

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](mailto: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]

BILLING CODE 4164-01-P

#### 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

### Subsection A. The Immediate Office of the General Counsel

1. The Immediate Office of the General Counsel. The Immediate Office of the General Counsel shall consist of the General Counsel, his or her executive assistant, a Principal Deputy General Counsel, such other Deputy General Counsel, both non-career and career, as the Secretary deems appropriate and appoints, Associate and Assistant Deputy General Counsel, Senior Counsel, and such other attorneys and assistants as the General Counsel deems appropriate, and the Office of Legal Resources (OLR).

a. The General Counsel. The General Counsel is the chief legal officer of the Department and is directly responsible to the Secretary.

b. Principal Deputy General Counsel. The Principal Deputy General Counsel shall be the second-ranking legal officer of the Department and is directly responsible to the General Counsel and the Secretary. He or she may act in the stead of the General Counsel when the General Counsel is absent or unavailable.

c. Deputy General Counsel. The Deputy General Counsel report to the General Counsel and each shall be responsible for overseeing such substantive areas as designated by the General Counsel. In certain instances, a Deputy General Counsel may be appointed by the Secretary or assigned by the General Counsel to serve as the chief counsel of an operating division.

(1) Non-Career Deputy General Counsel. Non-career Deputy General Counsel report to the General Counsel and each shall be responsible for overseeing the substantive legal areas and corresponding OGC components designated by the General Counsel.

(2) Career Deputy General Counsel. There shall be two career Deputy General Counsel who report to the General Counsel. First, a Deputy General Counsel who shall oversee OLR, the General Law Division (GLD), the ten Regional Offices, and will be generally responsible for OGC management and operations subject to the direction of the General Counsel. Second, a Deputy General Counsel who shall oversee litigation and the National Complex Litigation and Investigations Division (NCLID).

d. Associate General Counsel. Associate General Counsel either head a Division within OGC or are located in the Immediate Office. In either event, Associate General Counsel report to the General Counsel or to such Deputy General Counsel as the General Counsel may designate.

e. Associate or Assistant Deputy General Counsel to the General Counsel. The General Counsel may designate one or more attorneys to act as his or her special assistant and to carry the title of Associate Deputy General Counsel or Assistant Deputy General Counsel, all of whom shall report directly to the General Counsel or to such Deputy General Counsel as the General Counsel may designate.

f. Senior Counsel or Senior Advisor to the General Counsel. Senior Counsel or Senior Advisor to the General Counsel perform such duties as may be assigned to them by the General Counsel, Deputy General Counsel or Associate General Counsel. At least one Senior Counsel or Senior Advisor should have a security clearance of the level and type deemed appropriate by the General Counsel.

g. Office of Legal Resources. The Office of Legal Resources within the Immediate Office of the General Counsel, headed by a director, is responsible for providing personnel, budget, correspondence, and information technology support to the Office of the General Counsel.

2. Relation of Immediate Office to the Divisions and Regions. Each division and each region is under the general supervision of the General Counsel and the assigned Deputy General Counsel, unless that Division is headed by a Deputy General Counsel. Each Divisional Associate General Counsel and Regional Chief Counsel reports directly to the assigned Deputy General Counsel on substantive legal matters, litigation strategy, and other matters as directed by the General Counsel.

#### 3. Order of Succession.

a. General Counsel Vacancy. In the event of the General Counsel's absence, or in the event of a "vacancy" in the position of General Counsel as a result of death, resignation, or an inability to perform the functions and duties of the office, the Principal Deputy General Counsel shall act in the General Counsel's stead, or serve as the Acting General Counsel as dictated by the Vacancies Reform Act of 1998, 5 U.S.C. 3345 *et seq.*

b. Principal Deputy General Counsel Vacancy. In the event of the absence of or vacancies in offices of both the General Counsel and the Principal Deputy General Counsel, the non-career Deputy General Counsel with the greatest seniority in that position shall perform the functions of or serve as the Acting General Counsel as dictated by the Vacancies Reform Act of 1998. In the event that the disabilities or vacancies extend to or include all non-career deputies, then the career Deputy General Counsel with the greatest

seniority in that position shall act in or serve as the Acting General Counsel as dictated by the Vacancies Reform Act of 1998.

