SMG 9001.1

FDA Staff Manual Guides, Volume IV – Agency Program Directives

General or Multidiscipline

Scientific Integrity at FDA

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1. Purpose

Science—both its quality and integrity—is the touchstone of everything we do at FDA. Trust in scientific information depends on the integrity of the process by which such information is produced, evaluated, and communicated. The purpose of this Staff Manual Guide (SMG or Guide) is to provide an overview for all FDA staff about the principles, policies, and practices that relate to the preservation and promotion of scientific integrity. This SMG provides information on how to report violations of FDA's scientific integrity principles, including attempts at political interference.

2. Policy

In conducting our mission to protect, promote, and advance the public health, FDA must evaluate information according to scientific principles to make sound, objective regulatory decisions. Preserving and promoting scientific integrity is essential to ensuring that FDA's mission succeeds and that our regulatory decisions advance the public health.

Scientific integrity is the adherence to professional practices, ethical behavior, and the principles of honesty and objectivity when conducting, managing, using the results of, and communicating about science and scientific activities. Inclusivity, transparency, and protection from inappropriate influence are hallmarks of scientific integrity.

Establishing and maintaining integrity of the scientific process and scientific data is crucial to the Agency's ability to arrive at sound decisions and to maintain public trust. While there may be differing views about what can be concluded from scientific data, and while there are often multiple options that can be considered during policy development or regulatory decision-making, FDA presents evaluations and analyses of data—including

uncertainties—in an unbiased manner.

FDA has a long, and continuing, history of working to ensure integrity in its scientific and regulatory processes and, as a result, centers have put in place related policies, procedures and initiatives. The following key principles support FDA's approach to preserving and promoting scientific integrity:

Key Principles of Scientific Integrity at FDA

- Fostering a culture firmly committed to science-based, data-driven decision making that is accurate and transparent;
- Promoting diversity, equity, inclusion, and accessibility in the scientific workforce by providing support to all staff including but not limited to all genders, sexes, races, ethnicities, disabilities, and backgrounds;
- Shielding the Agency's science and its scientific staff from political interference and providing effective avenues for scientific staff to report and resolve scientific integrity concerns;
- Facilitating the free flow of scientific and technical information, to the extent permitted by law;
- Protecting the integrity of scientific data and ensuring its accurate presentation, including the underlying assumptions and uncertainties;
- Requiring a fair and transparent approach to resolving internal scientific disputes, including hearing and carefully considering differing interpretations and viewpoints;
- Supporting whistleblower protections;
- Selecting and promoting scientists based on their knowledge, expertise, and personal integrity, and fostering the professional development of our scientific staff;
- Maintaining openness and selecting qualified advisory committee members based on expertise, with appropriate and transparent processes to address any conflicts of interest; and
- Allowing FDA staff to communicate their personal scientific or policy views to the public, even when those views differ from official Agency opinions.

FDA has operationalized these key principles by implementing specific policies and procedures related to them, many of which are discussed later in this document. FDA expects all staff to be familiar not only with these principles but with the specific policies and procedures that implement them, both at the agency level and within their Center.

Open communication about science plays a valuable role in building public trust and understanding of the Agency's work. FDA will facilitate the free flow of scientific and technological information, to the extent permitted by law, and support scientific integrity in communication about scientific activities, findings, and products, in accordance with Center/Office policy and procedures. It is important to ensure that the work and conclusions of Agency scientists are accurately represented in Agency communications. Safeguarding scientific integrity is a fundamental Agency value and the responsibility of all who support FDA's mission to protect the public health.

3. Definitions

Center(s) includes the Office of the Commissioner, Office of Regulatory Affairs, Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, National Center for Toxicological Research, Center for Veterinary Medicine, Center for Tobacco Products, and the Oncology Center of Excellence.

FDA Staff or **Staff** refers to all FDA employees, political appointees, contractors, fellows, and any other individuals acting at the behest of the agency.

Political Interference refers to directing or encouraging agency staff to conduct scientific activities in a manner not supported by a valid scientific rationale, such as encouraging the departure from well-accepted methods without a scientifically valid basis, when done for partisan, ideological, regional, or any other political advantage.

Scientific Activities refers to activities that should involve the application of valid scientific methods and theories in a systematic manner, including research, policy development, decision-making, evaluation, analysis, and communications.

Scientific Integrity is the adherence to professional practices, ethical behavior, and the principles of honesty and objectivity when conducting, managing, using the results of, and communicating about science and scientific activities. Inclusivity, transparency, and protection from inappropriate influence are hallmarks of scientific integrity.

Scientific Integrity Official (SIO) is the Director of the Office of Scientific Integrity, who is a senior career employee designated as FDA's lead to oversee implementation and iterative improvement of scientific integrity policies and processes.

Scientific Staff refers to those FDA staff involved in scientific activities, including political appointees, contractors, fellows, and any other similarly situated personnel.

4. Background

Scientific and technological information, data, and evidence are central to the development and iterative improvement of sound policies, and to the delivery of equitable services and programs, across every area of government. The 2022 National Science and Technology Council Report of the Scientific Integrity Fast Track Action Committee (SI-FTAC), Protecting the Integrity of Government Science (the SI-FTAC Report), found that strong

scientific integrity policies and practices bolster the ability of federal agencies to protect scientific activities.

The SI-FTAC Report summarizes recent foundational Executive Branch actions on scientific integrity, including the 2009 Presidential Memorandum, the 2010 Office of Science and Technology Policy Memorandum, and the January 2021 Presidential Memorandum entitled Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking.

FDA participated alongside many other federal agencies to help produce the SI-FTAC Report and updated the scientific integrity policies and procedures in this SMG to reflect best practices.

5. Application

All FDA staff are expected to understand and follow this SMG and its implementing policies and procedures. Centers shall implement and follow the general principles and procedures set forth in this Guide and the policies and procedures at FDA to which it refers. Centers may supplement and expand upon these policies and procedures to meet their specific needs through issuance of written standard operating procedures (SOPs), so long as those SOPs support and do not conflict with the general principles set forth in this SMG and the policies and procedures to which it refers.

