

*Estimated Total Annual Burden Hours: 1,239.*

**Additional Information:** Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,  
ACF/OPRE Certifying Officer.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Statement of Organization, Functions, and Delegations of Authority

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Office of the Commissioner, Headquarters organizations, and Centers have modified their structures.

**FOR FURTHER INFORMATION CONTACT:** William Tootle, Director, Office of Budget, Office of the Commissioner, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 72094, Beltsville, MD 20705-4304, 301-796-4710.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56606, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; 74 FR 41713, August

18, 2009; and 76 FR 45270, July 28, 2011) is amended to reflect the reorganization of the Office of the Commissioner/FDA Headquarters and the following Centers: Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), Center for Food Safety and Applied Nutrition (CFSAN), Center for Tobacco Products (CTP), and Center for Veterinary Medicine (CVM).

The Office of the Commissioner reorganization will transition FDA away from the Directorate structure. Abolishing the current directorate structure and realigning many of those functions to the Centers/Office of Regulatory Affairs (ORA) establishes a direct line of communication between the Centers/ORA and the Commissioner of Food and Drugs. This direct report relationship with the Centers streamlines communications and better positions FDA to support its regulatory programs and mission. The intent is to create a more effective structure that better reflects FDA's priorities and streamlines operations.

The CDRH reorganization will more accurately reflect the functions performed by the Center and help to enhance CDRH's ability to advance FDA's mission and streamline operations and support functions.

The CDER reorganization changes the organizational structures and revises the functional statements of following organizations: Office of Communication (OCOMM), Office of Compliance (OC), Office of Executive Programs (OEP), Office of Hematology and Oncology Products (OHOP), and Office of New Drugs (OND). The proposed organizational changes will enhance CDER's ability to develop, coordinate, and evaluate public health communication and education activities in support of the following:

The CDER Office of Compliance proposed structure change will establish the framework for a stronger regulatory oversight of the compounded human drugs facilities and compounding related activities. The new structure will help ensure the following: That compounding pharmacies operate within the bounds of traditional pharmacy practice (not manufacturing); that outsourcing facilities operate according to the conditions in section 503B; and the new structure will protect patients from unsafe or ineffective compounded drugs.

The CDER Office of Communication is planning to expand CDER's communications outreach and educational efforts to inform the conversation among FDA's stakeholders. This will be managed through accessing

more communication channels, enhancing FDA's social media presence, and using more innovative tools. The impact of CDER's growth has impacted the volume of information posted on the web as the content management and development of tools used to connect stakeholders with web content are created. As new programs and initiatives are developed by the Center, the web content will increase. The new content management system will provide the Agency with the opportunity to finally have a true publishing tool. This will allow greater speed in posting the content in the web environment.

The CDER Office of Executive Programs houses all the executive functions for CDER and ensures the goals and priorities of the Center Director are carried out. These functions range from administrative support for the Center Director's Office, overseeing the Center's learning and organizational development program, to managing the Center's 18 different Advisory Committees. Restructuring these functions into defined organizational structures will improve decision making by promoting the direct flow of information from frontline employees to the managers directly responsible for making decisions and provide clarity to staff roles and responsibilities. Furthermore, the proposed organizational changes permit Office of Executive Programs' managers to better define critical business processes and identify opportunities for streamlining complex tasks, which will facilitate a more efficient and strategic deployment of these resources during public health emergencies and outbreaks. The proposed changes align with Reimagine HHS guiding principle #3—Generating Efficiencies through Streamlined Processes and Reimagine HHS guiding principle #5—HHS as a More Innovative and Responsive Organization.

The CDER Office of Hematology and Oncology Products reorganization is in response to Title III of the 21st Century Cures Act (Cures Act), enacted into law on December 13, 2016, which provides authorities FDA can use to help modernize drug, biological, and device product development and review to create greater efficiencies and predictability in product development and review. Numerous initiatives are currently taking place in the Agency to carry out the plan laid out in the Cures Act and include: Patient Focused Drug Development; Novel Clinical Trial Design; Real World Evidence; Summary-level Review and Inter-Center Institutes; as well as other initiatives. The Office of Hematology and Oncology Products

has been an active participant and at times a leader in many of these initiatives. To meet external and internal stakeholders' expectations and to effectively and efficiently carry out these initiatives delineated in the Cures Act, it is necessary to flatten out the organizational structure. The office proposes to expand their clinical review divisions from three to five, create a centralized safety reporting team, and create a labeling team. The office is dedicated in modernizing the drug, biological, and device product development and review and in creating greater efficiencies and predictability in oncology product development and review. With this restructuring, the office, working in partnership with the Oncology Center of Excellence, can ensure that the Agency's initiatives are being worked on in an efficient and cohesive manner so that industry and all other outside groups feel as if we are working with them in the fight against cancer.

