a.m. and 4 p.m., Monday through Friday.

• 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 to 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 this 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Kenneth Quinto, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5145, Silver Spring, MD 20993, 240–402–2221, *kenneth.quinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA has established a public docket, Docket No. FDA–2017–N–7022, to receive input on post-marketing pediatric-focused safety reviews of products posted between April 2, 2018, and September 14, 2018, available on FDA's website at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm* but not presented at the September 20, 2018, PAC meeting. FDA welcomes comments by members of the PAC, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108–155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket number is FDA–2017–N–7022. The docket will open for comments on September 17, 2018, and remain open until September 28, 2018. The post-marketing pediatric-focused safety reviews are for the following products from the following centers at FDA:

Center for Biologics Evaluation and Research

1. BEXSERO (Meningococcal Group B Vaccine)
2. QUADRACEL (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine)

Center for Drug Evaluation and Research

1. ADZENYS XR–ODT (amphetamine tablet) and DYANAVEL XR (amphetamine suspension)
2. ANTHIM (obiltoxaximab)
3. APTENSIO XR (methylphenidate hydrochloride) and QUILLICHEW ER (methylphenidate hydrochloride)
4. BANZEL (rufinamide)
5. CINQAIR (reslizumab)
6. CUTIVATE (fluticasone propionate)
7. DESCOVY (emtricitabine and tenofovir alafenamide)
8. ENTOCORT EC (budesonide)
9. EPIVIR (lamivudine)
10. EPZICOM (abacavir sulfate and lamivudine) and ZIAGEN (abacavir sulfate)
11. KALETRA (lopinavir and ritonavir)
12. KOVANAZE (tetracaine hydrochloride and oxymetazoline hydrochloride)
13. LAMICTAL (lamotrigine)
14. NATROBA (spinosad)
15. NOXAFIL (posaconazole)
16. ORALTAG (iohexol)
17. ORAVERSE (phentolamine mesylate)
18. OTOVEL (ciprofloxacin and fluocinolone acetonide)
19. PANCREAZE (pancrelipase) and PERTZYE (pancrelipase)
20. PRILOSEC (omeprazole)
21. PROAIR RESPICLICK (abuterol sulfate)
22. PROCYSBI (cysteamine bitartrate)
23. RENVELA (sevelamer carbonate)
24. SPIRIVA (tiotropium bromide)
25. TEFLARO (ceftaroline fosamil)
26. TETRACAINE HYDROCHLORIDE Ophthalmic Solution (tetracaine hydrochloride)
27. XOPENEX (levalbuterol)
28. ZOMIG Nasal Spray (zolmitriptan)

Center for Devices and Radiological Health

1. CONTEGRA PULMONARY VALVED CONDUIT (Humanitarian Device Exemption (HDE))
2. ELANA SURGICAL KIT (HDE)
3. ENTERRA THERAPY SYSTEM (HDE)
4. LIPOSORBER LA–15 SYSTEM (HDE)
5. MEDTRONIC ACTIVA DYSTONIA THERAPY (HDE)
6. PLEXIMMUNE (HDE)
7. PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICE (HDE)

Dated: September 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20214 Filed 9–17–18; 8:45 a.m.]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3159]

Endocrinologic and Metabolic Drugs Advisory Committee; 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 Endocrinologic and Metabolic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on 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 October 24 and 25, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31

Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation 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–2018–N–3159. The docket will close on October 23, 2018. Submit either electronic or written comments on this public meeting by October 23, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 23, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 23, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before October 10, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

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–2018–N–3159 for ''Endocrinologic and Metabolic Drugs Advisory Committee; 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *EMDAC@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 the 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 coming to the meeting.

SUPPLEMENTARY INFORMATION: *Agenda:* On both days, the committee will discuss the ''Guidance for Industry: Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes'' (*https://www.fda.gov/downloads/Drugs/Guidances/ucm071627.pdf*), and the cardiovascular risk assessment of drugs and biologics for the treatment of type 2 diabetes mellitus.

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: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 10, 2018, will be provided to

the committee. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 10:30 a.m. on October 25, 2018. 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 1, 2018. 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 2, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

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 LaToya Bonner (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. app. 2).

Dated: September 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20233 Filed 9–17–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC)/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT) has scheduled a public meeting. Information about the CHACHSPT can be found here: *https://www.cdc.gov/maso/facm/facmchachspt.html.* An agenda may be requested by emailing *CHACAdvisoryComm@hrsa.gov.*

DATES: November 7, 2018, 8:30 a.m.–5:00 p.m. ET and November 8, 2018, 8:30 a.m.–3:30 p.m. ET.

ADDRESSES: This meeting will be held in-person and by webinar and teleconference. The address for the meeting is DoubleTree by Hilton, Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

- *Adobe Connect URL link: https://hrsa.connectsolutions.com/chac_meeting/.*
- *Conference call-in number:* 888–324–9617, Passcode 9245865.

FOR FURTHER INFORMATION CONTACT: Theresa Jumento, Chief, Policy Development Branch, HRSA, HIV/AIDS Bureau (HAB), Division of Policy and Data, 5600 Fishers Lane, Room 9N156, or by email at *CHACAdvisoryComm@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The CHACHSPT was established under Section 222 of the Public Health Service (PHS) Act, [42 U.S.C. Section 217a], as amended.

The purpose of the CHACHSPT is to advise the Secretary of HHS, the Director of the CDC, and the Administrator of HRSA on the objectives, strategies, policies, and priorities for HIV, viral hepatitis, and other STD prevention and treatment efforts. This includes, but is not limited to, surveillance of HIV infection, viral hepatitis, and other STDs; responses to related emerging health needs; and epidemiologic, behavioral, health services, and laboratory research on HIV/AIDS, viral hepatitis, and other STDs. The CHACHSPT also provides advice regarding policy issues related to HIV/viral hepatitis/STD professional education, patient healthcare delivery, research and training, and prevention services.

During the November 7–8, 2018, meeting, the CHACHSPT will discuss the following topics:

- CHACHSPT workgroup reports and findings;
- updates from CDC, HRSA, and HRSA HAB;
- strategies for serving women, infants, children, and youth;
- agencies' responses to the opioid crisis; and
- telemedicine initiatives.

Agenda items are subject to change as priorities dictate. Refer to the CHACHSPT website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to CHACHSPT should be sent by email to *CHACAdvisoryComm@hrsa.gov* or by mail to Theresa Jumento at the address above at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Theresa Jumento at the address listed above at least 10 business days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–20269 Filed 9–17–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Council on Migrant Health

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Meeting notice.

SUMMARY: The Secretary's National Advisory Council on Migrant Health (NACMH) has scheduled a public meeting. Information about NACMH and the agenda for this meeting can be found on the NACMH website at: *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html.*