FDA is an Operating Division within the U.S. Department of Health and Human Services (HHS). In addition to the FDA-specific policies and procedures outlined here, all FDA staff are required to adhere to the HHS Scientific Integrity Policy (housed here).

A. Training

This SMG will be communicated to all FDA staff through periodic training provided by HHS that addresses both this policy and HHS's related Scientific Integrity Policy. FDA's scientific staff will also receive training from FDA with particular emphasis on recognizing and reporting violations of FDA's scientific integrity principles, including attempts at political interference, and the responsibilities of FDA's scientific staff related to scientific integrity. FDA will make training on this policy, including all training materials, available to all staff.

To further enhance a culture of scientific integrity, FDA shall post this SMG prominently on its publicly facing website and take other measures such as Agency townhalls, written and oral communications, and other avenues to keep scientific integrity visible at FDA**.**

B. Reporting

An annual report of Agency scientific integrity activities will be available on the FDA's publicly facing website, per the 2021 Presidential Memorandum. This report will include: (1) details regarding the issuance of, or meaningful updates to, any significant Agency-level

policy and/or process directly related to preserving and promoting scientific integrity and (2) the number of formal adjudications of scientific integrity allegations, including (a) the number of referrals of political interference allegations to the Department of Health and Human Services' Office of Inspector General per section 7.C.ii, (b) the number of formal adjudications requested on appeal under section 7.C.i, (c) the number of research misconduct investigations conducted, (d) the number of authorship dispute matters appealed to the Office of the Commissioner under SMG 9010.3 (Authorship Dispute Resolution at FDA), and (e) the number of scientific dispute resolution matter appealed to the Office of the Commissioner under SMG 9010.1 (Scientific Dispute Resolution at FDA).

6. Principles, Responsibilities, Procedures, and Resources

A. Foundations of Scientific Integrity

i. Ensuring a Culture of Scientific Integrity

A culture of scientific integrity is one that ensures that scientific decisions are the product of honest investigation, open discussion, refined understanding, and grounded in evidence, while shielding FDA staff from any inappropriate interference, including political interference. FDA is committed to a culture of scientific integrity and prohibits political interference and any other conduct inconsistent with the principles of scientific integrity listed above.

FDA's Office of Scientific Integrity (OSI) promotes a culture of scientific integrity across the Agency. Created in 2009, OSI is in the Office of the Chief Scientist and works with the Agency's Centers to preserve and promote integrity in scientific decision-making, as well as consistency on such issues across the Agency. OSI conducts an annual review of the agency's scientific integrity policies and identifies the need for additional policies and procedures through the work of its Office of the Ombudsman and the Office of Appeals. Based on this review, OSI also updates a scientific integrity evaluation plan that articulates expected activities and outcome measures designed to improve scientific integrity at FDA. FDA encourages those inside and outside FDA with an interest in the Agency's approach to scientific integrity to provide feedback on this policy at any time, directing such feedback to OSI (internal options and email).[1]

The Director of OSI (or designee), as the Scientific Integrity Official (SIO), is empowered with the independence necessary to gather and protect information to support the review and assessment of scientific integrity concerns. The SIO is also empowered to ensure implementation of corrective scientific actions and to coordinate with appropriate authorities to enforce preventative, corrective, and administrative actions. The SIO, in conjunction with the Chief Scientist, shall also advocate for appropriate engagement of scientific leadership in decision-making with respect to scientific integrity concerns.

[1] In formulating, implementing, and revising this policy, FDA also considered and will continue to consider public comments and information on scientific integrity issues, including those public comments solicited by HHS and the public listening sessions on scientific integrity issues organized by the Office of Science and Technology Policy.

FDA leadership at all levels should recognize, support, and promote this policy and its underlying principles, as well as model behavior exemplary of a strong culture of scientific integrity. FDA and the Department of Health and Human Services (HHS) will continue to develop and implement additional procedures, policies, guidelines, tools, and training and professional development opportunities necessary to support this SMG.

ii. Hiring and Retention of Scientific Staff

FDA's mission is to protect and advance public health by ensuring safe and effective medical products, keeping our food and cosmetics safe, and reducing harm from regulated tobacco products. This mission can only be achieved by leveraging the skills and talents of the many scientists working across the agency, and to this end FDA employs scientists in a wide variety of fields and disciplines, including biologists, chemists, epidemiologists, nurses, pharmacists, pharmacologists, physicians, social or behavioral scientists, statisticians, veterinarians, engineers, and others. FDA selects and retains these scientists based on their scientific and technical knowledge, credentials, experience, and integrity.

iii. Diversity, Equity, Inclusion, and Accessibility to Strengthen Scientific Integrity

A strong culture of scientific integrity begins with ensuring a professional environment that is safe, equitable, and inclusive of all staff. Diversity, equity, inclusion, and accessibility (DEIA) are integral to the entire scientific process. Attention to DEIA can improve the representativeness and eminence of the scientific workforce, foster innovation in the conduct and use of science, and provide for more equitable participation in science by diverse communities.

The overall vision for DEIA at FDA is to be a fair and united agency that leads the way on Diversity, Equity, Inclusion, and Accessibility for HHS and the Federal government. This vision is supported by the FDA's long-standing commitment to build and maintain a diverse workforce and to cultivate and support an inclusive culture. The Agency will preserve and promote scientific integrity in a manner that advances the needs of underrepresented groups and strengthens the equitable delivery of Agency programs.

FDA is committed to ensuring equal employment opportunity (EEO) and promoting workforce diversity to maintain a strong, effective, high performing public service organization. The No FEAR Act increases the accountability of federal departments and agencies for acts of discrimination or reprisal against employees and requires that federal agencies be accountable for violations of anti-discrimination and whistleblower protection laws.[2]

It is important that FDA staff feel empowered to report discrimination or other

[2] Pub. L. 101-12, Whistleblower Protection Act (WPA) of 1989; Pub. L. 112-199, Whistleblower Protection Enhancement Act of 2012.

inappropriate conduct without fear of reprisal, and have many avenues for recourse:

Any FDA employee, applicant for employment at FDA, or individual benefiting from an FDA-administered employment program may institute an EEO complaint if that employee or applicant believes they have been discriminated against, such as in hiring, work assignments, treatment once employed, or based on retaliation or reprisal for filing such a complaint.

