

a final draft of the guidance was submitted to the ICH Assembly and endorsed by the regulatory agencies on June 16, 2016.

Regulatory authorities approve drugs that are demonstrated to be safe and effective for human use. The meaning of “safe” has historically been interpreted to mean that the benefits of the drug outweigh its risks. This benefit-risk assessment of pharmaceuticals is the fundamental basis of regulatory decision-making. In the last several years, providing greater structure for the benefit-risk assessment has been an important topic in drug regulation. The M4E guidance directs applicants to include their conclusions on benefits and risks in the Clinical Overview of Module 2 of the Common Technical Document (CTD) under section 2.5.6. Although general guidance is provided in the M4E guidance regarding the expected content of section 2.5.6, no further structure is suggested to aid industry in developing the benefit-risk assessment. As a result, regulators observe a high degree of variability in the approaches taken by applicants in presenting this information. This variability may not facilitate efficient communication of industry views to regulators. Although regulators and industry have developed approaches for structured benefit-risk assessment and these approaches may take different forms, there is a common thread evident that can inform harmonization of the format and structure of benefit-risk assessments provided by applicants in their regulatory submissions.

The revised M4E(R2) guidance provides more specific guidance regarding the format and structure of the benefit-risk assessment in section 2.5.6. Section 2.5.6 is divided into four subsections: (1) Therapeutic context, (2) Benefit, (3) Risk, and (4) Benefit-Risk Assessment. Each subsection describes the aspects that are most pertinent to the benefit-risk assessment. This guidance also lists characteristics that should be considered when identifying and describing key benefits and key risks of the medicinal product. Recognizing that there are many reasonable approaches for conducting a benefit-risk assessment, M4E(R2) does not specify a particular approach to be used by industry. However, the document does offer specific guidance on the major elements that should be included in the benefit-risk assessment. Furthermore, the revised guidance does not dictate an approach used by a regulator in conducting a benefit-risk assessment.

This guidance also revises other sections of the guidance for clarification, given the proposed

revisions in section 2.5.6. In addition, the revised guidance changes the numbering and the section headings for consistency.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at <https://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: July 18, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Office of the Commissioner; 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 (OC), and Office of Operations (OO) have modified their structures. This new organizational structure was approved by the Secretary of Health and Human Services on

January 10, 2017 and effective on February 11, 2017.

FOR FURTHER INFORMATION CONTACT:

Segaran Pillai, Ph.D., Director, Office of Laboratory Science and Safety, Office of the Commissioner, Food and Drug Administration, White Oak Bldg. 1, Rm. 2218, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–2856.

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, and 76 FR 45270, July 28, 2011) is amended to reflect the reorganization of the Office of the Commissioner and the Office of Operations.

This reorganization establishes the Office of Laboratory Science and Safety, and will authorize the consolidation of the laboratory science, safety functions, and program activities across FDA under one organizational component that will report directly to the Office of the Commissioner. The Employee Safety and Environmental Management Staff will be realigned from the Office of Safety, Security and Crisis Management to the Office of Laboratory Science and Safety. As a result of the staff realignment the Office of Safety, Security and Crisis Management within the Office of Operations will be re-titled to the Office of Security and Emergency Management. The Office of Crisis Management within the newly titled Office of Security and Emergency Management will change its title to the Office of Emergency Management. Additionally, the Office of Security and Emergency Management has established the Emergency Planning, Evaluation, and Exercise Staff, and the Program Operations and Coordination Staff within the Office of Emergency Management.

The Food and Drug Administration, Office of the Commissioner (OC), has been restructured as follows:

DA. 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 (DA)
Office of the Chief Counsel (DAA)
Office of the Executive Secretariat (DAB)

Executive Secretariat Staff (DAB1)
Freedom of Information Staff (DAB2)

Dockets Management Staff (DAB3)
Office of the Chief Scientist (DAE)
National Center for Toxicological
Research (DAEC)
Office of the Center Director (DAECA)
Office of Management (DAECB)
Planning and Resource Management
Staff (DAECBA)
Office of Research (DAECC)
Division of Biochemical Toxicology
(DAECCA)
Division of Genetic and Molecular
Toxicology (DAECCB)
Genetic Toxicology Lab (DAECCB1)
Division of Microbiology (DAECCD)
Division of Systems Biology (DAECCE)
Division of Neurotoxicology (DAECCF)
Division of Bioinformatics and
Biostatistics (DAECCH)
Office of Scientific Coordination
(DAECF)
Office of Counter-Terrorism and
Emerging Threats (DAEG)
Office of Scientific Integrity (DAEH)
Office of Regulatory Science and
Innovation (DAEI)
Division of Science Innovation and
Critical Path (DAEIA)
Division of Scientific Computing and
Medical Information (DAEIB)
Office of Scientific Professional
Development (DAEJ)
Office of Health Informatics (DAEK)
Office of the Counselor to the
Commissioner (DAR)
Office of Women's Health (DAS)
Office of External Affairs (DAU)
Web and Digital Media Staff (DAU1)
Administrative Management Staff
(DAU2)
Office of Media Affairs (DAUA)
Web Communications Staff (DAUA2)
Office of Communications (DAUB)
Communications Staff (DAUB1)
FDA History Office (DAUB2)
Office of Health and Constituent Affairs
(DAUC)
Office of Minority Health (DAY)
Office of Laboratory Science and Safety
(DAZ)
Employee Safety and Environmental
Management Staff (DAZ1)
The Food and Drug Administration,
Office of Operations (OO), has been
restructured as follows:

DMM. ORGANIZATION. The Office of
Operations is headed by the Deputy
Commissioner for Operations and Chief
Operating Officer and includes the
following organizational units:

Office of Operations (DMM)
Office of Business Services (DMM1)
Business Operations Staff (DMM11)
Employee Resource and Information
Center (DMM1A)
Division of Ethics and Integrity (DMM3)
Ombudsman and Conflict Prevention
and Resolutions Staff (DMM4)

Office of Equal Employment
Opportunity (DMMA)
Compliance Staff (DMMA1)
Diversity Staff (DMMA3)
Office of Finance, Budget and
Acquisitions (DMMD)
Office of Budget (DMMDA)
Division of Budget Formulation
(DMMDAA)
Division of Budget Execution and
Control (DMMDAB)
Office of Acquisition and Grant Services
(DMMDB)
Division of Acquisition Operations
(DMMDBA)
Service Contract Branch (DMMDBA1)
Contract Operations Branch
(DMMDBA2)
Division of Acquisition Programs
(DMMDBB)
Scientific Support Branch (DMMDBB1)
Field Operations Branch (DMMDBB2)
Facilities Support Branch (DMMDBB3)
Division of Regulatory Inspections
Acquisitions and Grants and
Assistance Management (DMMDBC)
Grants Management Branch
(DMMDBC1)
Regulatory Inspections and Acquisitions
Branch (DMMDBC2)
Division of Information Technology
Acquisitions (DMMDBD)
Information Technology Acquisitions
Branch (DMMDBD1)
Systems Technology Acquisitions
Branch (DMMDBD2)
Division of Policy, Systems, and
Program Support (DMMDBE)
Office of Financial Operations and
Policy (DMMD C)
Office of Financial Management
(DMMDCA)
Internal Controls, Compliance and
Oversight Staff (DMMDCA1)
Business Transformation,
Administration and Management Staff
(DMMDCA2)
User Fee Staff (DMMDCA3)
Financial Systems Support Staff
(DMMDCA4)
Division of Accounting (DMMD CAB)
Division of Travel Services
(DMMDCAC)
Division of Payment Services
(DMMDCAD)
Office of Human Resources (DMME)
Commissioned Corps Affairs Staff
(DMME6)
Management Analysis Services Staff
(DMME7)
Business Operations Staff (DMME8)
Division of Workforce Relations
(DMMEB)
Employee and Labor Relations Branch I
(DMMEB1)
Employee and Labor Relations Branch II
(DMMEB2)
Division of Policy, Programs, and
Executive Resources (DMMEC)

Policy Branch (DMMEC1)
Executive Resources Branch (DMMEC2)
Accountability Branch (DMMEC3)
Division of Enterprise Support Services
(DMMED)
Resources and Information Branch
(DMMED1)
Systems and Records Management
Branch (DMMED2)
Benefits Branch (DMMED3)
FDA University (DMMEF)
Division of Human Resource Services
for Office of the Commissioner/Office
of Operations (DMMEG)
Office of the Commissioner/NCTR
Customer Solutions Branch
(DMMEG1)
Office of Operations Customer Solutions
Branch (DMMEG2)
Division of Human Resource Services
for Office of Medical Products and
Tobacco (DMMEH)
CDRH Customer Solutions Branch
(DMMEH1)
CBER and NCTR Customer Solutions
Branch (DMMEH2)
CDER Customer Solutions Branch
(DMMEH3)
CTP Customer Solutions Branch
(DMMEH4)
Division of Human Resource Services
for the OFVM/OGROP (DMMEI)
CFSAN/CVM Customer Solutions
Branch (DMMEI1)
ORA/OIP Customer Solutions Branch
(DMMEI2)
Office of Facilities, Engineering, and
Mission Support Services (DMMF)
Jefferson Laboratories Complex Staff
(DMMF1)
Facilities Program Staff (DMMF2)
Division of Operations Management and
Community Relations (DMMFA)
Logistics and Transportation
Management Branch (DMMFA1)
Facilities Maintenance and Operations
Branch (DMMFA2)
Auxiliary Program Management Branch
(DMMFA3)
Division of Planning, Engineering and
Space Management (DMMFB)
Portfolio and Space Management
Branch (DMMFB1)
Engineering Management Branch
(DMMFB2)
Office of Information Management and
Technology (DMMH)
Office of Information Management
(DMMHA)
Information Security Staff (DMMHA1)
Knowledge Management Staff
(DMMHA2)
Enterprise Architecture and Technology
Innovation Staff (DMMHA3)
Office of Technology and Delivery
(DMMHAA)
Delivery Management and Support Staff
(DMMHAA1)
Divisions of Infrastructure Operations
(DMMHAAA)

