4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0595]

Pediatric Postmarketing Pharmacovigilance and Drug Utilization Reviews; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect comments related to the pediatric postmarketing pharmacovigilance and drug utilization reviews of products posted between September 17, 2016, and February 24, 2017, on the FDA Web site, but will not be presented at the March 6-7, 2017, Pediatric Advisory Committee (PAC) 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 March 10, 2017. The docket will open on February 27, 2017, and remain open until March 10, 2017.

ADDRESSES: You may submit your 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, you 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 submission as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2017-N-0595 for "Pediatric Postmarketing Pharmacovigilance and Drug Utilization Reviews" that have been posted on the FDA Web site at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm between September 17, 2016, and February 24, 2017, but will not be

presented at the March 6-7, 2017 PAC meeting (82 FR 1345, January 5, 2017). Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Division of Dockets Management 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." The Agency 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 Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 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, email: 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 is establishing a public docket FDA-2017-N-0595 to receive input on pediatric postmarketing pharmacovigilance and drug utilization reviews posted between September 17, 2016, and February 24, 2017, on the FDA Web site at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm, but will not be presented at the March 6-7, 2017, PAC meeting (82 FR 1345, January 5, 2017). 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 (Pub. L. 108-155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket will open on February 27, 2017, and remain open until March 10, 2017. These pediatric postmarketing pharmacovigilance and drug utilization reviews are for the following products:

- ALEVE PM (diphenhydramine hydrochloride/naproxen sodium)
- ASTEPRO (azelastine hydrochloride)
- ECOZA (econazole nitrate)

- JETREA (ocriplasmin)
- QUARTETTE (levonorgestrel/ethinyl estradiol and ethinyl estradiol)
- TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
- XERESE (acyclovir/ hydrocortisone)

Dated: February 15, 2017.

Janice M. Soreth,
Associate Commissioner for Special Medical Programs.

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