ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Children's Health Insurance Program and Supporting Regulations; *Use:* States must submit title XXI plans and amendments for approval by the Secretary. We use the plan and its subsequent amendments to determine if the state has met the requirements of title XXI. Information provided in the state plan, state plan amendments, and from the other information we are collecting will be used by advocacy groups, beneficiaries, applicants, other governmental agencies, providers groups, research organizations, health care corporations, health care consultants. States will use the information collected to assess state plan performance, health outcomes and an evaluation of the amount of substitution of private coverage that occurs as a result of the subsidies and the effect of the subsidies on access to coverage.

This iteration proposes to: Remove certain reporting requirements, revise the information collection instrument, and revise reporting instructions. We are also proposing to change the respondent's occupation and hourly wage, adjust the number of respondents, and adjust the number of enrollees by using more recent data. *Form Number:* CMS–R–308 (OMB control number: 0938–0841); *Frequency:* Yearly, Once, and Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 9,677,272; *Total Annual Hours:* 485,940. (For policy questions regarding this collection contact Cassie Lagorio at 410–786–4554.)

Dated: September 7, 2021.

William N. Parham, III,

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

[FR Doc. 2021–19599 Filed 9–10–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0008]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. Members will participate via teleconference. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on November 4, 2021, from 9:30 a.m. to 5:20 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: *https://youtu.be/2Xz4YzkwNDs.*

FOR FURTHER INFORMATION CONTACT: Christina Vert or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993–0002, 240–402–8054, *Christina.Vert@fda.hhs.gov,* or 240–402–8106, *Joanne.Lipkind@fda.hhs.gov,* respectively, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On November 4, 2021, for Topic I, the committee will meet in open session to hear an overview of the research programs of the Plasma Derivatives Branch, Division of Plasma Protein Therapeutics, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research (CBER). For Topic II, the committee will meet in open session to hear an overview of the research programs of the Laboratory of Cellular Hematology, Division of Blood Components and Devices, Office of Blood Research and Review (OBRR), CBER. For Topic III, the committee will meet in open session to hear an overview of the research programs of the Laboratory of Emerging Pathogens, Division of Emerging & Transfusion Transmitted Diseases, OBRR, CBER. After the open sessions, the meeting will be closed to the public for committee deliberations.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is

available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On November 4, 2021, the meeting is open to the public, from 9:30 a.m. to 11:30 a.m. for Topic I; 12:50 p.m. to 2:10 p.m. for Topic II; and 3:10 p.m. to 4:30 p.m. for Topic III. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be submitted to the contact person on or before October 28, 2021. Oral presentations from the public will be scheduled between approximately 11:10 a.m. and 11:30 a.m. for Topic I; 1:50 p.m. and 2:10 p.m. for Topic II; and 4:10 p.m. and 4:30 p.m. for Topic III. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 20, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 21, 2021.

Closed Committee Deliberations: On November 4, 2021, from 11:30 a.m. to 12:20 p.m. for Topic I; 2:10 p.m. to 3 p.m. for Topic II; and 4:30 p.m. to 5:20 p.m. for Topic III, the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the individual investigator's research programs along with other information, will be discussed during this session. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Christina Vert (*BPAC@fda.hhs.gov*) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 3, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19686 Filed 9–10–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0104]

PolyMedica Industries 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 those NDAs.

DATES: Approval is withdrawn as of September 13, 2021.

FOR FURTHER INFORMATION CONTACT: Kimberly S. 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 March 3, 2021 (86 FR 12474), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of those NDAs because the holders of those NDAs had repeatedly failed to submit the required annual reports for those NDAs. The holders of the NDAs identified in table 1 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.

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

Application No.	Drug	NDA Holder
NDA 016401	Neopap (acetaminophen) Suppositories, 120 milligrams (mg).	PolyMedica Industries Inc., 2 Constitution Way, Woburn, MA 01801.
NDA 050266	Achromycin (tetracycline hydrochloride (HCl)) Ophthalmic Ointment, 10 mg/gram.	Storz Ophthalmics Inc. (subsidiary of American Cyanamid Co.), 401 North Middletown Rd., Pearl River, NY 10965.
NDA 050268	Achromycin (tetracycline HCl) Ophthalmic Suspension, 1%	Do.

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 September 13, 2021.