ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Second follow-up survey	4,800	1,600	1	1	1,600

Estimated Total Annual Burden Hours: 1,600.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 413 of the Social Security Act, as amended by the FY 2017 Consolidated Appropriations Act, 2017 (Pub. L. 115–31).

Emily B. Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–20223 Filed 9–17–18; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–7022]

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) has established a public docket to collect comments related to the post-marketing, pediatric-focused safety reviews of products posted between April 2, 2018, and September 14, 2018, on FDA's website but not presented at the September 20, 2018, 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 September 28, 2018.

ADDRESSES: FDA has established a docket for public comment on this document. The docket number is FDA–2017–N–7022. The docket will close on September 28, 2018. Submit either electronic or written comments by that date. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 28, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 28, 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.

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–2017–N–7022 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: 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