SUPPLEMENTARY INFORMATION:

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the CDC Director and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on adult immunization schedule, child/adolescent immunization schedule, Ebola vaccine, hepatitis vaccines, herpes zoster vaccines, Orthopoxviruses vaccine, influenza vaccines, pneumococcal vaccine, cholera vaccine and tickborne encephalitis vaccine. Recommendation votes on adult immunization schedule, child/adolescent immunization schedule, hepatitis vaccine, herpes zoster vaccine, Orthopoxviruses vaccine, pneumococcal vaccine and Ebola vaccine are scheduled. No Vaccines for Children votes are scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.*

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: The docket will be opened to receive written comments on October 1, 2021. Written comments must be received on or before October 21, 2021.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the October 20–21, 2021 ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EDT, October 18, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by October 19, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–20476 Filed 9–21–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0089]

Advisory Committee on Immunization Practices (ACIP); Correction Notice of Meeting

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment. The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

SUPPLEMENTARY INFORMATION: Notice is hereby given of a change in the meeting of the Advisory Committee on Immunization Practices (ACIP); August 30, 2021, 10:00 a.m. to 4:00 p.m., and August 31, 2021, 10:00 a.m. to 4:00 p.m., EDT (times subject to change), in the amended FRN.

The virtual meeting was published in the **Federal Register** on Thursday, August 26, 2021, Volume 86, Number 163, pages 47644–47645.

The virtual meeting is being corrected to change the dates and times, addresses and written public comment and should read as follows:

DATES: The meeting will be held on August 30, 2021, from 10:00 a.m. to 4:00 p.m., EDT (times subject to change). The docket will close on August 30, 2021. Written comments must be received on or before August 30, 2021.

A notice of this ACIP meeting has also been posted on CDC's ACIP website at: *http://www.cdc.gov/vaccines/acip/index.html.* In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP. The meeting is open to the public.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0089 by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, Georgia 30329–

4027, Attn: August 30, 2021 ACIP Meeting.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS–H24–8, Atlanta, GA 30329–4027; Telephone: 404–639–8367; Email: *ACIP@cdc.gov.*

Public Participation

Written Public Comment: The docket will close on August 30, 2021. Written comments must be received on or before August 30, 2021.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–20478 Filed 9–21–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0921]

B. Braun Medical, Inc.; Withdrawal of Approval of Abbreviated New Drug Application of Hydroxyethyl Starch

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) BA110013/0032 for 6 Percent Hydroxyethyl Starch 130/0.4 in 0.9 Percent Sodium Chloride Injection in EXCEL® Plastic Container, held by B. Braun Medical, Inc. B. Braun Medical, Inc., requested in writing that the Agency's approval of the application be withdrawn because the drug is no longer being marketed and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of October 22, 2021.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240 402–7911.

SUPPLEMENTARY INFORMATION: B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109, has requested that FDA withdraw approval of ANDA BA110013/0032, pursuant to § 314.150(c) (21 CFR 314.150(c)), because the drug is no longer being marketed. By its request, B. Braun Medical Inc. has also waived its opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Application No.	Proprietary name
ANDA BA 110013/0032	6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection in EXCEL® Plastic Container.

Therefore, approval of the application listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of October 22, 2021. Introduction or delivery for introduction into interstate commerce for products without an approved new drug application or ANDA violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). The drug product that is listed in the table above that is in inventory on October 22, 2021 may continue to be dispensed until the inventory has been depleted or the drug product has reached its expiration date or otherwise becomes violative, whichever occurs first.

Dated: September 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20511 Filed 9–21–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3326]

Reauthorization of the Biosimilar User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is hosting a virtual public meeting to discuss proposed recommendations for the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years (FYs) 2023 through 2027. The BsUFA authorizes FDA to collect user fees to support the process for the review of biosimilar biological product applications. The current legislative authority for BsUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting user fees in future fiscal years. Following discussions with the regulated industry and consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs FDA to publish the recommendations for the reauthorized program in the **Federal Register**, hold a meeting at which the public may present its views on such recommendations, and provide for a period of 30 days for the public to provide written comments on such recommendations. FDA will then consider such public views and comments and revise such recommendations, as necessary.

DATES: The public meeting will be held on November 2, 2021, from 9 a.m. to 12 p.m. Eastern Time, and will be held by webcast only. Submit either electronic or written comments on this public