The CDER Office of Therapeutic Biologics and Biosimilars reorganization is in response to the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), which was enacted on March 23, 2010. This law amended the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to or interchangeable with an already approved FDA-licensed biological product (the reference product). This pathway was established to provide more treatment options, increase access to lifesaving medications, and potentially reduce healthcare costs through increased competition. The current review management and policy development approach for biosimilar and interchangeable products lacks a "primary owner" and this impacts CDER's ability to set a singular goal and focus on internal operational requirements and communication similar to new drugs and generic drugs products. Specifically, policy development is fractured between the CDER Office of Medical Policy (OMP), Office of New Drugs (OND), and Office of Regulatory Policy (ORP). Since there is no office that holds primary responsibility for setting policy direction, the drafting and responding to inquiries such as citizen petitions and the development of policy positions is split between the various organizations. Likewise, the communication efforts are split between CDER OMP, OND, and OCOMM. While there is clear evidence of operational efficiencies associated with the review process for biosimilar

and interchangeable products, the biggest inefficiency is with policy development. This proposed reorganization will be part of FDA's ongoing efforts to achieve the performance goals agreed to by the Agency in conjunction with the reauthorization of Biosimilar User Fee Act (BsUFA II).

The CFSAN reorganization realigns functions and personnel, retitling and establishing of new organizations within the CFSAN offices of: Office of Cosmetics and Colors, Office of Food Additive Safety, and Office of Coordinated Outbreak Response and Evaluation Network, which formalize its organizational components and functions; distinguish operational culture between pre- and post-market review; clarify staff allocation; improve effectiveness; and increase efficiency in the management and leadership for internal and external stakeholders.

The CTP Office of Health Communication and Education reorganization establishes the Division of Research and Evaluation; changes the title of the Division of Health, Scientific, and Regulatory Communication to the Division of Regulatory Communication; and revises the functional statements of the Office of Health Communication and Education; the Division of Public Health Education; and the Division of Regulatory Communication. The proposed organizational changes will enhance the Center's ability to develop, coordinate, and evaluate public health communication and education activities in support of requirements of the Family Smoking Prevention and Tobacco Control Act.

The CVM reorganization affects the Center's Office of Management and Office of New Animal Drug Evaluation.

The CVM Office of Management reorganization establishes the Business Informatics Staff; abolishes the Management Logistics Staff; and revises the functional statements of the Office of Management. The organizational changes will enhance CVM's ability to promote information technology guidelines and policies; manage the center's information technology portfolio; and provide capital planning and investment controls to the Department of Health and Human Services.

The CVM Office of New Animal Drug Evaluation reorganization establishes the Division of Animal Bioengineering and Cellular Therapies and revises the functional statements of the Office of New Animal Drug Evaluation. The organizational changes will create a dedicated group for the review and approval of biologically derived

emerging technologies, such as animal bioengineering and cell and gene therapy products.

The Food and Drug Administration, Office of the Commissioner (OC) and Headquarters, Centers, and Offices, have been restructured as follows:

DCA. ORGANIZATION. The Office of the Commissioner is headed by the Commissioner of Food and Drugs, and includes the following organizational units:  
OFFICE OF THE COMMISSIONER  
Office of the Chief Counsel  
Office of the Executive Secretariat  
Freedom of Information Staff  
Office of the Counselor to the Commissioner

DCB. ORGANIZATION. The Center for Biologics Evaluation and Research is headed by the Center Director.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

