EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Total	1,800	900	$44.31	$39,879

* *Based upon the mean of the average wages for Life Scientists, All Other (19–1099), National Compensation Survey:* Occupational Employment Statistics, May 2020 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *https://www.bls.gov/oes/current/oes_nat.htm#19-0000.*

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: December 28, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–28441 Filed 12–30–21; 8:45 am]

BILLING CODE 4160–90–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's (FDA), Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Tobacco Products (CTP) have modified their organizational structures. These new organizational structures were approved by the Deputy Secretary of Health and Human Services and effective on November 24, 2021.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, FDA, 4041 Powder Mill Road, Beltsville, MD 20705–4304, 301–796–3843.

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, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect the Food and Drug Administration's reorganizations of CBER, CDER's Office of Medical Policy (OMP), Office of Prescription Drug Promotion (OPDP), CDRH's Office of Product Evaluation and Quality, and CTP's Office of Compliance and Enforcement and Office of Science.

This reorganization will help to enhance these organization's ability to advance FDA's mission and streamline operations and support functions.

The Center for Biologics Evaluation and Research's organizational changes in the Office of the Center Director (OD), the Office of Management, and the Office of Communications, Outreach, and Development refocus functions that support CBER's product offices to better support the expected growth in those offices. The OD's functions are streamlined into those that require intensive engagement from the Center Director and have no other natural home. Several responsibilities are realigned or consolidated to leverage synergies with other functions. Harnessing the power of real-world evidence is a priority in the FDA Priority Framework, the 21st Century Cures Act, and the PDUFA commitment letter. The changes proposed to CBER's Office of Biostatistics and Epidemiology (OBE) position the center to advance real-world evidence priorities for biologics.

The 21st Century Cures Act established the Regenerative Medicine Advanced Therapy (RMAT) designation program, in Office of Tissues and Advanced Therapies (OTAT), and called on FDA to work to advance standards development for regenerative medicine products in order to support the development, evaluation, and review of regenerative medicine products. The RMAT program has generated tremendous industry interest, and CBER has granted 129 RMAT designations since program inception in December 2016.

One of FDA's key priorities is leveraging innovation to advance public health goals by continually improving the product development process and strengthening FDA's gold standard. CBER's portfolio of products is currently seeing an unprecedented level of innovation and growth. These innovations range from the development of new pathogen inactivation technology that has the potential to drastically improve how FDA promotes blood safety, the explosion in submissions for gene therapies that have the potential to transform patients' lives, innovations in approaches to managing serious food allergies, and advances in manufacturing technology for vaccines. The changes proposed in two of CBER's product offices: OTAT and the Office of Blood Research and Review (OBRR) along with the crosscutting functions in OBE and Office of Compliance and Biologics Quality are intended to ensure CBER's regulatory structures and processes are prepared to respond to innovation and development in the industry while upholding FDA's standards for safety and effectiveness for biological products. Establishing the Office of Regulatory Operations will help CBER support continued efficiency and effectiveness in CBER's regulatory processes and provide strategic direction as the Center works to modernize its supporting information technology (IT) infrastructure.

The Center for Drug Evaluation and Research's OMP, Office of Prescription

Drug Promotion (OPDP) establishes the Division of Promotion Policy, Research, and Operations (DPPRO). This reorganization is critical to the FDA's ability to foster efficient oversight and development of national prescription drug promotion policy to enhance the dissemination and communication of high-quality drug information to healthcare professionals, patients, and consumers. The reorganization will also provide enhanced support, oversight, and direction to the OPDP's social science research program. This program is critical in helping shape the direction of OPDP's new and evolving policy initiatives through research studies designed to evaluate the impact of health communication and prescription drug promotion directed toward healthcare professionals and consumers. The reorganization will provide additional support and increased focus on the regulatory counsel functions necessary to develop sound and legally supportable policy documents and surveillance activities, particularly given First Amendment jurisprudence developments over the last few years. The reorganization will also provide enhanced operational support to all OPDP functions, including policy development and clearance, the multimillion-dollar research program, advisory comments to industry, compliance actions, and internal FDA review of approved labeling other activities.

