Regulatory Review Branch 2 (DCBGKB1)
Review Management Support Branch 2 (DCBGKB2)

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: September 23, 2022.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2022–20997 Filed 9–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of Regulatory Affairs, Food and Drug Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Headquarters (HQ) and Field Offices (RFO) have modified its structure.

DATES: This new organizational structure was approved by the Deputy Secretary of Health and Human Services on December 22, 2021, and became effective on February 9, 2022.

FOR FURTHER INFORMATION CONTACT: Glenda Barfell, Associate Commissioner for Regulatory Management Operations, Office of Regulatory Management Operations, Office of Regulatory Affairs, Food and Drug Administration, Element Building, Room 2002, 12420 Parklawn Drive, Rockville, MD 20857, Phone: 240–402–7562.

SUPPLEMENTARY INFORMATION: 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 amended to reflect the reorganization of the Office of Regulatory Affairs Headquarters Offices and Field Offices.

This reorganization is a continuation of the Program Alignment (PA) reorganization completed in 2017 to enhance organizational efficiencies identified after PA. The objective is to improve the Office of Regulatory Affairs (ORA) core functions, correct and enhance the structure with effective use of resources, and carry out the mission of protecting consumers by ensuring compliance of FDA-regulated products. As industry rapidly changes, the FDA must continue to evolve to ensure that public health is not negatively impacted by gaps in inspections and investigations of regulated firms.

The Food and Drug Administration, Office of Regulatory Affairs (ORA), has been restructured as follows:

DCI. ORGANIZATION. The Office of Regulatory Affairs is headed by the Associate Commissioner for Regulatory Affairs and includes the following organizational units:

Office of Regulatory Affairs (DCI)
Office of the Associate Commissioner for Regulatory Affairs (DCIA)
Data Analytics and Program Evaluation Staff (DCIA1)
Office of Regulatory Management Operations (DCIB)
Management Liaison Staff (DCIB1)
Office of Budget, Facilities, and Travel Support (DCIBB)
Division of Financial Operations (DCIBBA)
Budget Execution Branch (DCIBBA1)
Budget Formulation Branch (DCIBBA2)
Funds Control and Policy Branch (DCIBBA3)
Work Planning Branch (DCIBBA4)
Division of Facilities and Property Management (DCIBBBB)
Laboratory Support Branch (DCIBBBB1)
Real Property Management Branch East (DCIBBB2)
Real Property Management Branch West (DCIBBB3)
Fleet and Personal Property Management Branch (DCIBBB4)
Division of Contracts and Grants (DCIBBC)
State Contracts and Agreements Branch (DCIBBC1)
Scientific Contracts and Agreements Branch (DCIBBC2)
Operational Contracts and Agreements Branch (DCIBBC3)
Division of Travel Operations (DCIBBD)
Domestic Travel Branch (DCIBBD1)
Medical Products Travel Branch (DCIBBD2)
Human and Animal Food Travel Branch (DCIBBD3)
Travel Compliance Branch (DCIBBD4)
Office of Workforce Management (DCIBC)
Executive and Scientific Recruitment Staff (DCIBC1)
Division of Human Capital Staffing Services (DCIBCA)
Talent Acquisitions Branch 1 (DCIBCA1)
Talent Acquisitions Branch 2 (DCIBCA2)
Talent Acquisitions Branch 3 (DCIBCA3)
Talent Acquisitions Branch 4 (DCIBCA4)
Talent Acquisitions Branch 5 (DCIBCA5)
Special Hiring Branch (DCIBCA6)
Classification and Reorganization Branch (DCIBCA7)
Division of Human Capital Programs (DCIBCB)
Performance Management Branch (DCIBCB1)
Employee Engagement Branch (DCIBCB2)
Management Analysis Branch (DCIBCB3)
Office of Training, Education and Development (DCIBF)
Quality and Records Management Staff (DCIBF1)
Division of Programmatic Training (DCIBFA)
Programmatic Training Branch 1 (DCIBFA1)
Programmatic Training Branch 2 (DCIBFA2)
Division of Multi-Program, Leadership and Management Training (DCIBFB)
Multi-Program Leadership and Management Branch (DCIBFB1)
Leadership, Management, and Mentoring Training Branch (DCIBFB2)
Division of Instructional Systems and Technology (DCIBFC)
Instructional Systems Branch (DCIBFC1)
Learning Management Technology and Multimedia Branch (DCIBFC2)
Division of Testing, Measurement, Certification, and Program Analysis (DCIBFD)
Test, Measurement, and Analysis Branch (DCIBFD1)
Certification Branch (DCIBFD2)
Office of Criminal Investigations (DCIC)
Metro Washington Field Office (DCICA)
Philadelphia Resident Unit (DCICA1)
Chicago Field Office (DCICB)
New York Field Office (DCICC)