FDA has an anti-Harassment program and for more information please read the 2022 FDA Anti-Harassment Policy Statement that establishes the Agency-wide process under which FDA staff shall report allegations of inappropriate conduct, and harassment. The policy sets forth manager and supervisor responsibilities to maintain a harassment-free workplace and to take prompt and effective action when allegations of inappropriate conduct and harassment arise.

B. Protecting Regulatory Review and Safeguarding Scientific Integrity

The policies and procedures at FDA that preserve and protect scientific integrity (as discussed and set forth below) include the following Agency-wide examples, which are representative of the Agency's overall approach to the issue:

i. Internal Dispute Resolution

"Scientific Dispute Resolution at FDA" (Staff Manual Guide ("SMG") 9010.1) requires the Agency's Centers to establish processes for resolving scientific disputes. These processes must include, among other things: key messages that FDA staff are encouraged to voice scientific disagreements within their Center and that they are protected from retaliation and repercussions for raising such disagreements; a process for resolving such disputes at the lowest possible level, documenting differences of opinion, and elevating through increasingly higher levels of management when necessary; a requirement that the head of the Center render a written decision if the dispute cannot be resolved at a lower level; and appropriate timeframes. The Agency-wide SMG also provides a mechanism for staff to elevate scientific disputes to the Office of the Commissioner. An Agency Dispute Process Review Board, chaired by the Agency's Chief Scientist, is then responsible for conducting full and fair evaluations of disputes to determine whether the appropriate processes were followed, whether the decisions made were based on consideration of all relevant evidence and views bearing on the scientific question at issue, and whether the initiating staff member was provided an opportunity to express their concerns at all appropriate levels.

"Cross-Center Dispute Resolution at FDA" (SMG 9010.2) describes policies and procedures for addressing differences of opinion regarding scientific or regulatory issues among personnel in different Centers, including but not limited to teams engaged in coordinated or joint reviews of combination products or related co-development projects (e.g., companion diagnostic and related therapeutic drug or biologic, development of guidance, or development or adoption of standards). The policy establishes an expectation that FDA staff will follow an orderly progression in the process of addressing a difference of opinion. Reasonable, good-faith efforts should be made to consider and resolve

scientific or regulatory disagreements between Centers informally at the lowest operational level possible during the review process.

"Authorship Dispute Resolution at FDA" (SMG 9010.3). FDA encourages discussion among collaborating researchers at the outset of any research project concerning how authorship credit will be apportioned. A strong commitment to the successful resolution of authorship disputes is necessary to protect the overall integrity of research conducted by the Agency's scientific community. As this SMG explains in more detail, FDA has adopted the ICMJE definition of authorship, which defines an author as someone who meets four criteria: (a) substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work; (b) drafting the work or revising the work critically for important intellectual content; (c) final approval of the version to be published; and (d) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. FDA's SMG further describes how authorship disputes should be managed throughout FDA, sets forth recommended elements to be included in authorship dispute resolution processes adopted by Agency components, and establishes an Agency-wide process for authorship disputes.

ii. Research Misconduct

"Policy for Responding to Allegations of Research Misconduct" (SMG 9003.1) requires all FDA staff to report observed, suspected, or apparent research misconduct to FDA's Intramural Research Integrity Officer. This policy applies to allegations of research misconduct, which is fabrication, falsification, and/or plagiarism in proposing, performing, recording, or reviewing research, or in reporting research results.[3] FDA staff may discuss suspected research misconduct informally, anonymously, and hypothetically. This Agency-wide SMG provides an avenue for FDA officials to review allegations, conduct an administrative investigation, convene an investigation committee, and recommend institutional administrative actions. This scientific integrity policy prohibits research misconduct by FDA staff.

iii. Whistleblower and Retaliation Protection

Federal employees have the right to be free from prohibited personnel practices, including retaliation for whistleblowing. FDA is committed to making sure that all staff are aware of their rights as well as the safeguards that are in place to protect them.

FDA staff have a responsibility to the United States Government and its residents to place loyalty to the Constitution, laws, and ethical principles above private gain. To ensure that everyone can have complete confidence in the integrity of the federal government, staff shall respect and adhere to the standards of ethical conduct for employees of the executive

[3] Public Health Service Policies on Research Misconduct 42 CFR 93.

branch.[4]

To ensure that scientific integrity concerns, among others, are adequately addressed, FDA staff must feel free to express their concerns to Agency officials, or protected sources such as the two entities mentioned below, without fear of retribution:

HHS's Office of Inspector General (OIG) has jurisdiction to investigate whistleblower reprisal allegations brought by FDA staff. Information on how to report suspected reprisal to the OIG is available at: https://oig.hhs.gov/fraud/report-fraud/

The U.S. Office of Special Counsel (OSC) plays an important role in helping whistleblowers. OSC is an independent Agency that protects federal employees from prohibited personnel practices including whistleblower retaliation and unlawful hiring practices, such as nepotism. OSC also describes their role as providing an independent, secure channel for disclosing and resolving wrongdoing in federal agencies. Here is a summary published by OSC of whistleblower protections and avenues available to staff to disclose wrongdoing.

iv. Records and Record Keeping

Proper records management is an integral part of scientific integrity. Staff Manual Guide (SMG) 3291.9, Essential – Vital Records Management Policy, effective August 7, 2018, establishes the policy and procedures to implement an essential records management program in the FDA Centers and Offices. Proper record keeping and management is not only important to (and legally required for) FDA's regulatory decision making, but it is also a necessary foundation for sound scientific integrity at FDA. Adequate records help to ensure that open scientific debate is possible, and most of the scientific integrity principles implicitly rely on the availability of properly kept records, without which the scientific integrity of the agency would suffer tremendously. Therefore, among other obligations, it is the policy of this Agency to:

- Ensure the accuracy of the scientific record and to correct identified inaccuracies in accord with legal requirements;

- Require that staff represent their contributions to scientific work fairly and accurately and neither accept nor assume unauthorized and/or unwarranted credit for another's accomplishments; and

- Require that staff exercise appropriate diligence toward preserving and maintaining research resources, such as records of data and results that are entrusted to them.