The Center for Devices and Radiological Health's Office of Product Evaluation and Quality's (OPEQ) retitles the Office of In Vitro Diagnostics and Radiological Health (OIR) as the Office of Health Technology VII (OHT VII) and establish an Office of Health Technology VIII (OHT VIII) allowing the two offices to have greater focus on In Vitro Diagnostics (OHT VII) and Mammography and Radiological Health (OHT VIII). The OHT VII structure will mirror the former OIR with the exception of abolishing two divisions (Division of Radiological Health and Division of Mammography Quality Standards). OHT VII will be solely focused on in vitro diagnostics with responsibility for regulating laboratory and in-home diagnostic tests. In vitro diagnostic devices allow for tests to be completed using blood or tissue from the human body. The results of these tests are used to identify diseases and other conditions. The devices allow for individuals to monitor their health, and they help to treat, cure, and prevent diseases. Personnel utilizing the precision medicine approach utilize in vitro diagnostic devices in order to help identify individuals who can improve their health by undergoing specific therapies or treatments. The Mammography Quality Standards program will move in tact with its entire appropriated and User Fee budget to the OHT VIII and will continue to serve as the national focal point for the implementation of the Mammography Quality Standards Act.

The Center for Tobacco Products' Office of Compliance and Enforcement (OCE) establishes the Division of External Programs and Resource Management (DEPRM) and establishes the Division of Product Compliance (DPC). The CTP's Office of Science (OS) establishes the Division of Research and Knowledge Integration (DRKI). These reorganizations are critical to the FDA's ability to better utilize its resources in an efficient and effective way to meet its mission of promoting and protecting the public health by ensuring industry compliance with the requirements of the law and respond to public health emergencies. The reorganizations will also result in increased support of requirements of the Family Smoking Prevention and Tobacco Control Act.

The Food and Drug Administration's, Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research's Office of Medical Policy, the Center for Devices and Radiological Health's Office of Product Evaluation and Quality, and the Center for Tobacco Products' Office of Compliance and Enforcement and Office of Science has been restructured as follows:

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

Center for Biologics Evaluation and Research (DCB)

Office of the Center Director (DCBA)
Executive Operations Staff (DCBA1)
Regulations and Policy Staff (DCBA3)
Policy Staff (DCBA7)
Science Staff (DCBA8)
Office of Management (DCBB)
Division of Program Services (DCBBB)
Program Services Branch (DCBBB1)
Safety and Services Branch (DCBBB4)
Division of Scientific Advisors and Consultants (DCBBC)
Division of Veterinary Services (DCBBD)
Division of Management Planning and Analysis (DCBBE)
Capacity Planning and Management Analysis Branch (DCBBE1)
Planning, Performance, and Formulation Branch (DCBBE2)
Division of Acquisitions and Budget Resources (DCBBF)
Acquisition Management Branch (DCBBF1)
Budget Planning and Execution Branch (DCBBF2)
Division of Human Capital (DCBBG)
Management Services Branch (DCBBG1)
Workforce Management Branch (DCBBG2)
Office of Compliance and Biologics Quality (DCBC)
Division of Case Management (DCBCA)
Blood and Tissue Compliance Branch (DCBCA1)
Advertising and Promotional Labeling Branch (DCBCA2)
Biological Drug and Device Compliance Branch (DCBCA3)
Division of Inspections and Surveillance (DCBCB)
Program Surveillance Branch (DCBCB1)
Bioresearch Monitoring Branch (DCBCB2)
Division of Manufacturing and Product Quality (DCBCC)
Product Release Branch (DCBCC1)
Manufacturing Review Branch 1 (DCBCC2)
Manufacturing Review Branch 2 (DCBCC3)
Applications Review Branch (DCBCC4)
Manufacturing Review Branch 3 (DCBCC5)
Division of Biological Standards and Quality Control (DCBCD)
Laboratory of Analytical Chemistry and Blood Related Products (DCBCD1)
Quality Assurance Branch (DCBCD2)
Laboratory of Microbiology, In-vivo Testing and Standards (DCBCD3)
Laboratory of Analytical Chemistry Branch (DCBCD4)
Laboratory of Biochemistry, Virology, and Immunochemistry Branch (DCBCD5)
Laboratory of Blood Related Products Branch (DCBCD6)
Office of Biostatistics and Pharmacovigilance (DCBD)
CBER Surveillance Program Staff (DCBD1)
ABRA Staff (DCBD2)
Division of Biostatistics (DCBDA)
Vaccines Evaluation Branch (DCBDA1)
Therapeutics Evaluation Branch 1 (DCBDA2)
Device and Non-Clinical Evaluation Branch (DCBDA3)
Therapeutics Evaluation Branch 2 (DCBDA4)
Division of Pharmacovigilance (DCBDB)
Pharmacovigilance Branch 1 (DCBDB1)
Pharmacovigilance Branch 2 (DCBDB2)
Pharmacovigilance Branch 3 (DCBDB3)
Office of Blood Research and Review (DCBE)
Administrative Staff (DCBE1)
Division of Emerging and Transfusion Transmitted Diseases (DCBEA)
Laboratory of Molecular Virology (DCBEA1)
Laboratory of Parasitic and Emerging Pathogens (DCBEA2)