Boston, MA Resident Unit (DCICC1)
Los Angeles Field Office (DCICD)
San Francisco, CA Resident Unit (DCICD1)
Miami Field Office (DCICE)
San Juan, PR Resident Unit (DCICE1)
Atlanta, GA Resident Unit (DCICE2)
New Orleans, LA Resident Unit (DCICE3)
Kansas City Field Office (DCICF)
Dallas, TX Resident Unit (DCICF1)
Office of Communications and Project Management (DCID)
Executive Secretariat Staff (DCID2)
Division of Communications (DCIDA)
Public Affairs Branch (DCIDA1)
Web and Digital Media Branch (DCIDA2)
Strategic Communications Branch (DCIDA3)
Division of Project Management (DCIDB)
Project Management Resource Branch (DCIDB1)
Project Management Branch 1 (DCIDB1)
Project Management Branch 2 (DCIDB2)
Office of Human and Animal Food Operations (DCIE)
Audit Staff (DCIE1)
Office of State Cooperative Programs (DCIEA)
Division of Retail Food Protection (DCIEAA)
Retail Food Protection Branch 1 (DCIEAA1)
Retail Food Protection Branch 2 (DCIEAA2)
Retail Food Protection Branch 3 (DCIEAA3)
Division of Milk Safety (DCIEAB)
Milk Safety Branch 1 (DCIEAB1)
Milk Safety Branch 2 (DCIEAB2)
Milk Safety Branch 3 (DCIEAB3)
Division of Shellfish Sanitation (DCIEAC)
Shellfish Sanitation Branch 1 (DCIEAC1)
Shellfish Sanitation Branch 2 (DCIEAC2)
Office of Human and Animal Food Operations East (DCIEB)
Division of Foreign Human and Animal Food Operations (DCIEBA)
Foreign Human and Animal Food Inspections Branch 1 (DCIEBA)
Foreign Human and Animal Food Inspections Branch 2 (DCIEBA2)
Foreign Human and Animal Food Operations Branch (DCIEBA3)
Foreign Human and Animal Food Inspections Planning Branch (DCIEBA4)
Division of Human and Animal Food Operations East I (DCIEBB)
Human and Animal Food Investigations Branch (DCIEBB1)
Human and Animal Food Compliance Branch (DCIEBB2)
Division of Human and Animal Food Operations East II (DCIEBC)
Human and Animal Food Investigations Branch (DCIEBC1)
Human and Animal Food Compliance Branch (DCIEBC2)
Division of Human and Animal Food Operations East III (DCIEBD)
Human and Animal Food Investigations Branch (DCIEBD1)
Human and Animal Food Compliance Branch (DCIEBD2)
Division of Human and Animal Food Operations East IV (DCIEBE)
Human and Animal Food Investigations Branch (DCIEBE1)
Human and Animal Food Compliance Branch (DCIEBE2)
Division of Human and Animal Food Operations East V (DCIEBF)
Human and Animal Food Investigations Branch 1 (DCIEBF1)
Human and Animal Food Investigations Branch 2 (DCIEBF2)
Human and Animal Food Compliance Branch (DCIEBF3)
Division of Human and Animal Food Operations East VI (DCIEBG)
Human and Animal Food Investigations Branch (DCIEBG1)
Human and Animal Food Compliance Branch (DCIEBG2)
Office of Human and Animal Food Operations West (DCIEC)
Division of Domestic Human and Animal Food Operations (DCIECA)
Domestic Human and Animal Food Operations Branch (DCIECA1)
