Foreword 2022

The *Investigations Operations Manual* (IOM) is the primary operational reference for FDA employees who perform field activities in support of the agency's public health mission. Accordingly, it directs the conduct of all fundamental field activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations.

Other FDA manuals and field instructions supplement, but do not supersede, the information in this manual. We recognize this manual will not address all situations encountered in the performance of field activities. In such cases, your division management must be informed and concur with any significant departures from the IOM.

The 2022 version of the IOM contains important changes which clarify or present new information and procedures. As with each new edition of the IOM, please take time to review sections of the manual for changes which may apply to your work. Additions to the IOM are highlighted in light gray.

The IOM is also posted on ORA's Internet Website https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual, with all graphics included.

The COVID-19 pandemic continues to be a paradigm-shifting public health event. In May 2021, FDA issued a report titled, "Resiliency Roadmap for FDA Inspectional Oversight," outlining the agency's inspectional activities during the COVID-19 pandemic and its detailed plan to move toward a more consistent state of operations. From the beginning of this public health emergency, ORA's innovation and resiliency in the face of challenges has highlighted our true commitment to fulfilling the agency's mission to protect and promote the public health. Additionally, 2021 marked the first milestone of the IOM Refresh Project, a cover to cover, all-inclusive review of the IOM, with completion of the Chapter 8 refresh in July and initiation of the Chapters 1 and 2 refresh. In 2022 we will continue to use the new tools and alternative inspectional activities developed in response to the public health emergency to support oversight of regulated industries and agency decision making. As these new tools continue to be developed and refined, we will capture the processes and procedures across programs in the IOM.

The IOM is published hard copy annually. Until the IOM Refresh Project is completed, future updates to the IOM will continue to be performed periodically during the year to the online version. The online IOM version serves as ORA's official document of record.

ORA leadership is committed to continuously improving the quality and usefulness of the IOM. Suggestions for the 2023 edition of the IOM including recommended changes, deletions, and additions to the IOM may be sent via e-mail to IOM@FDA.HHS.GOV. Suggestions are accepted from within the agency, our state and local partners, industry and consumers. All changes are reviewed by the IOM Committee, which is composed of a cross-functional group consisting of representatives from each commodity area in addition to imports, recalls, and policy.

Thank you for your continued exceptional work and commitment to protecting and promoting the health and well-being of the American people. It is an honor serving with you.

Judith A. McMeekin, Pharm.D.

Associate Commissioner for Regulatory Affairs

U.S. Food and Drug Administration, Office of Regulatory Affairs

In August 2021, ORA published its five-year Strategic Plan covering FY2022 – 2025, which outlines ORA's direction and approach to accomplish our mission and meet our vision.

Vision

Public health is protected, promoted, and advanced.

Mission

Protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products.

Ultimate Outcome

Protect consumers and patients from injury or illness from FDA-regulated products while ensuring timely access to safe and quality products.

Core Values

ORA's core values define the organization's "character" and inform its actions and decisions.

Accountability
Commitment to Public Health
Communication
Inclusion, Diversity, Equity, and Accessibility
Integrity and Respect
Quality

Judith A. McMeekin, Pharm.D.

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