Product Review Branch (DCBEA4)
Division of Blood Components and Devices (DCBEB)
Devices Review Branch (DCBEB2)
Laboratory of Biochemistry and Vascular Biology (DCBEB5)
Laboratory of Cellular Hematology and Vascular Biology Branch (DCBEB6)
Division of Clinical and Regulatory Review (DCBEC)
Clinical Review Branch (DCBEC1)
Blood and Plasma Review Branch (DCBEC2)
Regulatory Project Management Branch (DCBEC3)
Office of Vaccine Research and Review (DCBF)
Program Operations Staff (DCBF1)
Division of Bacterial, Parasitic, and Allergenic Products (DCBFA)
Laboratory of Immunobiochemistry (DCBFA1)
Laboratory of Respiratory and Special Pathogens (DCBFA2)
Laboratory of Bacterial Polysaccharides (DCBFA3)
Laboratory of Mucosal Pathogens and Cellular Immunology (DCBFA4)
Division of Viral Products (DCBFB)
Laboratory of Pediatric and Respiratory Viral Diseases (DCBFB1)
Laboratory of Hepatitis Viruses (DCBFB2)
Laboratory of Retroviruses (DCBFB3)
Laboratory of DNA Viruses (DCBFB4)
Laboratory of Vector Borne Diseases (DCBFB5)
Laboratory of Method Development (DCBFB6)
Laboratory of Immunoregulation (DCBFB7)
Division of Vaccines and Related Products Applications (DCBFC)
CMC Review Branch 1 (DCBFC1)
CMC Review Branch 2 (DCBFC2)
CMC Review Branch 3 (DCBFC3)
Clinical Review Branch 1 (DCBFC4)
Clinical Review Branch 2 (DCBFC5)
Review Management Support Branch (DCBFC6)
Office of Tissues and Advanced Therapies (DCBG)
Division of Cellular and Gene Therapies (DCBGA)
Cellular Therapies Branch (DCBGA1)
Gene Therapies Branch 1 (DCBGA2)
Gene Transfer and Immunogenicity Branch (DCBGA3)
Tumor Vaccine and Biotechnology Branch (DCBGA4)
Cellular and Tissue Therapy Branch (DCBGA5)
Gene Therapies Branch 2 (DCBGA6)
Tissue Engineering Branch (DCBGA7)
Division of Clinical Evaluation and Pharmacological/Toxicology (DCBGB)
General Medicine Branch 1 (DCBGB1)
Pharmacology/Toxicology Branch 1 (DCBGB2)
Oncology Branch (DCBGB3)
General Medicine Branch 2 (DCBGB4)
Pharmacology/Toxicology Branch 2 (DCBGB5)
Malignant Hematology Branch (DCBGB6)
General Medicine Branch 3 (DCBGB7)
Benign Hematology Branch (DCBGB8)
Division of Human Tissues (DCBGC)
Division of Plasma Protein Therapeutics (DCBGD)
Hemostasis Branch (DCBGD1)
Plasma Derivatives Branch (DCBGD2)
Division of Regulatory Project Management (DCBGE)
Regulatory Project Management Branch 1 (DCBGE1)
Regulatory Project Management Branch 2 (DCBGE2)
Regulatory Project Management Branch 3 (DCBGE3)
Regulatory Project Management Branch 4 (DCBGE4)
Office of Communication, Outreach, and Development (DCBH)
Division of Disclosure and Oversight Management (DCBHA)
Congressional and Oversight Branch (DCBHA1)
Access Litigation and Freedom of Information Branch (DCBHA2)
Electronic Disclosure Branch (DCBHA3)
Division of Manufacturers Assistance and Training (DCBHB)
Career Development and Directed Training Branch (DCBHB1)
Manufacturers Assistance & Technical Training Branch (DCBHB2)
Division of Communication and Consumer Affairs (DCBHC)
Communication Technology Branch (DCBHC1)
Consumer Affairs Branch (DCBHC2)
Office of Regulatory Operations (DCBI)
Division of Informatics and Information Technology (DCBIA)
Data Standards Branch (DCBIA1)
Information Technology Branch (DCBIA2)
Records Management Branch (DCBIA3)
Regulatory Information Branch (DCBIA4)
Division of Regulatory Operations and Programs (DCBIB)
Regulatory Affairs and Business Operations Branch (DCBIB1)
Regulatory Programs Branch (DCBIB2)