Domestic Produce Safety Branch 1 (DCIECA2)
Domestic Produce Safety Branch 2 (DCIECA3)
Division of Human and Animal Food Operations West I (DCIECB)
Human and Animal Food Investigations Branch (DCIECB1)
Human and Animal Food Compliance Branch (DCIECB2)
Division of Human and Animal Food Operations West II (DCIECC)
Human and Animal Food Investigations Branch (DCIECC1)
Human and Animal Food Compliance Branch (DCIECC2)
Division of Human and Animal Food Operations West III (DCIECD)
Human and Animal Food Investigations Branch (DCIECD1)
Human and Animal Food Compliance Branch (DCIECD2)
Division of Human and Animal Food Operations West IV (DCIECE)
Human and Animal Food Investigations Branch (DCIECE1)
Human and Animal Food Compliance Branch (DCIECE2)
Division of Human and Animal Food Operations West V (DCIECF)
Human and Animal Food Investigations Branch 1 (DCIECF1)
Human and Animal Food Investigations Branch 2 (DCIECF2)
Human and Animal Food Compliance Branch (DCIECF3)
Division of Human and Animal Food Operations West VI (DCIECG)
Human and Animal Food Investigations Branch (DCIECG1)
Human and Animal Food Compliance Branch (DCIECG2)
Office of Regulatory Science (DCIF)
Informatics and Business Operations Staff (DCIF1)
Office of Research, Coordination, Evaluation, and Training (DCIFA)
Scientific Research Staff (DCIFA1)
Evaluation Staff (DCIFA2)
Office of Medical Products and Specialty Laboratory Operations (DCIFB)
Medical Products and Tobacco Scientific Staff (DCIFB1)
Forensic Chemistry Center (DCIFBA)
Inorganic Branch (DCIFBA1)
Organic Branch (DCIFBA2)
Satellite Laboratory Branch (DCIFBA3)
Winchester Engineering and Analytical Center (DCIFBB)
Analytical Branch (DCIFBB1)
Engineering Branch (DCIFBB2)
Detroit Medical Products Laboratory (DCIFBC)
New York Medical Products Laboratory (DCIFBD)
Irvine Medical Products Laboratory (DCIFBE)
Philadelphia Medical Products Laboratory (DCIFBF)
San Juan Medical Products Laboratory (DCIFBG)
Tobacco Products Laboratory (DCIFBH)
Office of Human and Animal Foods Laboratory Operations (DCIFC)
Human and Animal Food Scientific Staff (DCIFC1)
Arkansas Human and Animal Food Laboratory (DCIFCA)
Chemistry Branch 1 (DCIFCA1)
Chemistry Branch 2 (DCIFCA2)
Microbiology Branch (DCIFCA3)
Denver Human and Animal Food Laboratory (DCIFCB)
Chemistry Branch (DCIFCB1)
Microbiology Branch (DCIFCB2)
Kansas City Human and Animal Food Laboratory (DCIFCC)
Chemistry Branch 1 (DCIFCC1)
Chemistry Branch 2 (DCIFCC2)
New York Human and Animal Food Laboratory (DCIFCD)
Chemistry Branch (DCIFCD1)
Microbiological Sciences Branch (DCIFCD2)
Seattle Human and Animal Food Laboratory (DCIFCE)
Chemistry Branch (DCIFCE1)
Microbiology Branch (DCIFCE2)
Applied Technology Branch (DCIFCE3)
San Francisco Human and Animal Food Laboratory (DCIFCF)
Chemistry Branch (DCIFCF1)