DCC. ORGANIZATION. The Center for Devices and Radiological Health is headed by the Center Director and includes the following organizational units:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Office of the Center Director  
Quality Management Staff  
Office of Science and Engineering Laboratories  
Management Support Staff  
Division of Biomedical Physics  
Division of Imaging, Diagnostics, and Software Reliability  
Division of Applied Mechanics  
Division of Administrative and Laboratory Support  
Division of Biology, Chemistry and Materials Science  
Office of Communication and Education  
Program Management Operations Staff  
Division of Communication  
Web and Graphics Branch  
External Communications Branch  
Internal Communications Branch  
Division of Industry and Consumer Education  
Postmarket and Consumer Branch  
Premarket Programs Branch  
Division of Information Disclosure  
Freedom of Information Branch A  
Freedom of Information Branch B  
Division of Employee Training and Development  
Employee Development Branch  
Technology and Learning Management Branch  
Office of Management  
Planning and Program Analysis Staff  
Division of Workforce Management  
Division of Financial Management  
Division of Management Services  
Division of Acquisition Services  
Office of Product Evaluation and Quality  
Quality and Analytics Staff  
Clinical and Scientific Policy Staff  
Strategic Initiatives Staff  
Regulation, Policy and Guidance Staff  
Office of Regulatory Programs  
Division of Regulatory Programs I  
Division of Regulatory Programs II  
Division of Regulatory Programs III  
Office of Clinical Evidence and Analysis

Division of Clinical Evidence and Analysis I  
 Division of Clinical Evidence and Analysis II  
 Office of Health Technology I  
 Division of Health Technology I A  
 Division of Health Technology I B  
 Division of Health Technology I C  
 Office of Health Technology II  
 Division of Health Technology II A  
 Division of Health Technology II B  
 Division of Health Technology II C  
 Office of Health Technology III  
 Division of Health Technology III A  
 Division of Health Technology III B  
 Division of Health Technology III C  
 Office of Health Technology IV  
 Division of Health Technology IV A  
 Division of Health Technology IV B  
 Office of Health Technology V  
 Division of Health Technology V A  
 Division of Health Technology V B  
 Office of Health Technology VI  
 Division of Health Technology VI A  
 Division of Health Technology VI B  
 Division of Health Technology VI C  
 Office of In Vitro Diagnostics and  
 Radiological Health  
 Division of Chemistry and Toxicology  
 Devices  
 Chemistry Branch  
 Diabetes Branch  
 Toxicology Branch  
 Cardio-Renal Diagnostics Branch  
 Division of Immunology and Hematology  
 Devices  
 Hematology Branch  
 Immunology and Flow Cytometry Branch  
 Division of Microbiology Devices  
 Viral Respiratory and Human Papilloma  
 Respiratory Branch  
 General Viral and Hepatitis Branch  
 General Bacterial and Antimicrobial  
 Susceptibility Branch  
 Bacterial Respiratory and Medical  
 Countermeasures Branch  
 Division of Radiological Health  
 Magnetic Resonance and Electronic Products  
 Branch  
 Diagnostic X-Ray Systems Branch  
 Nuclear Medicine and Radiation Therapy  
 Branch  
 Mammography, Ultrasound and Imaging  
 Software Branch  
 Division of Mammography Quality Standards  
 Program Management Branch  
 Information Management Branch  
 Division of Program Operations and  
 Management  
 Division of Molecular Genetics and  
 Pathology  
 Molecular Pathology and Cytology Branch  
 Molecular Genetics Branch  
 Office of Strategic Partnerships and  
 Technology Innovation  
 Division of All Hazards Response, Science  
 and Strategic Partnerships  
 Division of Digital Health  
 Division of Technology and Data Services  
 Office of Policy

DCD. ORGANIZATION. The Center for  
 Drug Evaluation and Research is headed by  
 the Director and includes the following  
 organization units:

#### CENTER FOR DRUG EVALUATION AND RESEARCH

Office of the Center Director  
 Office of Regulatory Policy

Office of Management  
 Office of Communications  
 Office of Compliance  
 Office of Manufacturing Quality  
 Office of Unapproved Drugs and Labeling  
 Compliance  
 Office of Scientific Investigations  
 Office of Program and Regulatory Operations  
 Office of Medical Policy  
 Office of Prescription Drug Promotion  
 Office of Medical Policy Initiatives  
 Office of Translational Sciences  
 Office of Biostatistics  
 Office of Clinical Pharmacology  
 Office of Computational Science  
 Office of Study Integrity and Surveillance  
 Office of Executive Programs  
 Office of Surveillance and Epidemiology  
 Office of Medication Error Prevention and  
 Risk Management  
 Office of Pharmacovigilance and  
 Epidemiology  
 Office of New Drugs  
 Office of Drug Evaluation I  
 Office of Drug Evaluation II  
 Office of Drug Evaluation III  
 Office of Antimicrobial Products  
 Office of Drug Evaluation IV  
 Office of Hematology and Oncology Products  
 Office of Strategic Programs  
 Office of Program and Strategic Analysis  
 Office of Business Informatics  
 Office of Generic Drugs  
 Office of Research Standards  
 Office of Bioequivalence  
 Office of Generic Drug Policy  
 Office of Regulatory Operations  
 Office of Pharmaceutical Quality  
 Office of Biotechnology Products  
 Office of New Drug Products  
 Office of Policy for Pharmaceutical Quality  
 Office of Process and Facilities  
 Office of Surveillance  
 Office of Testing and Research  
 Office of Program and Regulatory Operations  
 Office of Lifecycle Drug Products

DCE. ORGANIZATION. The Center for  
 Food Safety and Applied Nutrition is headed  
 by the Center Director.

#### CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

DCED. ORGANIZATION. The Office of  
 Food Additive Safety is headed by the  
 Director, Office of Food Additive Safety, and  
 includes the following organizational units:

Office of Food Additive Safety  
 Operations Staff  
 Division of Food Contact Substances  
 Toxicology Review Branch  
 Chemistry Review Branch  
 Regulatory Review Branch  
 Division of Food Ingredients  
 Toxicology Review Branch  
 Chemistry Review Branch  
 Regulatory Review Branch  
 Division of Biotechnology, Regulatory  
 Science, and Surveillance  
 Post-Market Review Branch  
 Scientific Support Branch

DCEE. ORGANIZATION. The Office of  
 Cosmetics and Colors is headed by the  
 Director, Office of Cosmetics and Colors, and  
 includes the following organizational units:

Office of Cosmetics and Colors  
 Division of Cosmetics and Colors

Color Certification Branch  
 Color Technology Branch  
 Division of Cosmetics  
 Cosmetics Regulatory Activities Branch  
 Cosmetics Regulatory Science Branch

DCEN. ORGANIZATION. The Office of  
 Coordinated Outbreak Response and  
 Evaluation Network is headed by the  
 Director, Office of Coordinated Outbreak  
 Response and Evaluation Network, and  
 includes the following organizational units:  
 Office of Food Additive Safety  
 Signals and Analysis Staff

DCF. ORGANIZATION. The Center for  
 Tobacco Products is headed by the Center  
 Director.

#### CENTER FOR TOBACCO PRODUCTS

DCFF. ORGANIZATION. The Center for  
 Tobacco Products Office of Health  
 Communication and Education is headed by  
 the Director of Health Communication and  
 Education and includes the following  
 organizational units:

Office of Health Communication and  
 Education  
 Division of Public Health Education  
 Division of Regulatory Communication  
 Division of Research and Evaluation

DCG. ORGANIZATION. The Center for  
 Veterinary Medicine is headed by the Center  
 Director.

#### CENTER FOR VETERINARY MEDICINE

DCGB. ORGANIZATION. The Center for  
 Veterinary Medicine Office of Management is  
 headed by the Associate Director for  
 Management and includes the following  
 organizational units:

Budget Planning and Evaluation Staff  
 Business Informatics Staff  
 Human Capital Management Staff  
 Program and Resources Management Staff  
 Talent Development Management Staff

DCGC. ORGANIZATION. The Center for  
 Veterinary Medicine Office of New Animal  
 Drug Evaluation is headed by the Director of  
 New Animal Drug Evaluation and includes  
 the following organizational units:

Division of Animal Bioengineering and  
 Cellular Therapies  
 Division of Business Information Science and  
 Management  
 Division of Generic Animal Drugs  
 Division of Human Food Safety  
 Division of Manufacturing Technologies  
 Division of Production Drugs  
 Division of Scientific Support  
 Division of Therapeutic Drugs for Food  
 Animals  
 Division of Therapeutic Drugs for Non-Food  
 Animals

DCH. ORGANIZATION. The Oncology  
 Center of Excellence is headed by the  
 Director and includes the following  
 organizational units:

#### ONCOLOGY CENTER OF EXCELLENCE

DCI. ORGANIZATION. The Office of  
 Regulatory Affairs is headed by the Associate  
 Commissioner for Regulatory Affairs.