### Subsection B. Divisions in the Office of the General Counsel

The Office of the General Counsel's nine divisions are as follows: General Law Division (GLD); the Children, Families and Aging Division (CFAD); the Ethics Division (ETHICSD); the Food and Drug Division (FDD); the Public Health Division (Ph.D.); the Legislative Division (LEGD); the Centers for Medicare & Medicaid Services Division (CMSD); the Civil Rights Division (CRD); and National Complex Litigation and Investigations Division (NCLID). Each Division shall be headed by either an Associate General Counsel or Deputy General Counsel, as determined by the General Counsel.

1. The General Law Division shall be headed by an Associate General Counsel who reports to the General Counsel through a career Deputy General Counsel. The Division consists of two branches, each headed by a Deputy Associate General Counsel reporting to the Associate General Counsel:

- a. Claims and Employment Law Branch
- b. Procurement, Fiscal and Information Law Branch

2. The Children, Families and Aging Division shall be headed by an Associate General Counsel who reports to the General Counsel through a designated Deputy General Counsel.

3. The Ethics Division shall be headed by an Associate General Counsel who reports to the General Counsel. The Division consists of two branches, each headed by a Deputy Associate General Counsel reporting to the Associate General Counsel:

- a. Ethics Advice and Policy Branch
- b. Ethics Program Administration Branch

The Associate General Counsel and Deputy Associate for Ethics Advice and Policy simultaneously serve by secretarial delegation as the Department's Designated Agency Ethics Official and Alternate Designated Agency Ethics Official, respectively.

4. The Food and Drug Division shall be headed by a Chief Counsel who shall be either a Deputy General Counsel or Associate General Counsel. In the event that the Chief Counsel is an Associate General Counsel, he or she shall report to the General Counsel through a designated Deputy General Counsel. The Division consists of two major branches, each of which is headed by a Deputy Associate General Counsel who reports to the Chief Counsel, as follows:

- a. Litigation Branch
- b. Program Review Branch, divided into the following three sub-branches:
  - (1) Foods & Veterinary Medicine
  - (2) Drugs and Biologics
  - (3) Tobacco & Devices

5. The Public Health Division shall be headed by an Associate General Counsel who reports to the General Counsel through a designated Deputy General Counsel. The Division is divided into four branches, each of which is headed by a Deputy Associate General Counsel reporting to the Associate General Counsel:

- a. Indian Health Service Branch
- b. Centers for Disease Control and Prevention Branch
- c. National Institutes of Health Branch
- d. Public Health and Science Branch

6. The Legislation Division shall be headed by an Associate General Counsel who reports to the General Counsel through a designated Deputy General Counsel.

7. The Centers for Medicare & Medicaid Services Division shall be headed by a Chief Legal Officer who shall be either a Deputy General Counsel or an Associate General Counsel. The Division consists of three major organizational groups, each of which is headed by a Deputy Associate General Counsel reporting to the Associate General Counsel or the Deputy General Counsel through an Associate General Counsel, as follows:

- a. Litigation Group
- b. Program Review Group
- c. Program Integrity Group

8. The Civil Rights Division shall be headed by an Associate General Counsel who reports to the General Counsel through a designated Deputy General Counsel, and by a Deputy Associate General Counsel who reports to the Associate General Counsel.

9. The National Complex Litigation and Investigations Division (NCLID) has an Associate General Counsel who reports to General Counsel through a career Deputy General Counsel. In addition, NCLID has a Deputy Associate General Counsel for E-Discovery reporting to the Associate General Counsel.

### Subsection C. Regional Offices

There are ten regional offices. Each regional office has a Chief Counsel who reports to the General Counsel through a designated career Deputy General Counsel. Regional offices may also have one or more Deputy Chief Counsel who report to the Chief Counsel. The regional offices are located in the following cities and provide legal services to the Department in the following states and territories:

1. Region I—Boston (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont)
2. Region II—New York City (New York, New Jersey, Puerto Rico, Virgin Islands)
3. Region III—Philadelphia (Delaware, Maryland, Pennsylvania, Virginia, West Virginia, District of Columbia)
4. Region IV—Atlanta (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee)
5. Region V—Chicago (Illinois, Indiana, Ohio, Michigan, Minnesota, Wisconsin)
6. Region VI—Dallas (Arkansas, Louisiana, New Mexico, Oklahoma, Texas)
7. Region VII—Kansas City, MO (Iowa, Kansas, Missouri, Nebraska)
8. Region VIII—Denver (Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming)
9. Region IX—San Francisco (Arizona, California, Hawaii, Nevada, Guam, American Samoa, Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau)
10. Region X—Seattle (Alaska, Idaho, Oregon, Washington)