DCDH. Organization. The Center for Drug Evaluation and Research's Office of Medical Policy is headed by the Director, Office of Medical Policy and includes the following:

Office of Medical Policy (DCDH)
Office of Prescription Drug Promotion (DCDHA)
Division of Advertising and Promotion Review I (DCDHAA)
Division of Advertising and Promotion Review II (DCDHAB)
Division of Promotion Policy, Research, and Operations (DCDHAC)
Office of Medical Policy Initiatives (DCDHB)
Division of Medical Policy Development (DCDHBA)
Division of Medical Policy Programs (DCDHBB)
Division of Clinical Trial Quality (DCDHBC)

DCCF. Organization. The Center for Devices and Radiological Health's Office of Product Evaluation and Quality is headed by the Director, Office Product Evaluation and Quality and includes the follow:

Office of Product Evaluation and Quality (DCCF)
Quality and Analytics Staff (DCCF1)
Clinical and Scientific Policy Staff (DCCF2)
Strategic Initiatives Staff (DCCF3)
Regulation, Policy and Guidance Staff (DCCF4)
Office of Regulatory Programs (DCCFA)
Division of Regulatory Programs I (DCCFAA)
Division of Regulatory Programs II (DCCFAB)
Division of Regulatory Programs III (DCCFAC)
Division of Regulatory Programs IV (DCCFAD)
Office of Clinical Evidence and Analysis (DCCFB)
Division of Clinical Evidence and Analysis I (DCCFBA)
Division of Clinical Evidence and Analysis II (DCCFBB)
Office of Health Technology I (DCCFC)
Division of Health Technology I A (DCCFCA)
Division of Health Technology I B (DCCFCB)
Division of Health Technology I C (DCCFCC)
Office of Health Technology II (DCCFD)
Division of Health Technology II A (DCCFDA)
Division of Health Technology II B (DCCFDB)
Division of Health Technology II C (DCCFDC)
Office of Health Technology III (DCCFE)
Division of Health Technology III A (DCCFEA)
Division of Health Technology III B (DCCFEB)
Division of Health Technology III C (DCCFEC)
Office of Health Technology IV (DCCFF)
Division of Health Technology IV A (DCCFFA)
Division of Health Technology IV B (DCCFFB)
Office of Health Technology V (DCCFG)
Division of Health Technology V A (DCCFGA)

