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 Toole, 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 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: 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 CFP 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 RADIOLICAL 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
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
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 organizational 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 Pharmaco vigilance 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.
OFFICE OF REGULATORY AFFAIRS
Commissioner for Regulatory Affairs.
Regulatory Affairs is headed by the Associate Commissioner for Regulatory Affairs.
Division of Therapeutic Drugs for Non-Food Animals
Division of Therapeutic Drugs for Food Animals
Division of Scientific Support
Division of Production Drugs
Division of Manufacturing Technologies
Division of Generic Animal Drugs
Office of Health Communication and Education
Office of Pharmacovigilance and Epidemiology
Office of Medication Error Prevention and Risk Management
Office of Pharmaco vigilance 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
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 Food Additive Safety
Signals and Analysis Staff
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
DCO. 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
### 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 Pediatric Therapeutics

### DDC. 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 Policy and Response is headed by the Deputy Commissioner for Policy and Response, and includes the following organizational units:
- OFFICE OF FOOD POLICY AND RESPONSE
- Office of Resource Planning and Strategic Management

### DCN. 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/GTP 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
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...