[4] Standards of Ethical Conduct for Employees of the Executive Branch 5 CFR 2635; Employee Responsibilities and Conduct regulations at 5 CFR 735; Office of Government Ethics. Standards of Ethical Conduct for Employees of the Executive Branch. The Fourteen General Principles; 45 CFR 73 - HHS Residual Standards of Conduct

The Agency must document every significant decision – and the basis for that decision – in an administrative file that must include, among other things, "relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meetings, and other pertinent written documentation" and must reflect "significant controversies or differences of opinion and their resolution" (21 CFR 10.70).

C. Transparency to Support Scientific Integrity

Transparency can serve multiple functions in building a culture of scientific integrity, from promoting robust and vigorous debate on the scientific principles and scientific activities that underlie Agency decisions to reinforcing the generation of knowledge while promoting accountability to the American public.

FDA collects, and often creates, a vast amount of scientific information regarding the products it regulates. Facilitating the free flow of information underlying the Agency's decision-making, to the extent permitted by law, allows the public, Congress, media, industry, and other stakeholders to better understand FDA's decisions.[5] This policy as a whole ensures the free flow of scientific information and activities, including ensuring that scientists' work and conclusions are accurately represented in agency communications. FDA's standard clearance processes ensure that our scientific staff be provided an opportunity for input on agency communications that rely directly on their research, identify them individually as an author, or represent their personal scientific opinion to help ensure the accuracy of those communications. If a member of FDA's scientific staff believes that a particular agency communication or proposed communication that relies on their research, identifies them individually as an author, or represents their personal scientific opinion is not scientifically accurate, that individual may contact OSI using the process for reporting a scientific integrity violation described later in this document.

i. Information Transparency

In 2009, FDA launched an Agency-wide Transparency Initiative to make its activities and decision-making more transparent to the public as well as to regulated industry. Since then, FDA has developed and published resources to facilitate transparency, such as:

- A collection of FDA's Transparency initiatives developed to help those in the private and public sectors use FDA public data to spur innovation, advance academic research, educate the public, and protect public health.

- FDA Meetings, Conferences, and Workshops – FDA sponsors or co-sponsors meetings, conferences, and workshops about various topics to educate the public and seek the opinion of interested parties. Minutes, transcripts, summaries, and/or

[5] If an FDA staff member is uncertain regarding whether a particular disclosure is permitted, they should consult with relevant disclosure staff in their Center and/or the Office of the Chief Counsel.

presentations for sponsored or co-sponsored meetings and workshops are made available as soon after the meeting as possible.

- Freedom of Information Act Requests – FDA makes many of its records containing scientific and technical information available to the public through its regulations in 21 CFR part 20, which implement the Freedom of Information Act. As stated in 21 CFR 20.20, FDA makes "the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the Agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption." Many FDA Centers have also implemented their own specific policies on disclosure. Additionally, FDA has established electronic reading rooms that contain categories of frequently requested FDA documents.

FDA also encourages staff to share scientific or technological information that may benefit the public health by giving speeches and publishing articles in professional journals or other publications, consistent with applicable laws and agency policies, as reflected in the following SMGs:

Public access to the results of FDA-funded scientific research (SMG 2126.4) furthers the Agency's public health mission. FDA has developed a policy to increase public access to peer-reviewed articles and data generated from FDA-funded research, whether conducted by FDA staff or outside organizations with funding from FDA. The broad availability of scientific information and underlying data allow for the critical review, replication, and verification of findings that are central to the scientific method. Making research findings and the data supporting those findings accessible and analyzable promotes robust and open communication with the scientific community, thereby bolstering the credibility of scientific findings and the regulatory decision-making based upon those findings.

"Review of FDA-Related Articles and Speeches" (SMG 2126.3). This SMG is important for both FDA and public health in that it provides for a clear set of processes for staff to follow when they are contemplating an article or presentation that relates to their work, or the work of others, at FDA. Perhaps just as importantly, the policy makes it clear that FDA staff, including scientists, are free to publish or present their findings even when they are not in agreement with the Agency on the findings, conclusions, or policy implications in the article or speech, provided they identify the findings, conclusions, or policy implications as their own and follow all statutes and regulations applicable to such activities. This policy and process thereby prevent agency officials from inappropriately preventing publication of scientific information and/or disrupting such publication through unreasonable delay, suppression, or alteration, because scientific staff are free to publish without supervisory or leadership approval, provided they do so according to the process described in detail in this SMG.

ii. Openness in Scientific Decision-Making

The following FDA policies and programs seek to strengthen the scientific quality, integrity, and credibility of scientific activities at the Agency:

FDA Advisory Committees and Public Hearings - FDA seeks expert and public input on a broad scope of complex issues related to the products it regulates, consistent with the Federal Advisory Committee Act and the Agency's implementing regulations (e.g. 21 CFR part 14). FDA has many advisory committees, some with multiple panels. The committees are established to provide functions that support the FDA's mission of protecting and promoting the public health, while meeting the requirements set forth in the Federal Advisory Committee Act.[6] FDA's advisory committees provide valuable independent expert advice on a range of complex scientific, technical and policy issues. As the Agency makes its final decision, FDA considers the advice provided by advisory committees.

Advisory committees provide advice to FDA, but FDA is responsible for the final Agency decisions. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

The Science Board to the FDA is one such advisory committee and provides advice to the Agency on keeping pace with technical and scientific developments, including with respect to regulatory science, the Agency's research agenda, research facilities, and training opportunities.

