INTRODUCTION

The Regulatory Procedures Manual is a reference manual for FDA personnel. It provides FDA personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

This document supersedes the March 2010 edition of the Regulatory Procedures Manual (RPM).

PURPOSE

The primary purpose of the Regulatory Procedures Manual (RPM) is to provide FDA personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters. While the RPM is intended mainly to provide guidance to FDA inspectors, investigators, and compliance officers, the document is useful to all of FDA.

UPDATES AND COMMENTS

The RPM content is subject to ongoing revisions and additions. Please send any comments, suggestions for recommended changes, deletions, and updates to the Division of Compliance Policy via e-mail at ORA RPM Updates. If you are recommending a change or revision, please use the RPM Change Request Form available from the web site and included in the RPM as Appendix A. Your comments, suggestions, and change requests will be transmitted and considered by the appropriate responsible organization.

DISTRIBUTION

The 2011 edition of the RPM is only available electronically. It is posted on the internet at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm. It is also posted in the electronic reading room on the internet at: http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/default.htm.