### Section III. Functions

#### A. General Counsel and Immediate Office of the General Counsel

1. The General Counsel. The General Counsel is authorized to promulgate such directives and issue such legal opinions as may be necessary to carry out the responsibilities of the Office. The General Counsel directly (or through attorneys in the Office of the General Counsel), undertakes the following activities unless an applicable statute provides otherwise or the General Counsel has delegated the responsibility elsewhere:

a. Furnishes all legal services and advice to the Secretary, Deputy Secretary, and all offices, branches, or units of the Department in connection with the operations and administration of the Department and its programs, except with respect to functions expressly delegated by statute to the Inspector General.

b. Furnishes legal services and advice on such other matters as may be submitted by the Secretary, the Deputy Secretary, any other senior leaders, and other persons authorized by the Secretary to request such service or advice.

c. Represents the Department in all litigation when such direct representation is not precluded by law,

and in other cases, making and supervising all contacts with attorneys responsible for the conduct of such litigation.

d. Acts as the Department's sole representative in communicating with the Department of Justice, including all United States Attorneys, on all civil matters and on all criminal matters, other than those criminal matters referred to the Department of Justice by the Inspector General.

e. Acts as the Department's sole representative in communicating with Office of White House Counsel or the Offices of General Counsel for any other Department or Agency.

f. Performs all liaison functions in connection with legal matters involving the Department, and formulating or reviewing requests for formal opinions or rulings by the Attorney General and the Comptroller General.

g. Issues pre-enforcement rulings or advisory opinions to the public on questions of law, except to the extent that that such authority has previously been delegated to the Inspector General under section 1128D of the Social Security Act.

h. Authorizes indemnification, as appropriate, pursuant to 45 CFR part 36.

i. Conducts internal investigations at the request of the Secretary or Deputy Secretary, or for matters that could lead to litigation.

j. Drafts all proposals for legislation originating in the Department and reviewing all proposed legislation submitted to the Department or to any operating agency of the Department for comment; preparing reports and letters to congressional committees, the Office of Management and Budget, and others on proposed legislation; and prescribing procedures to govern the routing and review, within the Department, of material relating to proposed Federal legislation.

k. Performs liaison functions with the Office of the Federal Register, National Archives and Records Service.

l. Reviews and approves all administrative complaints and enforcement actions by any agency within the Department before those complaints are filed or transmitted, or enforcement actions instituted to ensure that the complaint or enforcement action is legally sound.

m. Leads all negotiations on behalf of any agency within the Department.

n. Supervises all legal activities of the Department and its operating agencies.

o. Ensures that no one in the Department, other than those in OGC or expressly authorized by statute to do so, provides any legal advice to anyone in the Department or uses any title that

implies that they are functioning as a departmental lawyer.

2. **Principal Deputy General Counsel.** The Principal Deputy General Counsel is the second ranking legal officer in the Department and performs the functions of the General Counsel in his or her absence or disability, including recusal, and, unless otherwise noted, oversees for the General Counsel all litigation involving the Department, its officers, inferior officers, and employees.

3. **Deputy General Counsel.** The Deputy General Counsel assist the General Counsel in carrying out his or her responsibilities and performs such duties as the General Counsel or Principal Deputy General Counsel may assign. The Associate General Counsel for a Division shall report to the General Counsel through one or more Deputy General Counsel, as may be assigned by the General Counsel. Regional Chief Counsel shall report to the General Counsel through a career Deputy General Counsel.

#### *B. Functions, Authorities and Responsibilities of the Divisions*

The Divisions within OGC provide legal counsel to their clients, as described below, subject to the professional supervision and control of the General Counsel and assigned Deputy General Counsel.