#### OFFICE OF REGULATORY AFFAIRS

DCJ. ORGANIZATION. The Office of  
 Clinical Policy and Programs is headed by  
 the Director, Office of Clinical Policy and

Programs, and includes the following organizational units:

**OFFICE OF CLINICAL POLICY AND PROGRAMS**

Healthcare Provider Staff  
Patient Affairs Staff  
Office of Clinical Policy  
Good Clinical Practice Staff  
Office of Combination Products  
Office of Orphan Products Development  
Office of Pediatric Therapeutics

**DCK. ORGANIZATION.** The Office of External Affairs is headed by the Associate Commissioner for External Affairs and includes the following organizational units:

**OFFICE OF EXTERNAL AFFAIRS**

Operations Staff  
FDA History Office  
Stakeholder Engagement Staff  
Web & Digital Services Staff  
Office of Media Affairs  
Office of Editorial and Creative Services

**DCL. ORGANIZATION.** The Office of Food Policy and Response is headed by the Deputy Commissioner for Food Policy and Response, and includes the following organizational units:

**OFFICE OF FOOD POLICY AND RESPONSE**  
Office of Resource Planning and Strategic Management

**DCM. ORGANIZATION.** The Office of Minority Health and Health Equity is headed by the Assistant Commissioner for Minority Health and Health Equity and includes the following organizational units:

**OFFICE OF MINORITY HEALTH AND HEALTH EQUITY**

**DCN. ORGANIZATION.** The Office of Operations is headed by the Chief Operating Officer and includes the following organizational units:

**OFFICE OF OPERATIONS**

Office of Enterprise Management Services  
Program Effectiveness Staff  
Division of Compliance and Conflict Prevention  
Conflict Prevention and Resolution Staff  
Division of Human Capital  
Division of Information Governance  
Dockets Management Staff  
Division of Resource Management  
Division of Vendor Management  
Office of Equal Employment and Opportunity Compliance Staff  
Office of Ethics and Integrity  
Office of Facilities, Engineering and Mission Support Services  
Jefferson Laboratories Complex Staff  
Facilities Program Staff  
Employee Safety and Occupational Health Staff  
Division of Operations Management and Community Relations  
Logistics and Transportation Management Branch  
Facilities Maintenance and Operations Branch  
Auxiliary Program Management Staff  
Division of Planning, Engineering and Space Management  
Portfolio and Space Management Branch  
Engineering Management Branch  
Office of Finance, Budget, and Acquisitions  
Business Management Services Staff

Office of Acquisitions and Grants Services  
Division of Acquisition Operations  
Service Contracts Branch  
Contracts Operations Branch  
Division of Acquisition Programs  
Scientific Support Branch  
Field Operations Branch  
Facilities Support Branch  
Division of State Acquisitions, Agreements and Grants  
Grants and Assistance Agreements Branch  
ORA Inspection Branch  
CTP Inspection Branch  
Division of Information Technology Acquisitions  
Information Technology Acquisitions Branch  
Systems Technology Acquisitions Branch  
Information Technology Strategic Support Branch  
Division of Policy, Systems and Program Support  
Training and Development Branch  
Acquisitions Policy and Oversight Branch  
Office of Budget  
Division of Budget Formulation and Program Alignment  
Division of Budget Execution and Control  
Office of Financial Management  
Financial Systems Support Staff  
Division of Accounting  
Division of Controls, Compliance and Oversight  
Division of Payment Services  
Division of Travel Services  
Field Operations Staff  
Division of User Fees  
Office of Human Capital Management  
Business Operations Staff  
Management and Administrative Inquiries Staff  
Performance Management and Awards Staff  
Division of FDA Training and Development  
Organization Development and Learning Solutions Branch  
Training Delivery and Program Operations Branch  
Division of Human Resources Systems and Operations Support  
Data Quality and Services Management Branch  
Human Resources Information Systems and Records Branch  
Human Resources Information Technology Branch  
Retirement and Benefits Branch  
Timekeeping and Payroll Services Branch  
Division of Employee and Labor Relations  
Employee Relations Branch I  
Employee Relations Branch II  
Labor Relations Branch  
Division of Strategic Talent Management Programs  
Workforce Support and Development Branch  
Quality of Work-life Programs Branch  
Office of Information Management and Technology  
Office of Information Management  
Office of Information Security  
Office of Technology and Delivery  
Delivery Management and Support Staff  
Division of Infrastructure Operations  
Infrastructure Management Services Staff  
Implementation Branch  
Infrastructure Engineering Branch  
Systems Monitoring & Response Branch  
Systems Operations Branch

