manufactured Food Regulatory Program Alliance and the Partnership for Food Protection Governing Council. We consider any formal comments received on the previous edition of the program standards and feedback obtained from our collaboration with the States.

Description of Respondents: Respondents are State Departments of Agriculture or Health enrolled in the MFRPS (State Governments).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Type of respondent; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State Governments; Development and reporting of data consistent with MFRPS	44	1	44	569	25,036

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Type of respondent; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State Governments; Maintenance of data records consistent with MFRPS	44	10	440	40	17,600

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

We have adjusted the number of respondents to the information collection to reflect the enrollment of an additional State since our last evaluation.

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15737 Filed 7–21–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–2203]

Determination of Regulatory Review Period for Purposes of Patent Extension; TAUVID

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for TAUVID and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 20, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 18, 2023. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

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 September 20, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 20, 2022. 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–E–2203 for “Determination of Regulatory Review Period for Purposes of Patent Extension; TAUVID.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.