1. **General Law Division.** The General Law Division, acting through its Associate General Counsel, performs the following:

a. Provides legal services on business management activities and administrative operations throughout the Department, including employment, compensation, personnel, appropriations, real and personal property (including National Environmental Policy Act), procurement, information, travel, and certain claims by and against the Department.

b. Represents the Department in all aspects of administrative litigation before the Merit Systems Protection Board (MSPB), Equal Employment Opportunity Commission (EEOC), and in labor arbitrations, as needed. Acts as agency counsel in support of the Department of Justice on employment cases filed in federal court.

c. Represents the Department in bid protests filed before the Comptroller General and contract disputes filed before the Civilian Board of Contract Appeals. Acts as agency counsel in support of the Department of Justice in bid protests and contract disputes filed before the U.S. Court of Federal Claims and appealed to the Federal Circuit.

d. Provides legal services to Department Freedom of Information Act (FOIA) Officers on the disclosure of agency records requested under FOIA, and communicates with the Department of Justice on the administration of the Freedom of Information Act.

e. Provides legal services to the Department on the Privacy Act of 1974, as amended, the Paperwork Reduction Act, the Federal Records Act, and the Government in the Sunshine Act.

f. Provides all legal services with respect to the formation, maintenance, and administration of the advisory committees under the Federal Advisory Committee Act.

g. Acts as the Department Claims Officer, responsible for adjudicating all administrative claims filed under the Federal Tort Claims Act, approval of claims filed under the Federal Medicare Recovery Claims Act in amounts of at least \$20,000 but not exceeding \$300,000, tort liability claims under the U.S. Constitution and other laws under which claims for money damages may be filed with the Department, as provided by 5 U.S.C. 5584, 10 U.S.C. 2774, except for claims arising under the Social Security Act. Also responsible for making final determinations on legally enforceable non tax debts owed to the United States government arising from HHS programs under the Federal Claims Collection Act, as amended, 31 U.S.C. 3711 *et seq.*, on the compromise of, and the suspension or termination of collection activities for, claims in amounts of \$100,000 or less, exclusive of interest, and on the waiver of interest.

2. **Children, Families, and Aging Division.** The Children, Families, and Aging Division Provides legal services to the Administration for Children and Families and its various agencies including the Office of Refugee Resettlement and Administration for Community Living.

3. **Ethics Division.** The Ethics Division administers and oversees Department-wide implementation of comprehensive government ethics program requirements under the Ethics in Government Act of 1978, as amended, Executive Order 12731, and implementing regulations at 5 CFR part 2638. The Division, without limitation, performs the following:

a. Provides legal advice and policy guidance on interpretation and compliance issues involving the criminal conflict of interest statutes, 18 U.S.C. 210–219, political activity restrictions, anti-lobbying provisions, outside activity limitations, travel reimbursement guidelines, procurement integrity rules, financial disclosure

obligations, and standards of ethical conduct matters including gifts between employees and from outside sources, conflicting financial interests and impartiality concerns, misuse of position and agency resources, and outside employment, fundraising, testimony, and teaching, speaking or writing, to Department officials, agency personnel, advisory committees and others.

b. Reviews executive branch public financial disclosure reports submitted by Presidential nominees/appointees subject to Senate confirmation, non-career SES and Schedule C political appointees, OGC career SES officials, and Op/Staff Division ethics officials (DECs) to assess potential violations of applicable laws or regulations, ensure transparency through accurate reporting, provide counseling on the avoidance of conflicts, and, if necessary, recommending appropriate corrective action, including drafting waivers, disqualification statements, ethics agreements, and certificate of divestiture materials; ensuring identical review and counseling responsibilities with respect to both the public and confidential financial disclosure forms filed by career employees are performed Department-wide by the DECs.

c. Plans, develops, and provides initial ethics orientation for new employees, annual ethics training for employees who file financial disclosure forms and others occupying certain sensitive positions, initial and annual ethics training for members of federal advisory committees, and specialized, topic-specific training on post-employment restrictions, political activity restrictions, insider trading, and procurement integrity rules.

d. Monitors component ethics programs and reviewing compliance with core ethics program elements, including advice, financial disclosure, outside activities, conflict of interest waivers, ethics agreements and travel payments from non-federal sources.

e. Communicates on matters related to government ethics with the Office of Counsel to the President, the Office of Government Ethics, the Office of Special Counsel, the Office of the Inspector General, Special Investigations Unit, the Office of Personnel Management, and the General Services Administration.

f. Develops component-specific conduct regulations and implementing procedures.