Assessments of FDA Policies Made Public – FDA is subject to the requirements in the Information Quality Act (IQA),[7] and regularly offers staff trainings on these requirements. The IQA requires that information disseminated by the Agency meet quality, utility, objectivity, and integrity standards, and that influential scientific information be peer reviewed by qualified specialists before it is disseminated.[8] The Agency adheres to the Office of Management and Budget Final Information Quality Bulletin for Peer Review.[9] Peer reviews of influential scientific information can be found on FDA's public-facing website, Completed Reviews.

Agency Review Request – An Agency regulation, 21 CFR 10.75, includes provisions that enable interested persons outside the Agency to request internal Agency review of a decision. See also "Requests for Review under 21 CFR 10.75 Submitted to the Office of the Commissioner by Interested Persons outside the Agency" (SMG 9010.5).

Agency Petitions and Comments – Agency regulations permit interested persons to petition

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[6] Pub. L. 92–463, §1, Oct. 6, 1972, 86 Stat. 770. Federal Advisory Committee Act.

[7] Pub. L. 106-554, Section 515, The Information Quality Act.

[8] Office of Management and Budget. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies." *Federal Register*. 67 FR 8451, Doc. R2-59.

[9] Office of Management and Budget. "Final Information Quality Bulletin for Peer Review." *Federal Register*. 70 FR 2664, Doc. 05-769.

the Agency to revise our approach to particular scientific issues (21 CFR 10.30); petition the Agency to stay or extend the effective date of any administrative action (21 CFR 10.35), petition the Agency issue, amend, or revoke a regulation, or take or refrain from taking any administrative action (21 CFR 10.25), and to comment on the regulations and guidance documents, including those that bear directly on scientific issues before the Agency (21 CFR 10.40, 10.115 (f)-(g)).

iii. Ethics

FDA's ethics program is structured to provide advice and assistance to current and former staff in order to help ensure that decisions they make, and actions they take, are not, nor appear to be, tainted by any question of conflict of interest. The ethics laws and regulations were established to promote and strengthen the public's confidence in the integrity of the federal government.

Federal Standards of Conduct – FDA requires all staff to comply with all applicable rules and regulations regarding financial conflicts of interest (see 5 CFR 2635, 5501, and 5502). Training modules on conflicts of interest are available on the Agency intranet and requires all confidential and public filers to take annual training. FDA's Ethics and Integrity Staff provide advice and assistance to staff on a variety of ethics-related matters including, but not limited to, financial disclosure, prohibited financial interests, outside activities, and post-employment restrictions. For example, FDA employees are subject to rules that restrict financial holdings in organizations that sell products regulated by FDA, also known as Significantly Regulated Organizations: FDA's Prohibited Financial Interests for FDA Employees webpage.

FDA employees must also abide by the Hatch Act, a law that restricts federal employees' political activity: The Hatch Act: Political Activity and the Federal Employee.

D. Communication and Collaboration in Scientific Integrity

i. External Communication

FDA uses various modes of communication to reach and collaborate with stakeholders. Below are some of the open and transparent avenues used to communicate regulatory information:

The Office of External Affairs (OEA) in the Office of the Commissioner oversees Agency-wide communications activities regarding the FDA's public health and regulatory activities. This includes the development and coordination of all FDA communications as well as outreach efforts to the news media, health professionals, patient advocates, industry, states, consumer groups, and the general public. External materials include FDA press announcements, FDA Voices blogs, and FDA Consumer Updates.

FDA's Office of Legislation (OL) ensures that Congress has the most accurate and up-to-date information about biomedical research, coordinates legislative activities with the Department of Health and Human Services, and manages FDA's response to requests from

the various entities that serve Congress. As part of this role, OL helps to ensure that FDA's responses to Congressional inquiries, testimony, and other requests accurately represent scientific information.

ii. Speaking on Behalf of FDA in an Official Capacity

The Agency is committed to a culture of openness in its interaction with the news media and the public, and follows HHS's news media policy, Guidelines on the Provision of Information to the News Media. FDA's Centers/Offices may have additional communications policies that govern Center/Office-specific communications efforts with external parties (e.g., reports, scientific articles). FDA staff speaking on behalf of FDA should familiarize themselves with all applicable policies and limitations.

iii. Sharing Personal Views as FDA Staff

FDA's Social Media Policy (and HHS's News Media Guidelines) – FDA encourages staff to use social media to share information that may benefit the public health, consistent with the guidelines set forth in these policies. It is important to remember that when a staff member uses social media tools in a personal capacity, they are not speaking for the agency, and it shouldn't appear to others as though they are speaking for FDA. Before engaging in the use of social media related to FDA matters, FDA staff should be familiar with the guidelines and limitations discussed in FDA's Social Media Policy, including, but not limited to, legal limitations related to the Hatch Act (discussed above) and limitations related to the disclosure of confidential, commercial information or trade secret information. FDA's Social Media Policy thus recognizes the interest of staff in expressing their views via social media and does not require that staff obtain permission or approval from supervisors or agency management before using social media in a personal capacity. In addition, HHS's News Media Guidelines describe how HHS staff are both permitted and encouraged to speak to members of the press about their work.

iv. Other External Communication Policies

The FDA Learning Portal for Students, Academia, and Industry provides education and resources related to FDA's regulatory, product quality, and safety responsibilities.

Risk Communication – Risk communication means conveying both the risks and benefits of FDA-regulated products. The goal of FDA risk communication is to help people make informed decisions about FDA-regulated products. It is an interactive process that targets both public and regulated industries.

HHS and FDA developed the Strategic Plan for Risk Communication and Health Literacy (SPRCHL), which aims to empower people to make informed choices for their health by clarifying how FDA can more effectively communicate the benefits and risks of FDA-regulated products to our target audiences. FDA's mission includes helping people protect their health through informed decisions about using FDA-regulated products. FDA strives to help patients, consumers, and health care professionals make informed decisions about FDA-regulated products using the best science and communication practices.

v. Scientific and Professional Development

In 2011, FDA's Office of the Chief Scientist created the Office of Scientific and Professional Development (OSPD), which promotes and facilitates scientific excellence and the professional development of scientists throughout the Agency. OSPD supports a range of dynamic and innovative programs and activities targeted at FDA's scientific staff and its stakeholder community. The OSPD program complements scientific activities throughout the organization and includes continuing education.

