| Application No. | Drug | Applicant |
|---|---|---|
| ANDA 075695 | Butorphanol Tartrate Injection, 1 milligram (mg)/milliliter (mL), and 2 mg/mL. | Baxter Healthcare Corporation, One Baxter Pkwy., Deerfield, IL 60015. |
| ANDA 075697 | Butorphanol Tartrate Injection, 2 mg/mL | Do. |
| ANDA 077290 | Oxycodone Hydrochloride (HCl) Tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg. | Nesher Pharmaceuticals (USA) LLC, 13910 St. Charles Rock Rd., Bridgeton, MO 63044. |
| ANDA 078564 | Granisetron HCl Injection, Equivalent to (EQ) 1 mg base/mL (EQ 1 mg base/mL). | Morton Grove Pharmaceuticals Inc., 6451 Main St., Morton Grove, IL 60053. |
| ANDA 078565 | Granisetron HCl Injection, EQ 4 mg base/4 mL (EQ 1 mg base/mL). | Do. |
| ANDA 078566 | Granisetron HCl Injection, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL). | Do. |
| ANDA 088342 | Fluoxymesterone Tablets, 10 mg | Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369. |
| ANDA 202032 | Lamivudine Tablets, 150 mg and 300 mg | Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520. |
| ANDA 205322 | Efavirenz Tablets, 600 mg | Do. |
| ANDA 205690 | Choline C–11 Injection, 4–100 millicurie/mL | University of Texas MD Anderson Cancer Center, 1881 East Rd., Unit 1903, Houston, TX 77054. |
| ANDA 207653 | Rosuvastatin Calcium Tablets, EQ 5 mg base, EQ 10 mg base, EQ 20 mg base, EQ 40 mg base. | SciRegs International, Inc., 6333 Summercrest Dr., Columbia, MD 21045. |
| ANDA 208199 | Azelastine HCl Metered Spray, 0.2055 mg/spray | Amneal Pharmaceuticals LLC, 50 Horseblock Rd., Brookhaven, NY 11719. |
| ANDA 210032 | Azelastine HCl Metered Spray, 0.2055 mg/spray | Akorn Operating Company LLC, 1925 West Field Ct., Suite 300, Lake Forest, IL 60045. |
| ANDA 211461 | Bosentan Tablets, 62.5 mg and 125 mg | Syneos Health Global Headquarters, 1030 Sync St., Third Floor, Morrisville, NC 27560. |

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 25, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on May 25, 2022 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: April 19, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–08744 Filed 4–22–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–0801]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export Notification and Recordkeeping Requirements

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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 May 25, 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 0910–0482. 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, *PRAStaff@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.

### Export Notification and Recordkeeping Requirements

*OMB Control Number 0910–0482—Extension*

Sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381 and 382) charge the Secretary of Health and Human Services, through FDA, with the responsibility of helping to ensure that exports of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products that are not to be sold in the United States meet the requirements of the country to which the product is to be exported. The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or offered for sale in domestic commerce in the United States as allowed under section 801(e) of the FD&C Act. In general, the notification

identifies the product being exported (*e.g.,* name, description, and in some cases, country of destination) and specifies where the notifications were sent. These notifications are sent only for an initial export. Subsequent exports of the same product to the same destination or to certain countries identified in section 802(b) of the FD&C Act would not result in a notification to FDA.

Respondents to the information collection are exporters of products that may not be sold in the United States and are regulated by FDA's Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Veterinary Medicine (CVM); Center for Food Safety and Applied Nutrition (CFSAN); and Center for Tobacco Products. Respondents to this collection of information maintain records demonstrating their compliance with the requirements in 21 CFR 1.101.

In the **Federal Register** of January 25, 2022 (87 FR 3811), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 1.101(d) (CBER) | 4 | 35 | 140 | 15 | 2,100 |
| 1.101(d) (CDER) | 3 | 57 | 171 | 15 | 2,565 |
| 1.101(d) (CDRH) | 22 | 4 | 88 | 15 | 1,320 |
| Total | | | | | 5,985 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 1.101(b), (c), and (e) (CBER, CDER, CDRH, CFSAN, and CVM) | 181 | 4.12 | 746 | 22 | 16,412 |
| 1.101(b) Office of International Programs only | 1 | 65 | 65 | 22 | 1,430 |
| 1.101(b) (currently regulated Tobacco Products) | 322 | 3 | 966 | 22 | 21,252 |
| Total | | | | | 39,094 |

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

Based on a review of Agency data, we decreased our estimate by 24,251 burden hours. This decrease reflects an overall downward trend in the number of export certification requests across programs and commodities. The estimate for tobacco products remains steady.

Dated: April 19, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–08739 Filed 4–22–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Special Topics: Vision Imaging, Bioengineering and Low Vision Technology Development.

*Date:* May 25–26, 2022.

*Time:* 9:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Susan Gillmor, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 240–762–3076, *susan.gillmor@nih.gov.*

*Name of Committee:* Bioengineering Sciences & Technologies Integrated Review Group; Gene and Drug Delivery Systems Study Section.

*Date:* June 13–14, 2022.

*Time:* 9:00 a.m. to 8:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Jain Krotz, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 672–8670 *jain.krotz@nih.gov.*

*Name of Committee:* Vascular and Hematology Integrated Review Group; Hemostasis, Thrombosis, Blood Cells and Transfusion Study Section.

*Date:* June 14–15, 2022.

*Time:* 10:00 a.m. to 9:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Katherine M Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, (301) 435–0912, *malindakm@csr.nih.gov.*

*Name of Committee:* Bioengineering Sciences & Technologies Integrated Review Group; Instrumentation and Systems Development Study Section.