4. **Food and Drug Division.** The Food and Drug Division acts as the Commissioner's legal advisor and provides legal services to FDA. FDD, for example, performs the following:

a. Represents the FDA in connection with judicial and administrative proceedings involving programs administered by the FDA. Provides legal advice and policy guidance for programs administered by the FDA.

b. Acts as the Department and FDA's sole liaison to the Department of Justice and other Federal Departments for programs administered by FDA; all criminal prosecutions, investigations, and civil matters may only be referred to the Department of Justice through the Chief Counsel.

c. Drafts or reviews all proposed and final regulations and **Federal Register** notices prepared by FDA.

d. Performs legal research and gives legal opinions on regulatory issues, actions, and petitions submitted to FDA.

e. Reviews proposed legislation affecting FDA that originates in the Department or on which Congress requests the views of the Department.

f. Provides legal advice and assistance to the Office of the Secretary on matters within the expertise of the Chief Counsel.

5. *Public Health Division.* The Public Health Division provides legal services to all Public Health Service agencies (except to the Food and Drug Administration) and their programs, including the Office of the Surgeon General and the Commissioned Corps of the U.S. Public Health Service. Represented Public Health Service agencies include, but are not limited to the (i) the Office of the Assistant Secretary for Health, and its various programs, (ii) the Office of the Secretary's Office of Minority Health, (iii) the Centers for Disease Control and Prevention, (iv) the National Institutes of Health, (v) the Health Resources and Services Administration, (vi) the Indian Health Service, (vii) the Substance Abuse and Mental Health Services Administration, (viii) the Agency for Healthcare Research and Quality, and (ix) the Office of the Assistant Secretary for Preparedness and Response. In addition, the Public Health Service Division serves as the lead office within the Office of the General Counsel for grants-related and intellectual property issues, other than federal court or PTAB litigation.

6. *Legislation Division.* The Legislation Division performs the following:

a. Drafts all proposed legislation originating in the Department, reviewing specifications for such proposed legislation, and reviewing all proposed legislation submitted to the Department or to any constituent unit of the Department for comment.

b. Prepares or reviews reports and letters to Congressional Committees, the Office of Management and Budget, and others on proposed legislation.

c. Reviews proposed testimony of Department officials before Congressional Committees relating to pending or proposed legislation.

d. Acts as Department liaison with the Office of Management and Budget on legislative matters.

e. Prescribes procedures to govern the routing and review, within the Department, of material relating to proposed Federal legislation.

7. *Centers for Medicare & Medicaid Services Division.* The Centers for Medicare & Medicaid Services Division, acting through the Deputy General Counsel serving as the CMS Chief Legal Officer or an Associate General Counsel,

a. Acts as the CMS Administrator's legal advisor.

b. Represents CMS and the Office of the National Coordinator for Health Information Technology ("ONC") in court proceedings and administrative hearings with respect to programs administered by CMS or ONC.

c. Provides legal advice and policy guidance for programs administered by CMS and ONC.

d. Acts as the Department's and CMS's and ONC's liaison to the Department of Justice and other Federal Departments for programs administered by those operating divisions.

e. Drafts or reviews all proposed and final regulations and **Federal Register** notices prepared by CMS, ONC, and other agencies.

f. Performs legal research and gives legal opinions on regulatory issues, actions, and petitions submitted to CMS and ONC.

g. Reviews proposed legislation affecting CMS, ONC, Office of Medicare Hearing Appeals (OMHA) and DAB that originates in the Department or on which Congress requests the views of the Department.

h. Provides legal advice and assistance to the Office of the Secretary on matters within the expertise of the CMS Chief Legal Officer.

i. Provides legal advice and assistance to the Office of the Secretary on matters relating to the COVID-19 Provider Relief Fund (PRF) and similar provider relief programs, including advice regarding the administration of the PRF, civil litigation relating to the PRF, and fraud and abuse involving PRF payments.

8. *Civil Rights Division.* The Civil Rights Division provides legal services for the Office for Civil Rights (OCR) and provides legal advice with respect to the civil rights laws to all agencies and

offices within the Department, and in coordination with the assigned Deputy General Counsel, evaluates complaints, advises whether there is legal basis to proceed, assists OCR in developing and implementing investigation plans, and clears the imposition of any civil money penalties. CRD likewise represents the Department in administrative proceedings and federal litigation, together with the Department of Justice. CRD provides these legal services with respect to:

a. Traditional civil rights laws such as, by way of example, title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.* and 47 U.S.C. 225, 661), section 1557 of the Affordable Care Act (42 U.S.C. 18116).

b. Conscience statutes, such as the Church Amendments, the Weldon Amendment, and the Coats-Snowe Amendment.

c. The Health Insurance and Portability and Accountability Act of 1996 (Social Security Act section 1171 *et seq.*), the Health Information Technology for Economic and Clinical Health (HITECH) Act, and the rules implementing them.