The OSPD Intranet page serves as a resource for scientific personnel. Among other things, the OSPD intranet page provides training opportunities, a scientific professional development calendar, and the nomination processes for internal awards.

FDA policies also encourage both the publication of research findings in professional journals and the presentation of research findings at professional meetings. FDA further permits its scientific staff to become editorial board members for scientific journals, to participate in professional societies, and to receive scientific honors and awards, consistent with applicable ethical rules.

vi. Collaboration

FDA is interested in partnering with stakeholders to further its public health mission. By leveraging resources and expertise, through appropriate mechanisms, FDA can effectively collaborate to address critical public health needs and bridge scientific gaps, thereby stimulating innovation in the development of FDA-regulated products.

Collaborations with FDA can be formalized through multiple mechanisms including Cooperative Research and Development Agreements, memoranda of understanding, contracts, cooperative agreements, or through other public-private partnership mechanisms.

7. Reporting Scientific Integrity Violations

A. When to Report a Potential Violation of FDA's Scientific Integrity Policies

Maintaining scientific integrity at FDA is the responsibility of all FDA staff. Whenever possible, as a first step toward resolving potential scientific integrity issues, FDA staff should work directly with their colleagues, supervisors, Center ombuds, and other relevant personnel to attempt to address potential scientific integrity issues using the existing FDA policies and guiding principles described earlier in this SMG. Typically, a particular concern related to scientific integrity has a specific implementing policy and process that provides a path to address that concern. For example, a concern related to the publication of research conducted at FDA may be addressed by FDA's "Review of FDA-related Articles and Speeches" (SMG 2126.3), whereas a disagreement concerning the appropriate scientific approach to measure a particular component of a drug product under review,

would be best addressed by "Scientific Dispute Resolution at FDA" (SMG 9010.1). Many of the policies implemented to promote and maintain scientific integrity are referenced and described earlier in this SMG, and FDA staff are encouraged to seek help from OSI and ombuds staff to identify the appropriate Agency policies and procedures to address specific scientific integrity concerns. Once identified, the governing process should be used to resolve the matter (e.g., SMG 9010.1 describes the process of resolving scientific disputes at FDA, including informal and formal procedures, appeals, etc.).

Center-specific policies and procedures for resolving scientific integrity related issues take various forms, such as standard operating procedure documents and manuals of policies and procedures (MAPP). For example, the FDA Center for Drug Evaluation and Research (CDER) MAPP, 'Equal Voice: Collaboration and Regulatory and Policy Decision-Making in CDER,' describes the principles behind Equal Voice and how the process is used for collaborative review and regulatory and policy decision-making in CDER.[10]

When such good-faith efforts and/or existing policies and procedures do not resolve an issue related to scientific integrity, FDA staff may consult with their component ombuds or equivalent and/or OSI staff for help determining next steps.

When existing policies or procedures do not clearly describe processes for addressing concerns about scientific integrity at the Agency, including deviations from the principles articulated in this SMG, FDA encourages staff to report those concerns using the process described in the next subsection.[11]

B. How to Report a Potential Violation of FDA's Scientific Integrity Policy

Because FDA has implemented a variety of specific policies and processes in different contexts to address scientific integrity-related concerns, FDA staff are encouraged to discuss their particular concern with OSI and/or Center ombuds staff prior to submitting a report of a potential scientific integrity violation as described below. Such discussions are confidential and typically help FDA staff to better understand which pathways for resolution of a particular issue are available to them, often under other existing policies and procedures. Please note, however, that such a discussion is not a requirement for submitting information related to a potential violation as described below.

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[10] Equal Voice is a process and set of principles aimed at ensuring input from all levels of staff is heard and valued to create a mutually respectful and professional environment.

[11] Nothing in this SMG is intended to discourage FDA staff from using any and all legal avenues available to report wrongdoing or to seek whistleblower protections provided to them by other laws and policies, including independently seeking advice and assistance from HHS's Office of Inspector General, the Office of Special Counsel, and other sources. The reporting system described in this section is not intended to supplant these mechanisms for redress. Resources and contact information for these sources are provided in the References section.

This SMG is not intended to limit FDA staff's use of other means to report potential wrongdoing as provided elsewhere by law or policy. FDA encourages staff to report potential violations of scientific integrity to the Agency using the reporting mechanism described here, in addition to any other applicable remedies available. To report a potential violation of scientific integrity at FDA that is not adequately addressed by other existing policies related to scientific integrity, the Agency encourages FDA staff to contact OSI using "Reporting SI Issues" located on the OSI intranet site. This internal webpage provides mechanisms for direct and/or anonymous reporting as well as contact information for OSI staff.

When reporting a potential scientific integrity violation, regardless of method of communication, a reporter of a potential scientific integrity violation should include the following information:

Violation. What specific aspect of scientific integrity, key principle, or implementing policy/process at FDA may have been violated?
Detailed Description. How specifically did the alleged violation occur? Explain what occurred with relevant details, including a timeline and other relevant facts that may be used to establish whether and how scientific integrity was compromised and who was responsible for the violation.
Supporting Information. Are witnesses and records available that would help to prove the violation occurred? (No witnesses or documents are required to report an SI concern but should be provided, if possible.)
Contact information. If the reporter is willing to be contacted regarding this report, provide a preferred contact method and information.

The FDA reporting website referenced above allows for anonymous reporting, and FDA staff who wish to remain anonymous may report issues using this portal. Please be aware that follow-up by OSI with the reporter of a potential violation is frequently critical to establishing whether a scientific integrity violation occurred and to making use of the appropriate process to address it. As a result, FDA encourages all staff to identify themselves when reporting a scientific integrity issue if they feel comfortable doing so.

i. Retaliation for Reporting Scientific Integrity Issues

Reprisals of any kind for the reporting of scientific integrity issues are antithetical to an atmosphere of open scientific discourse and are contrary to the scientific integrity principles of this Agency. All FDA staff, regardless of their role, must refrain from any such reprisals and should respect the often-difficult decision of their colleagues to report potential scientific integrity issues. Further, FDA staff must respect the importance of such reporting to FDA's overall scientific integrity. If any staff member experiences retaliation of any kind as a result of reporting a scientific integrity issue–in addition to other remedies available to federal employees, as noted above and below in this SMG–FDA, staff may contact OSI for assistance in addressing those concerns.

