DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1153]

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 September 23, 2019, and September 1, 2020, on FDA's website but not presented at the September 15, 2020, 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 22, 2020.

ADDRESSES: FDA is establishing a docket for public comment on this document. The docket number is FDA–2020–N–1153. The docket will close on September 22, 2020. 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 September 22, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 22, 2020. 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–2020–N–1153 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, 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 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.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: 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–2020–N–1153, to receive input on post-marketing pediatric-focused safety reviews of products posted between September 23, 2019, and September 1, 2020, available on FDA's website at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm* but not presented at the September 15, 2020, 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–2020–N–1153. The docket will open on September 1, 2020, and remain open until September 22, 2020. 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. AFSTYLA (antihemophilic factor (recombinant), single chain)
2. EPICEL (cultured epidermal autografts)
3. FLUCELVAX QUADRIVALENT (influenza vaccine)
4. FLUCELVAX (influenza vaccine)
5. FLULAVAL (influenza vaccine)
6. FLULAVAL QUADRIVALENT (influenza vaccine)
7. HIBERIX (Haemophilus b conjugate vaccine (tetanus toxoid conjugate))
8. KOVALTRY (antihemophilic factor (recombinant))
9. QPAN H5N1 Vaccine (Influenza A (H5N1) virus monovalent vaccine, adjuvanted)

Center for Drug Evaluation and Research

1. BUTRANS (buprenorphine transdermal system)
2. CANASA (mesalamine suppositories for rectal use)
3. DESCOVY (emtricitabine and tenofovir alafenamide)
4. DRAXIMAGE DTPA (technetium TC–99m pentetate kit) injection and inhalation
5. DYSPORT (abobotulinumtoxinA)
6. GENVOYA (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide) oral tablets
7. LUMASON (sulfur hexafluoride lipid-type A microspheres) injectable suspension
8. LUMIFY (brimonidine tartrate) OTC
9. LUZU (luliconazole) cream, 1%
10. OMIDRIA (phenylephrine and ketorolac intraocular solution)
11. SENSIPAR (cinacalcet)
12. STELARA (ustekinumab) injection
13. SYMFI LO (efavirenz 400 milligram (mg) + lamivudine 300 mg + tenofovir disoproxil fumarate 300 mg) and SYMFI (efavirenz 600 mg + lamivudine 300 mg + tenofovir disoproxil fumarate 300 mg)
14. TRIUMEQ (abacavir, dolutegravir, and lamivudine)
15. XEPI (ozenoxacin)

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 IN–VITRO DIAGNOSTIC TEST (HDE)
7. PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICE (HDE)

Dated: August 28, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–19385 Filed 9–1–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1117]

Janssen Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 16 New Drug Applications; Correction

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on May 14, 2020. The document announced the withdrawal of approval (as of June 15, 2020) of 16 new drug applications (NDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of NDA 050641, Monodox (doxycycline monohydrate) Capsules, Equivalent to (EQ) 50 milligrams (mg) base, EQ 75 mg base, and EQ 100 mg base, after receiving a withdrawal request from Aqua Pharmaceuticals, LLC, 707 Eagleview Blvd., Suite 200, Exton, PA 19341. Before FDA withdrew the approval of NDA 050641, Aqua Pharmaceuticals, LLC, informed FDA that it did not want the approval of the NDA withdrawn. Because Aqua Pharmaceuticals, LLC, timely requested that approval of the NDA not be withdrawn, the approval of NDA 050641 is still in effect.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 14, 2020 (85 FR 28950), appearing on page 28950 in FR Doc. 2020–10367, the following correction is made:

On page 28951, in the table, the entry for NDA 050641 is removed.

Dated: August 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–19364 Filed 9–1–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

August 27, 2020.

AGENCY: Office of the General Counsel, Office of the Secretary, Department of Health and Human Services.

This document revises the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Office of the General Counsel (OGC) as published on August 4, 2020 (85 FR 47228) to correct a typographical error and to better reflect the functions of the Office. The August 4, 2020 Statement is retracted and replaced by this document. As revised, it reflects a new component, changes in titles and order of succession, and changes in the law, and is being re-compiled so that the Statement of Organization incorporates all amendments, as may be amended herein, after the issuance of the last compiled Statement of Organization in 1973. *See* 38 FR 17032 (June 28, 1973).

SUPPLEMENTARY INFORMATION: The Office of the Secretary (OS)'s Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Office of the General Counsel (OGC), should now read as follows:

Section I. Mission

The Mission of the Office of the General Counsel and the General Counsel, who is the special advisor to the Secretary on legal matters, is to provide all legal services and advice to the Secretary, Deputy Secretary, and all subordinate organizational components of the Department.

Section II Organization

The Office of the General Counsel, under the supervision of a General Counsel, consists of:

1. The General Counsel and Immediate Office of the General Counsel
2. Divisions in the Office of the General Counsel
3. Ten Regional Offices