TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Compounding outsourcing facility | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Submission of adverse event reports including copy of labeling and other information as described in the guidance | 55 | 1 | 55 | 1.1 | 61 |

[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 recordkeeping | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Records of adverse events, including records of efforts to obtain the data elements for each adverse event report | 55 | 1 | 55 | 16 | 880 |

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

This is the first extension of the information collection and we have retained the currently approved burden estimate. Based on our review of Agency data, we estimate that annually 55 outsourcing facilities (''Number of Respondents'' and ''Total Annual Responses'' in table 1) will submit adverse event reports to FDA as specified in the guidance and that preparing and submitting this information will take approximately 1.1 hours per registrant (''Average Burden per Response'' in table 1). Likewise, we estimate that annually 55 outsourcing facilities (''Number of Recordkeepers'' in table 2) will maintain records of adverse events as specified in the guidance and that preparing and maintaining the records will take approximately 16 hours per registrant (''Average Burden per Recordkeeping'' in table 2).

Dated: June 14, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–13294 Filed 6–20–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–2194]**

### Novartis Pharmaceuticals Corporation, et al.; Withdrawal of Approval of Five New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of five new drug applications (NDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of July 23, 2018.

**FOR FURTHER INFORMATION CONTACT:** Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

**SUPPLEMENTARY INFORMATION:** The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

| Application No. | Drug | Applicant |
|---|---|---|
| NDA 020831 | Foradil Aerolizer (formoterol fumarate) Powder, 0.012 milligram (mg)/inhalation. | Novartis Pharmaceuticals Corp., One Health Pl., East Hanover, NJ 07936. |
| NDA 022504 | Axiron (testosterone) Transdermal Metered Solution, 30 mg/1.5 milliliter (mL) actuation. | Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285. |
| NDA 050585 | Rocephin (ceftriaxone sodium) for Injection, equivalent to (EQ) 10 gram (g) base/vial, EQ 250 mg base/vial (IV/IM), EQ 500 mg base/vial (IV/IM), EQ 1 g base/vial (IV/IM), EQ 2 g base/vial (IV/IM), EQ 500 mg base/vial, N/A; N/A, 1% (Rocephin kit), EQ 1 g base/vial, N/A; N/A, 1% (Rocephin kit). | Hoffmann-La Roche, Inc., c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080. |
| NDA 050624 | Rocephin (ceftriaxone sodium) with Dextrose in Plastic Container Injection, EQ 10 mg base/mL, EQ 20 mg base/mL, and EQ 40 mg base/mL. | Do. |
| NDA 202763 | Testosterone Gel, 25 mg/2.5 g packet, 50 mg/5 g packet | ANI Pharmaceuticals, Inc., 210 Main St. West, Baudette, MN 56623. |

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 23, 2018. 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 July 23, 2018 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: June 14, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–13293 Filed 6–20–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID: FEMA–2018–0009; OMB No. 1660—NEW]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request; Transcript Request Form

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

**DATES:** Comments must be submitted on or before July 23, 2018.

**ADDRESSES:** Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address *FEMA-Information-Collections-Management@fema.dhs.gov* or Clarence (Smiley) White, Chief, Operations and Support Branch, United States Fire Administration, 301–447–1055 or by email at *Smiley.White@fema.dhs.gov.*

**SUPPLEMENTARY INFORMATION:** This proposed information collection previously published in the **Federal Register** on February 22, 2018 at 83 FR 7752 with a 60 day public comment period. FEMA received two anonymous public comments that were not relevant to the information collection. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

**Collection of Information**

*Title:* Transcript Request Form.

*Type of Information Collection:* New information collection.

*OMB Number:* 1660—NEW.

*Form Titles and Numbers:* FEMA Form 064–0–0–12, Transcript Request Form.

*Abstract:* FEMA provides training to advance the professional development of personnel engaged in fire prevention and control and emergency management activities through its Center for Domestic Preparedness (CDP), Emergency Management Institute (EMI), National Fire Academy (NFA), National Training and Education Division, National Domestic Preparedness Consortium, and Rural Domestic Preparedness Consortium. FEMA collects information from students who have completed courses at the National Fire Academy (NFA) and the Emergency Management Institute (EMI) for the purpose of fulfilling the student's request to provide a copy of their transcript for their personal records and/or for transmittal to an institution of higher education that delivers training and education also in support of the FEMA mission.

*Affected Public:* Individuals or households; Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government.

*Estimated Number of Respondents:* 4,500.

*Estimated Number of Responses:* 4,500.

*Estimated Total Annual Burden Hours:* 225 hours.

*Estimated Total Annual Respondent Cost:* $7,978.50.

*Estimated Respondents' Operation and Maintenance Costs:* $0.

*Estimated Respondents' Capital and Start-Up Costs:* $0.

*Estimated Total Annual Cost to the Federal Government:* $28,899.24.

**Comments**

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

**Rachel Frier,**

*Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.*

[FR Doc. 2018–13291 Filed 6–20–18; 8:45 am]

**BILLING CODE 9111–45–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID: FEMA–2018–0024; OMB No. 1660–0140]**

### Agency Information Collection Activities: Proposed Collection; Comment Request; Integrated Public Alert and Warning Systems (IPAWS) Memorandum of Agreement Applications

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, without change, of a currently approved