Infrastructure Management Services Staff (DMMHAAA1)
 Implementation Branch (DMMHAAA2)
 Infrastructure Engineering Branch (DMMHAAA3)
 Systems Monitoring and Response Branch (DMMHAAA4)
 Systems Operations Branch (DMMHAAA5)
 Network and Communications Operations Branch (DMMHAAA6)
 Division of Application Services (DMMHAAB)
 Application Management Services Staff (DMMHAAB1)
 Data Management and Operations Branch (DMMHAAB2)
 Medical Products Branch (DMMHAAB3)
 OC/CVM/CTP Branch (DMMHAAB4)
 ORA/CFSAN Branch (DMMHAAB5)
 Enterprise Application Branch (DMMHAAB6)
 Division of Delivery Management and Support (DMMHAAC)
 Delivery Management Branch (DMMHAAC1)
 Process Management and Control Branch (DMMHAAC2)
 Office of Business and Customer Assurance (DMMHAB)
 Records, eDiscovery and Risk Management Staff (DMMHAB1)
 Division of Business Partnership and Support (DMMHABA)
 Internet and Intranet Branch (DMMHABA1)
 Call Center Branch (DMMHABA2)
 Regional Support Branch (DMMHABA3)
 Property, Receiving and Distribution Branch (DMMHABA4)
 Division of Management Services (DMMHABB)
 Internal Services and Response Branch (DMMHABB2)
 Acquisitions Services Branch (DMMHABB3)
 Human Capital and Visual Media Branch (DMMHABB4)
 Office of Enterprise Portfolio Management (DMMHAC)
 Office of Security and Emergency Management (DMMJ)
 Office of Security Operations (DMMJA)
 Office of Emergency Management (DMMJB)
 Emergency Planning, Evaluation, and Exercise Staff (DMMJB1)
 Program Operations and Coordination Staff (DMMJB2)
 Office of Emergency Operations (DMMJBA)

I. 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.

II. 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 Web site at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>.

Authority: 44 U.S.C. 3101.

Dated: July 17, 2017.

Thomas E. Price,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee; Call for Applications

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Call for applications.

SUMMARY: The Office of the National Coordinator for Health Information Technology (ONC) is seeking applications to the Health Information Technology Advisory Committee.

SUPPLEMENTARY INFORMATION:

Name of Committee: Health Information Technology Advisory Committee.

General Function of the Committees: The Health Information Technology Advisory Committee (HITAC) shall make recommendations to the National Coordinator on a policy framework to advance an interoperable health information technology infrastructure. The Health Information Technology Advisory Committee shall recommend to the National Coordinator a policy framework for adoption by the Secretary consistent with the strategic plan under section 3001(c)(3) for advancing the following target areas (described in more detail in the Description of Duties section): (1) Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information; (2) the promotion and protection of privacy and security of health information in health information technology; (3) the facilitation of secure access by an

individual to such individual's protected health information; and (4) any other target area that the HITAC identifies as an appropriate target area to be considered. Such policy framework shall seek to prioritize achieving advancements in these target areas and may incorporate policy recommendations made by the HIT Policy Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

Date and Time: Applications must be received by 12:00 p.m. on Friday, August 4, 2017.

Contact Person: Michelle Consolazio, email: michelle.consolazio@hhs.gov.

Background: Section 3002 of the 21st Century Cures Act (Pub. L. 114-255) establishes the Health Information Technology Advisory Committee (referred to as the "HITAC"). Once established, the Health Information Technology Advisory Committee will be governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92-463), as amended, (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees. HHS is seeking applications for two members of the HITAC; one of whom shall be appointed to be a public health official representative. Members of the HITAC shall at least reflect providers, ancillary healthcare workers, consumers, purchasers, health plans, technology vendors, researchers, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy and security, and on the electronic exchange and use of health information.

Members will be selected in order to achieve a balanced representation of viewpoints, areas of experience, subject matter expertise, and representation of the health care landscape. Terms will be three (3) years from the appointment date. Members serve without pay, but will be provided per diem and travel costs for committee services.

Submitting Applications:

Applications should be submitted electronically through the application database on the [HealthIT.gov](http://www.healthit.gov/facas/faca-workgroup-membership-application) Web site at: <http://www.healthit.gov/facas/faca-workgroup-membership-application>. An application package must include: A short bio, a current resume or CV including contact information, and two letters of support.

Dated: July 10, 2017.

Michelle Consolazio,

Office of Policy, Office of the National Coordinator for Health Information Technology.

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