Division of Health Technology V B (DCCFGB)
Office of Health Technology VI (DCCFH)
Division of Health Technology VI A (DCCFHA)
Division of Health Technology VI B (DCCFHB)
Division of Health Technology VI C (DCCFHC)
Office of Health Technology VII (DCCFI)
Division of Chemistry and Toxicology (DCCFIA)
Division of Immunology and Hematology (DCCFIB)
Division of Microbiology (DCCFIC)
Division of Program Management and Operations (DCCFIE)
Division of Molecular Genetics and Pathology (DCCFIG)
Office of Health Technology VIII (DCCFJ)
Division of Health Technology VIII A (DCCFJA)
Division of Health Technology VIII B (DCCFJB)
Division of Health Technology VIII C (DCCFJC)

DCFF. Organization. The Center for tobacco Product's Office of Compliance and Enforcement is headed by the Director, Office of Compliance and Enforcement and includes the following:

Division of Enforcement and Manufacturing (DCFFA)
Division of Promotion, Advertising, and Labeling (DCFFB)
Division of State Programs (DCFFC)
Division of Business Operations (DCFFD)
Division of External Programs and Resource Management (DCFFE)
Division of Product Compliance (DCFFF)

DCFD. Organization. The Center for tobacco Product's Office of Science is headed by the Director, Office of Science and includes the following:

Division of Regulatory Project Management (DCFDA)
Division of Regulatory Science Informatics (DCFDB)
Division of Product Science (DCFDC)
Division of Individual Health Science (DCFDD)
Division of Population Health Science (DCFDE)
Division of Non-Clinical Sciences (DCFDF)
Division of Research and Knowledge Integration (DCFDG)

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 (SMG). 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.

Dated: October 22, 2021.

Andrea Palm,

Deputy Secretary of Health and Human Services.

[FR Doc. 2021–28386 Filed 12–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1243]

Prospective Grant of an Exclusive Patent License: A Diagnostic Tool Based Upon Magnetic Resonance Spectroscopy Pre-Processing and Renormalization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is contemplating the grant of an Exclusive Patent License to practice the invention embodied in the U.S. Patent listed in the **SUPPLEMENTARY INFORMATION** section of this notice to Voxel Systems, LLC located in Houston, Texas.

DATES: Only written comments and/or applications for a license that are received by FDA's Technology Transfer Office on or before January 18, 2022, will be considered.

ADDRESSES: Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Ken Millburne, Food and Drug Administration Technology Transfer Office, Bldg. 1, Rm. 4213, Silver Spring, MD 20993, 240–478–1662; email: *Kenneth.Millburne@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

FDA Reference No.: E–2009–011/US–04: ''System for Magnetic Resonance Spectroscopy of Brain Tissue for Pattern-Based Diagnostics''

I. U.S. Non-Provisional Application 13/509,539, filed November 12, 2010 (FDA Reference No.: E–2009–011/US–04).

II. U.S. Patent granted November 4, 2014: U.S. Patent 8,880,354 B2 (FDA Reference No. E–2009–011/US–04).

The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in fields of use that may be limited to: (1) Any and all in vivo use, application, or developmental activity related to the software, processing algorithm, and Licensed Processes and Products; (2) all human and animal diagnostics, in pre-clinical, or clinical utilizations for any and all maladies; (3) all human research applications for expanded magnetic resonance imaging (MRI) utilization, application development, drug development tools, molecular compound characterization, algorithms, and biomarker identification and development; and (4) all animal or other research applications and translational studies for ultra high-field MRI investigations, drug development, metabolite, and biomarker identification.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing. The prospective exclusive license may be granted unless, within 15 days from the date of this published notice, FDA receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.