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