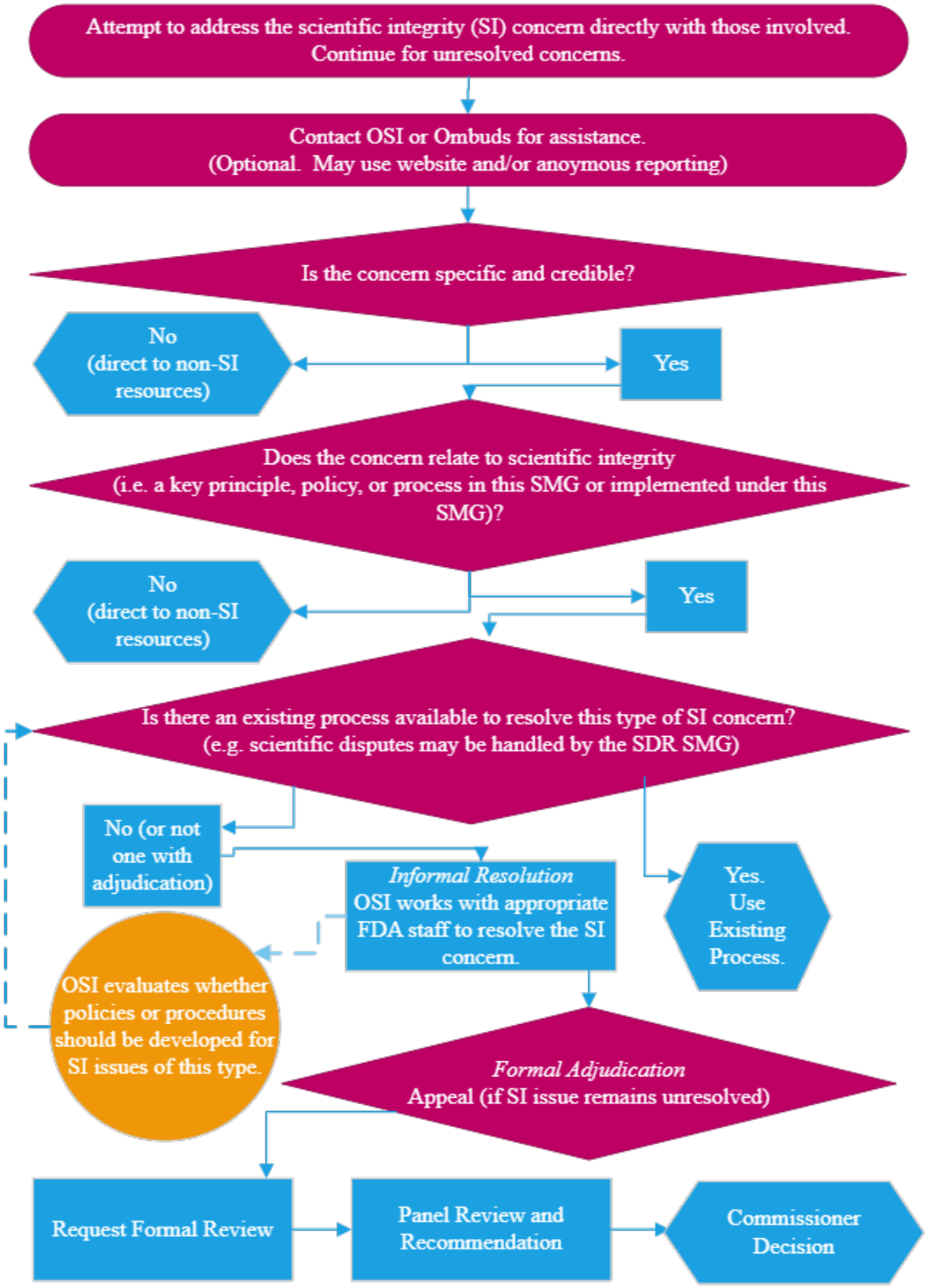
C. FDA's Process for Evaluating Scientific Integrity Violation Reports

i. General Allegation Review and Adjudication

OSI will evaluate all reports of potential violations of scientific integrity reported under subsection B. If an existing policy or process would adequately address the concern raised in a report, OSI staff will work with the reporter and other appropriate parties to address the concern through the applicable existing pathway. OSI will assess and work to address all credible and specific allegations that relate to scientific integrity but are not adequately covered by existing policies. If such allegations are substantiated and raise scientific integrity concerns, OSI will then work informally with appropriate Center leadership, ombuds staff, managers, and other appropriate FDA staff to resolve the concern in a manner consistent with the guiding principles of scientific integrity described earlier in this SMG.

If a reporter's scientific integrity concern does not involve political interference (as discussed in the next subsection) and is not subject to an existing scientific integrity policy that includes an adjudication component, the reporter may request formal adjudication following the informal efforts to resolve the concern by OSI described above. To initiate such an adjudication and challenge any informal resolution, the reporter should submit a written request for formal review to OSI using the contact information provided earlier in this section. For all qualifying adjudication requests (i.e., those requests following informal efforts to seek resolution that are not subject to an existing scientific integrity policy with an adjudication component and do not involve political interference), OSI will assemble a three-person panel from FDA staff to evaluate the concern and make a written recommendation to the Commissioner describing the scientific integrity concern and specifying appropriate remedial measures, if any, that the panel determines would address the scientific integrity concern consistent with the scientific integrity principles described earlier in this guide. The panel should include three members who do not have, or appear to have, a personal or professional interest in the outcome of the dispute. When possible, panel members should be selected based on any relevant knowledge or experience useful in understanding and evaluating the scientific integrity concern at issue. After reviewing the panel recommendation, the Commissioner will render a final decision for the Agency, directing such remedial action as the Commissioner deems appropriate, if any. OSI will facilitate the implementation of any remedial actions directed as a result of this process and will work with all involved parties to ensure that remedial measures consistent with the Commissioner's determination are taken. The following flowchart provides a visual overview of the process described in this section.

