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.*

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,* Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–10418 Filed 5–17–19; 8:45 am]

BILLING CODE 4184–41–P

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