Microbiology Branch (DCIFCF2)
Atlanta Human and Animal Food Laboratory (DCIFCG)
Chemistry Branch (DCIFCG1)
Microbiology Branch (DCIFCG2)
Nutrient Analysis Branch (DCIFCG3)
Irvine Human and Animal Food Laboratory (DCIFCH)
Chemistry Branch (DCIFCH1)
Microbiology Branch (DCIFCH2)
Office of Safety (DCIFD)
Office of Medical Products and Tobacco Operations (DCIG)
Tobacco Operations Staff (DCIG1)
Office of Bioresearch Monitoring Operations (DCIGA)
Bioresearch Monitoring Operations Staff (DCIGA1)
Operations Staff (DCIGA2)
Bioresearch Monitoring Dedicated Foreign Cadre Staff (DCIGA3)
Division of Bioresearch Monitoring Operations I (DCIGAA)
Division of Bioresearch Monitoring Operations II (DCIGAB)
Office of Pharmaceutical Quality Operations (DCIGB)
Division of Pharmaceutical Quality Program (DCIGBA)
Pharmaceutical Quality Initiatives Branch (DCIGBA1)
Pharmaceutical Quality Programs Branch (DCIGBA2)
Division of Foreign Pharmaceutical Quality Inspections (DCIGBB)
Foreign Pharmaceutical Quality Inspection Branch I (DCIGBB1)
Foreign Pharmaceutical Quality Inspection Branch II (DCIGBB2)
Division of Pharmaceutical Quality Operations I (DCIGBC)
Pharmaceutical Quality Investigations Branch I (DCIGBC1)
Pharmaceutical Quality Investigations Branch II (DCIGBC2)
Pharmaceutical Quality Compliance Branch (DCIGBC3)
Division of Pharmaceutical Quality Operations II (DCIGBD)
Pharmaceutical Quality Investigations Branch (DCIGBD1)
Pharmaceutical Quality Compliance Branch (DCIGBD2)
Division of Pharmaceutical Quality Operations III (DCIGBE)
Pharmaceutical Quality Investigations Branch (DCIGBE1)
Pharmaceutical Quality Compliance Branch (DCIGBE2)
Division of Pharmaceutical Quality Operations IV (DCIGBF)
Pharmaceutical Quality Investigations Branch (DCIGBF1)
Pharmaceutical Quality Compliance Branch (DCIGBF2)
Office of Biological Product Operations (DCIGC)
Biological Products Operations Staff (DCIGC1)
Division of Biological Product Operations I (DCIGCA)
Biological Products Investigations Branch (DCIGCA1)
Biological Products Compliance Branch (DCIGCA2)
Biological Products Inspection Staff (DCIGCA3)
Division of Biological Product Operations II (DCIGCB)
Biological Products Investigations Branch (DCIGCB1)
Biological Products Compliance Branch (DCIGCB2)
Biological Products Inspection Staff (DCIGCB3)
Office of Medical Devices and Radiological Health Operations (DCIGD)
Medical Devices and Radiological Health Operations Staff (DCIGD1)
Foreign Medical Devices and Radiological Health Inspection Staff (DCIGD2)
Division of Medical Devices and Radiological Health Operations I (DCIGDA)
Medical Devices and Radiological Health Investigations Branch (DCIGDA1)
Medical Devices and Radiological Health Compliance Branch (DCIGDA2)
Division of Medical Devices and Radiological Health Operations II (DCIGDB)
Medical Devices and Radiological Health Investigations Branch (DCIGDB1)
Medical Devices and Radiological Health Compliance Branch (DCIGDB2)
Division of Medical Devices and Radiological Health Operations III (DCIGDC)
Medical Devices and Radiological Health Investigations Branch (DCIGDC1)
Medical Devices and Radiological Health Compliance Branch (DCIGDC2)
Office of Partnerships and Operational Policy (DCIH)
Office of Partnerships (DCIHB)
Division of Partnership Investigations and Agreements (DCIHBA)
Human and Animal Food Branch (DCIHBA1)
Laboratory, Medical Products, and Innovation Branch (DCIHBA2)
Division of Integration (DCIHBB)
Division of Standards Implementation (DCIHBC)
Division of Information Disclosure Policy (DCIHBD)
Freedom of Information Act Branch 1 (DCIHBD1)
Freedom of Information Act Branch 2 (DCIHBD2)
