

Regulatory Procedures Manual

INTRODUCTION

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1. Purpose

The Regulatory Procedures Manual (RPM) is a reference manual that provides internal procedures and related information to be used by FDA employees who process certain regulatory and enforcement matters in support of the agency's public health mission. Adherence to this manual is paramount to assure quality, consistency, and efficiency in FDA operations.

2. Scope

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

The RPM does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

3. Responsibility

While the RPM is intended mainly to describe procedures for FDA investigation and compliance officers, and programs and divisions in ORA, the document is useful to all of FDA.

4. Background

This version of the RPM contains important changes which clarify or present new information and procedures. For example, this year we have

included information relating to the recent Program Alignment changes. We are continuing to update the RPM in response to our May 15, 2017 rollout of program alignment across ORA. These program alignment updates will continue as we incorporate new program-specific sections within the RPM. As with each new edition of the RPM, please take time to review sections of the manual for changes which may apply to your work.

We are committed to the continual improvement of the quality and usefulness of the RPM. Suggestions for the next edition of the RPM or recommended changes, deletions, additions to the RPM may be sent via e-mail to the Outlook address for ORA RPM Updates. If you are recommending a change or revision, please use the RPM Change Request Form available at [RPM Appendix A](#). Suggestions are accepted from the within the Agency, our state and local partners, industry and consumers. Thank you for your continued hard work and dedication in protecting and promoting the health and well-being of the American people.

The RPM has been posted on ORA's Internet Website at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual>. Future updates to the RPM will be performed periodically during the year to the on-line version. Remember, whether reviewing a printed copy or the *on-line* version of the RPM, the most recent version on line is the document of record.

5. Attachment - Vision, Mission and Values

Vision

All food is safe; all medical products are safe and effective; and the public health is advanced and protected.

Mission

Protecting consumers and enhancing public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products. Quality Commitment ORA is committed to quality and continual improvement. Our actions are dedicated to effectively meeting our customers' needs.

Values

Accountability - We take personal responsibility for meeting individual, team, and organizational commitments

Commitment to Public Health - We demonstrate our commitment to safeguarding the public health in our actions.

Communication - We provide information that is accurate and clear, and in our interactions with others, we actively listen to understand other points of view.

Diversity & Inclusion - We embrace each individual's uniqueness and seek out their ideas and perspectives.

Integrity and Respect - We adhere to the highest ethical standards by consistently being honest and trustworthy in our actions.

Quality - We set high standards of excellence for our work and take the necessary actions to continuously improve.