Accordingly, FDA revokes EUA 26382 for emergency use of COVID-19 convalescent plasma pursuant to section 564(g)(2) of the Act. As of the date of this letter, COVID-19 convalescent plasma which was authorized by FDA for emergency use under EUA 26382, is no longer authorized by FDA.

FDA does not intend to object to the use of any remaining inventory of the COVID-19 convalescent plasma that was distributed before revocation of the EUA.[1] The Guidance for Industry, *Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma*, July 2024,[2] addresses FDA's recommendations with respect to the use of any remaining inventory of COVID-19 convalescent plasma that was distributed prior to revocation of the EUA.

Notice of this revocation will be published in the Federal Register, pursuant to section 564(h)(1) of the Act.

Sincerely,

VINAYAK K. PRASAD -S

Digitally signed by VINAYAK K. PRASAD -S
Date: 2025.08.27 10:38:12 -04'00'

Vinayak Prasad, M.D., M.P.H
Director
Center for Biologics Evaluation and Research

[1] See *Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma* Guidance for Industry, July 2024 (https://www.fda.gov/media/180209/download).
[2] The guidance also provides FDA's recommendations to blood establishments for the submission of a Biologics License Application for the manufacture of COVID-19 convalescent plasma.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2025–19270 Filed 10–1–25; 8:45 am]
BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No: FDA–2025–N–3774]

Pediatric Advisory Committee (PAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC). The general function of the Committee is to provide advice and recommendations to FDA on pediatric regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on virtually on November 13, 2025, from 10:00 a.m. to 4:00 p.m. Eastern Time (ET).

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings, may be accessed at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2025–N–1246. The docket will close on November 12, 2025. Submit either electronic or written comments on this public meeting on or before November 12, 2025. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 12, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before November 5, 2025, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

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–2025–N–3774 for ''Pediatric Advisory Committee meeting; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 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 the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 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: Shivana Srivastava, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5157, Silver Spring, MD 20993–0002, 301–796–8695, *shivana.srivastava@fda.hhs.gov,* 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 FDA'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 the meeting.

SUPPLEMENTARY INFORMATION: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Agenda: On November 13, 2025, the PAC will meet to discuss post-marketing pediatric-focused safety reviews of the following products:

1. Center for Devices and Radiological Health
   a. ENTERRA THERAPY SYSTEM (Humanitarian Device Exemption (HDE))
   b. CONTEGRA PULMONARY VALVED CONDUIT (HDE)
   c. PLEXIMMUNE (HDE)
   d. SONALLEVE MR–HIFU (HDE)
2. Center for Biologics Evaluation and Research
   a. QUELIMMUNE (HDE)
   b. SEVENFACT (coagulation factor VIIa (recombinant)-jncw)
   c. VAXCHORA (Cholera Vaccine, Live, Oral)
3. Center for Drug Evaluation and Research

a. ABRAXANE (paclitaxel)
b. ARMONAIR RESPICLICK (fluticasone propionate), ARMONAIR DIGIHALER (fluticasone propionate), AIRDUO RESPICLICK (fluticasone propionate and salmeterol xinafoate), AIRDUO DIGIHALER (fluticasone propionate and salmeterol xinafoate)
c. AUBAGIO (teriflunomide)
d. AUSTEDO (deutetrabenazine)
e. BREXAFEMME (ibrexafungerp)
f. BYDUREON (exenatide), BYDUREON BCISE (exenatide), BYETTA (exenatide)
g. CIBINQO (abrocitinib)
h. COSENTYX (secukinumab)
i. DESCOVY (emtricitabine and tenofovir alafenamide)
j. DUPIXENT (dupilumab)
k. EDURANT (rilpivirine), EDURANT PED (rilpivirine)
l. ENBREL (etanercept)
m. EVOTAZ (atazanavir and cobicistat)
n. LIALDA (mesalamine)
o. LINZESS (linaclotide)
p. LITFULO (ritlecitinib)
q. MYRBETRIQ EXTENDED–RELEASE TABLETS (mirabegron), MYRBETRIQ GRANULES (mirabegron)
r. NUCYNTA (tapentadol), NUCYNTA ER (tapentadol)
s. OPANA (oxymorphone hydrochloride)
t. PIFELTRO (doravirine), DELSTRIGO (doravirine, lamivudine, and tenofovir disoproxil fumarate)
u. RAPIVAB (peramivir)
v. REXULTI (brexpiprazole)
w. RYALTRIS (olopatadine hydrochloride and mometasone furoate)
x. SELZENTRY (maraviroc)
y. SIMPONI ARIA (golimumab)
z. SMOFLIPID (lipid injectable emulsion)
aa. SOLOSEC (secnidazole)
bb. TAYTULLA (norethindrone acetate/ethinyl estradiol capsules and ferrous fumarate capsules)
cc. TEZSPIRE (tezepelumab-ekko)
dd. TRINTELLIX (vortioxetine)
ee. VIIBRYD (vilazodone hydrochloride)
ff. XOFLUZA (baloxavir marboxil)
gg. YCANTH (cantharidin)
hh. ZEGALOGUE (dasiglucagon)
ii. ZEPATIER (elbasvir and grazoprevir)
jj. ZERBAXA (ceftolozane and tazobactam)
kk. ZOSYN (piperacillin and tazobactam)

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 on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.*

Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before November 5, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:15 p.m. to 2:15 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the 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 28, 2025. 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 29, 2025.

For press inquiries, please contact the FDA Newsroom at *www.fda.gov/news-events/fda-newsroom.*

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 Shivana Srivastava (see **FOR FURTHER INFORMATION CONTACT**) 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* 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. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–19281 Filed 10–1–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of additional draft and revised draft product-specific guidances. The draft guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The draft guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by December 1, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.