Disclosure Policy Branch (DCIHBD3)
Produce Branch (DCIHBBD4)
Office of Policy, Compliance, and Enforcement (DCIHE)
Division of Operational Policy (DCIHEA)
Human and Animal Food Policy Branch (DCIHEA1)
Medical Products and Tobacco Policy Branch (DCIHEA2)
Imports Policy Branch (DCIHEA3)
Division of Planning and Evaluation (DCIHEB)
Division of Enforcement (DCIHEC)
Recall Operations Branch (DCIHEC1)
Health Fraud Branch (DCIHEC2)
Office of Strategic Planning and Quality Management (DCIHF)
Strategic Planning Staff (DCIHF1)
Division of Quality Management Systems (DCIHFA)
Office of Import Operations (DCII)
Division of Food Defense Targeting (DCIIB)
Division of Import Operations (DCIIC)
Import Operations Branch (DCIIC1)
Import Compliance Branch (DCIIC2)
Division of Analysis and Program Evaluation (DCIID)
Program Development Branch (DCIID1)
Import Technical Assistance Branch (DCIID2)
Division of Southwest Imports (DCIIE)
Southwest Import Investigations Branch (DCIIE1)
Southwest Import Compliance Branch (DCIIE2)
Division of Southeast Imports (DCIIF)
Southeast Import Investigations Branch I (DCIIF1)
Southeast Import Investigations Branch II (DCIIF2)
Southeast Import Compliance Branch (DCIIF3)
Division of Northeast Imports (DCIIG)
Northeast Import Investigations Branch (DCIIG1)
Northeast Import Compliance Branch (DCIIG2)
Division of Northern Border Imports (DCIIH)
Northern Boarder Import Investigations Branch I (DCIIH1)
Northern Boarder Import Investigations Branch II (DCIIH2)
Northern Boarder Import Compliance Branch (DCIIH3)
Division of West Coast Imports (DCIII)
West Coast Import Investigations Branch (DCIII1)
West Coast Import Compliance Branch (DCIII2)
Division of Planning and Public Response (DCIIJ)
Office of Information Systems Management (DCIJ)
Division of Enforcement Systems Solutions (DCIJA)
Enforcement Systems Branch (DCIJA1)

Enforcement Data Management Branch (DCIJA2)
Division of Import Systems Solutions (DCIJB)
Import Systems Branch (DCIJB1)
Import Data Management Branch (DCIJB2)
Division of Information Technology Planning and Management Services (DCIJC)
Solutions Planning Branch (DCIJC1)
Information Technology Management and Governance Services Branch (DCIJC2)

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.

Electronic Access

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(Authority: 44 U.S.C. 3101)

Dated: September 23, 2022.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2022–20996 Filed 9–27–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6569]

Clinical Decision Support Software; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Clinical Decision Support Software.'' This final guidance provides clarity on FDA's oversight of clinical decision support (CDS) software intended for health care professionals with the purpose of describing FDA's regulatory approach to CDS software functions. This guidance clarifies the types of CDS functions that do not meet the definition of a device as amended by the 21st Century Cures Act (Cures Act).

DATES: The announcement of the guidance is published in the **Federal Register** on September 28, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2017–D–6569] for ''Clinical Decision Support Software; Guidance for Industry and Food and Drug Administration Staff.'' Received comments 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, 240–402–7500.

- 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 for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Clinical Decision Support Software; Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire