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 Regulatory Procedures Manual (RPM) printed in March 2006.

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 check the electronic edition of the RPM on the Internet at www.fda.gov/ora/compliance_ref/rpm/default.htm for the most current version.

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

For FDA personnel:

Copies of the RPM are provided to all FDA field and headquarters offices. Additional copies may be obtained by contacting the Division of Compliance Policy at (240) 632-6860.

For state and local government officials:

State and local government officials may obtain copies of the RPM and updates by contacting the Division of Federal-State Relations (HFC-150), 5600 Fishers Lane, Rockville, Maryland, USA 20857, telephone number (301) 827-6906.

Public:

The electronic edition of the RPM is posted on the Internet at www.fda.gov/ora/compliance_ref/rpm/default.htm

The paper version of the RPM may be obtained for a fee by sending a Freedom of Information

request to: Food and Drug Administration, Office of Management Programs, Division of Freedom of Information (HFI-35), 5600 Fishers Lane, Rockville, MD 20857, or by faxing an FOIA request to (301) 443-1726. Information about submitting FOIA requests can be found on the Internet at www.fda.gov/FOI/FOIA2.htm.)