The authorities of CRD and the General Counsel described here do not supersede the terms of any statute, regulation, or delegation granting authority or responsibility to OCR.

9. *National Complex Litigation and Investigations Division.* The National Complex Litigation and Investigations Division provides legal services across the Department, as directed by the General Counsel or Principal Deputy General Counsel. In that regard, NCLID, performs the following:

a. Coordinates litigation spanning multiple OGC divisions, regional offices, or geographic areas.

b. Provides legal services in connection with complex litigation or anticipated complex litigation by or against the Department. Such litigation may include cases for which other OGC divisions or OGC regions request NCLID participation; cases spanning multiple OGC divisions or regional offices, or cases outside the scope of other OGC divisions or regional offices.

c. Conducts internal investigations at the request of the Secretary or Deputy Secretary, or on matters that could lead to litigation.

d. Administers the OGC-wide e-discovery program, and coordinates the

use of e-discovery technology with other HHS staff and operating divisions.

e. Identifies and supports the implementation of best practices for litigation management, e-discovery, and virtual staffing across OGC.

### *C. Functions, Authorities and Responsibilities of the Regions*

The Chief Counsel of each Region is HHS' legal representative in that Region. Regional offices within OGC provide a full range of legal services including, by way of example, legal counsel to their departmental clients and client agencies in the regions, as described below, subject to the professional supervision and direction of the General Counsel.

The Office of the General Counsel's ten regional offices provide legal advice, administrative and judicial litigation support and counseling services to the regional components of the Department. Regional attorneys provide general law support to regional clients and handle work in most areas within HHS' jurisdiction with particular emphasis on litigation for, among others, CMS, ACF, OCR, CDC, and IHS. Regional offices also provide leadership with respect to bankruptcy cases. In the area of civil rights, they work in close consultation with the Associate General Counsel for the Civil Rights Division to ensure that the regional positions align closely with those of the Division thereby fostering national uniformity. In other areas, the Divisions and Regions work collaboratively to provide consistent, uniform legal advice.

Dated: August 27, 2020.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2020-19325 Filed 8-28-20; 8:45 am]

**BILLING CODE P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Neurological Sciences Training Initial Review Group; NST-1, Subcommittee NST-1.

*Date:* September 21-22, 2020.

*Time:* 9:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, NSC, 6001 Executive Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS, NIH, NSC, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892-9529, (301) 496-0660, [benzingw@mail.nih.gov](mailto:benzingw@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel, NST-1 Member Conflict Review Panel.

*Date:* September 22, 2020.

*Time:* 1:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, NSC, 6001 Executive Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS, NIH NSC, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892-9529, (301) 496-0660, [benzingw@mail.nih.gov](mailto:benzingw@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 27, 2020.

**Tyeshia M. Roberson,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-19318 Filed 9-1-20; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group; Behavioral Medicine, Interventions and Outcomes Study Section.

*Date:* October 5-6, 2020.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Mark Allen Vosvick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, Bethesda, MD 20892, 301-402-4128, [mark.vosvick@nih.gov](mailto:mark.vosvick@nih.gov).

*Name of Committee:* Population Sciences and Epidemiology Integrated Review Group; Behavioral Genetics and Epidemiology Study Section.

*Date:* October 6-7, 2020.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Andrew Loudan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3137, Bethesda, MD 20817, 301-435-1985, [loudenan@csr.nih.gov](mailto:loudenan@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; S10 Programs for Shared Instrumentation Grant (SIG) and Shared Instrumentation for Animal Research (SIFAR) Grant.

*Date:* October 6, 2020.

*Time:* 10:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Jan Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, Bethesda, MD 20892, 301.402.9607, [Jan.Li@nih.gov](mailto:Jan.Li@nih.gov).

*Name of Committee:* Oncology 1-Basic Translational Integrated Review Group; Molecular Oncogenesis Study Section.

*Date:* October 7-8, 2020.

*Time:* 9:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.