Flowchart: Overview of the Evaluation and Adjudication of Scientific Integrity (SI) Concerns at FDA

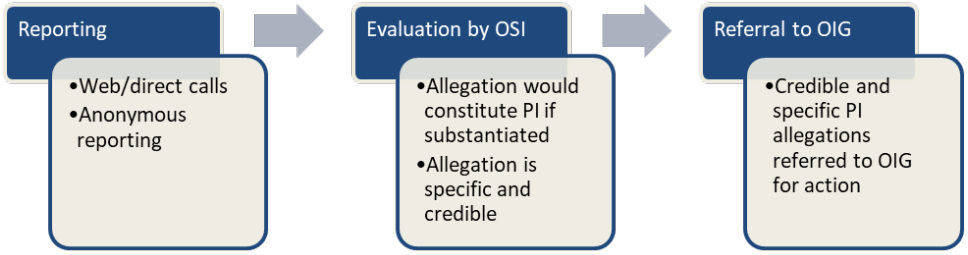


ii. Allegations of Political Interference

As reflected in the Key Scientific Integrity Principles above, FDA regards shielding its staff from political interference as a core scientific integrity principle and encourages reporting any attempt at such interference by anyone with knowledge of such an attempt.

Anyone with knowledge of political interference at FDA should report that information using the contact information and requested submission of information described in section 7.B (How to Report a Violation of FDA's Scientific Integrity Policy). In addition to the other processes described in the previous subsection, OSI will evaluate each allegation of political interference and determine whether: (a) an allegation, if substantiated, would constitute political interference, and (b) whether the allegation is specific and credible such that further investigation is both possible and warranted. Specific and credible allegations of political interference within the definition of this policy will be referred to OIG for further action by OIG as appropriate. Nothing in this SMG or FDA policy is intended to discourage FDA staff from reporting such allegations directly to OIG or other appropriate entities, but FDA encourages staff to report political interference at FDA using FDA's reporting process described in section 7.B. of this SMG in addition to using any other appropriate processes. The following flowchart provides a visual summary of this process.

Flowchart: Process for Evaluation and Referral of Political Interference (PI) Allegations



Reporting an allegation of political interference will not preclude other appropriate parallel activities and processes to ensure that FDA's scientific decision-making is not compromised. For example, if a reporter believes that political interference compromised the scientific basis for a regulatory decision, it would be appropriate to both report the political interference using the reporting mechanism described in section 7.B. of this SMG and to follow the Agency's policies and process in "Scientific Dispute Resolution at FDA" (SMG 9010.1) to ensure that the decision at issue has a sound scientific basis. Questions about the appropriate processes for a particular issue should be directed to OSI staff. In most instances when there is an allegation that political interference undermined scientific decision-making, OSI will advise the reporter that the appropriate recourse for challenging the scientific decision at issue is to work through the processes for resolving scientific disagreements and disputes reflected in SMG 9010.1.

8. References

A. Internal FDA Resources

- Office of Scientific Integrity
  - Reporting and contact information: For reporting of scientific integrity violations or for reporting allegations of political interference, please visit this page for updated contact information.

- Office of Equal Employment Opportunity (OEEO)
  - Reporting and contact information: Diversity, Equity, Inclusion, and Accessibility - EEO complaints process – DEIA Strategic Plan

- Office of Ethics and Integrity
  - Reporting and contact information: Ethics Advice Hotline at (240) 402-1111 or email FDAEthics_Advice@fda.hhs.gov.

- Office of Legislation
  - To contact the Office of Legislation please call 301-796-8900 or email legislation@fda.hhs.gov

- FDA Anti-Harassment Program
  - Reporting and contact information: AHP-CREW@fda.hhs.gov or ERIC Help Desk at 301-827-3742, (Option 3,3,3)
  - To report and allegation please go to: Anti-Harassment Program

- Ombudsman, Conflict Prevention and Resolution
  - Reporting and contact information: For addressing general workplace conflicts, email FDA's Alternative Dispute Resolution (ADR) program at adr@fda.hhs.gov or call 301-796-9420

- FDA Records Management Program

HHS establishes policies and principles designed to ensure the integrity of scientific and scholarly activities that the Department conducts and supports, and the science it uses to inform management and public policy decisions.

- HHS Scientific Integrity
- Policies and Principles for Assuring Scientific Integrity

Below are helpful links to resources for FDA staff on whistleblower protections and the reporting of whistleblower reprisal.

B. External resources

HHS - Office of Inspector General Resources
OIG Hotline or 1-800-HHS-TIPS
Whistleblower Protection Coordinator Website or email
Whistleblower.Coordinator@oig.hhs.gov
Whistleblower Protection FAQs
Whistleblower Protection Information Brochure

Office of Special Counsel Resources *(for federal civilian employees)*
If you are a civilian federal employee and wish to make a whistleblower disclosure or report reprisal for doing so outside HHS, you may contact the U.S. Office of Special Counsel.

Whistleblower Disclosure Hotline: For Inquiries on How to Report Fraud, Waste, Abuse or Dangers to Health and Safety, call 1-800-872-9855 or 1-202-804-7000, or email info@osc.gov
Prohibited Personnel Practices Information
OSC Fact Sheet: Your Rights as a Federal Employee
OSC Fact Sheet: Know Your Rights When Reporting Wrongs
OSC Fact Sheet: Your Role in an OSC Investigation

9. Effective date

The effective date of this guide is December 6, 2023.

10. History – SMG 9001.1, Scientific Integrity at FDA

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	02/03/2012	N/A	OC/OSI	Jesse Goodman, Chief Scientist
Change	08/03/2023	URL in Sect. 5.C. for FDCA	OCS/ACOMS	Russell Fortney, Director, ACOMS
Revision	09/30/2023	N/A	OC/OSI	Namandjé Bumpus, Chief Scientist