Network & Communications Operations Branch  
Division of Application Services  
Application Management Services Staff  
Data Management & Operations Branch  
Medical Products Branch  
OC/CVM/CTP Branch  
ORA/CFSAN Branch  
Enterprise Applications Branch  
Office of Business & Customer Assurance  
Division of Business Partnership & Support  
Internet & Intranet Branch  
Call Center Branch  
Regional Support Branch  
Property, Receiving & Distribution Branch  
Employee Resource and Information Center  
Division of Management Services  
Office of Enterprise Portfolio Management  
Office of Informatics & Technology Innovation  
Informatics Staff  
Knowledge Management Staff  
Enterprise Architecture Staff  
Office of Planning and Evaluation  
Planning Staff  
Program Evaluation and Process Improvement Staff  
Office of Security and Emergency Management  
Office of Security Operations  
Office of Emergency Management  
Emergency Planning, Exercises and Evaluation Staff  
Program Operations and Coordination Staff  
Office of Emergency Operations  
Office of Talent Solutions  
Commission Corps Staff  
Executive Resources Staff  
Policy and Accountability Staff  
Scientific Talent Recruitment Staff  
Division of Talent Services I  
CDER Branch A  
CDER Branch B  
CDER Branch C  
Division of Talent Services II  
CFSAN and CVM Branch  
OC and National Center for Toxicological Research Branch  
OO Branch  
Division of Talent Services III  
CBER Branch  
CDRH Branch  
CTP Branch  
Division of Talent Services IV  
ORA Branch A  
ORA Branch B  
ORA Branch C  
Division of Talent Sourcing and Staffing  
Corporate Recruitment & Title 38 Branch  
Scientific Staffing & Outreach Branch  
Customer Care and Data Quality Branch  
**DCO. ORGANIZATION.** The Office of Policy, Legislation, and International Affairs is headed by the Deputy Commissioner for Policy, Legislation, and International Affairs and includes the following organizational units:  
**OFFICE OF POLICY, LEGISLATION, AND INTERNATIONAL AFFAIRS**  
Intergovernmental Affairs Staff  
Management and Operations Staff  
Office of Congressional Appropriations  
Office of Economics and Analysis  
Office of Global Policy and Strategy  
Office of Global Diplomacy and Partnerships  
Office of Global Operations

Regional Field Office, China Office  
Regional Field Office, Europe Office  
Regional Field Office, India Office  
Regional Field Office, Latin America Office  
Office of Trade, Mutual Recognition and  
International Arrangements

Office of Legislation

Office of Policy

Policy Engagement and Coordination Staff

Regulations Editorial Staff

Regulations Policy and Management Staff

DCP. ORGANIZATION. The Office of the Chief Scientist is headed by the Chief Scientist and includes the following organizational units:

OFFICE OF THE CHIEF SCIENTIST

Advisory Committee Oversight and

Management Staff

Office of Counter-Terrorism and Emerging Threats

Office of Laboratory Safety

Office of Regulatory Science and Innovation

Office of Scientific Integrity

Office of Scientific Professional Development

National Center for Toxicological Research

DCQ. ORGANIZATION. The Office of Women's Health is headed by the Assistant Commissioner for Women's Health and includes the following organizational units:

OFFICE OF WOMEN'S HEALTH

## II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

## III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide. Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>.

Authority: 44 U.S.C. 3101.

Alex M. Azar, II,

Secretary, HHS.

[FR Doc. 2019-10431 Filed 5-17-19; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0662]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug; Patent Submission and Listing Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements for submission and listing of patent information associated with a new drug application (NDA), an amendment or a supplement to an NDA.

**DATES:** Submit either electronic or written comments on the collection of information by July 19, 2019.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 19, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 19, 2019. 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.

#### 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 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 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-2013-N-0662 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug; Patent Submission and Listing Requirements." 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." 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