4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1215]

Post-Marketing Pediatric-Focused Product Safety Reviews; 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) is establishing a public docket to collect comments related to the post-marketing pediatric-focused safety reviews of products posted between April 12, 2019, and September 23, 2019, on FDA's website but not presented at the September 26 or 27, 2019, Joint Pediatric Advisory Committee (PAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee meeting. These reviews are intended to be available for review and comment by members of the PAC, interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public.

DATES: Submit either electronic or written comments by October 7, 2019.

ADDRESSES: FDA is establishing a docket for public comment on this document. The docket number is FDA-2019-N-1215. The docket will close on October 7, 2019. Submit either electronic or written comments by that date. Please note that late, untimely comments will not be considered. Electronic comments must be submitted on or before October 7, 2019. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of October 7, 2019. 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.

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 make 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-2019-N-1215 for "Post-Marketing Pediatric-Focused Product Safety Reviews; 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 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: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240-402-3838, marieann.brill@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 is establishing a public docket, Docket No. FDA-2019-N-1215, to receive input on post-marketing pediatric-focused safety reviews of products posted between April 12, 2019, and September 23, 2019, available on FDA's website at https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm but not presented at the September 26 or 27, 2019, Joint PAC or DSaRM 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-2019-N-1215. The docket will open on September 23, 2019, and remain open until October 7, 2019. 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) GAMMAPLEX - Immune Globulin Intravenous (Human) 5% Liquid

(2) NUWIQ® - (simoctocog alfa)

(3) TACHOSIL® - Absorbable Fibrin Sealant Patch

(4) WILATE - von Willebrand Factor/Coagulation Factor VIII Complex (Human)

Center for Drug Evaluation and Research

(1) ATIVAN INJECTION (lorazepam injection)

(2) E-Z-HD (barium sulfate)

(3) LIQUID E-Z-PAQUE (barium sulfate)

(4) READI-CAT 2 and READI-CAT 2 SMOOTHIE (barium sulfate)

(5) VARIBAR PUDDING (barium sulfate)

(6) CALCIUM GLUCONATE INJECTION (calcium gluconate)

(7) CEREBYX® (fosphenytoin sodium)

(8) DOTAREM (gadoterate meglumine)

(9) FYCOMPA ORAL TABLETS AND SUSPENSION (perampanel)

(10) HARVONI (ledipasvir and sofosbuvir)

(11) ISENTRESS AND ISENTRESS HD (raltegravir)

(12) LATUDA (lurasidone hydrochloride)

(13) RAPIVAB® (peramivir)

(14) RYZODEG 70/30 (insulin degludec and insulin aspart injection) for subcutaneous use 100 units/mL (U-100) in 3ml FlexTouch Pen

(15) SIMPONI (golimumab SC) and SIMPONI ARIA (golimumab IV)

(16) SOVALDI (sofosbuvir)

(17) STRIBILD (elvitegravir, cobicistat, emtricitabine/tenofovir disoproxil fumarate)

(18) TRESIBA (insulin degludec injection), for subcutaneous use, 100 units/mL (U-100) in 3ml single-patient-use FlexTouch Pen; 200 units/mL (U-200) in 3mL single-patient-use FlexTouch Pen; 100 units/mL (U-100) 10mL in multiple-dose vial

(19) VIGAMOX (moxifloxacin hydrocholoride ophthalmic solution 0.5%)

(20) VISIPAQUE INJECTION (iodixanol)

(21) ZEMPLAR (paricalcitol)

(22) ZYMAR® 0.3% (gatifloxacin ophthalmic solution)

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) PLEXIMMUNE™ IN-VITRO DIAGNOSTIC TEST (HDE)

(5) PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICE (HDE)

Dated: September 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-20658 Filed: 9/23/2019 8:45 am; Publication Date: 9/24/2019]