Foreword 2012

The *Investigations Operations Manual* (IOM) is the primary source regarding Agency policy and procedures for field investigators and inspectors. This extends to all individuals who perform field investigational activities in support of the Agency's public health mission. Accordingly, it directs the conduct of all fundamental field investigational activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations. The specific information in this manual is supplemented, not superseded, by other manuals and field guidance documents. Recognizing that this manual may not cover all situations or variables arising from field operations, any significant departures from IOM established procedures should have the concurrence of district management.

For 2012, the IOM contains some important changes which clarify or present new procedures. For instance, Chapter 5 has been updated with the new FSMA Re-Inspection User Fee procedures. The “In-Plant Photographs” section in Chapter 5 has been revised to specify actions required by the investigator and district management when a firm’s management refuses photography during an inspection. Additionally, tobacco product guidance has been included in Chapters 2, 4, 5, and 8. In Chapter 4, the open controls portion of “Environmental Sampling” section has been simplified and the “Sample Basis” section has been revised to clarify the values used for environmental samples in reporting sample collections.

As with each new edition of the IOM, please take time to review sections of the IOM for changes which may apply to your work.

Since December 1996, the IOM has been posted on ORA's Internet Website, http://www.fda.gov/ICECI/Inspections/IOM/default. The entire IOM is available there. Future updates to the IOM will be performed periodically during the year to this on-line version. The hard copy will be published annually. Remember, whether reviewing the "hard copy" or the "on-line' version of the IOM, the most recent version is the document of record.

We are committed to the continual improvement of the quality and usefulness of the IOM. Suggestions for the 2013 edition of the IOM or recommended changes, deletions, additions to the IOM may be sent to the Division of Domestic Field Investigations (HFC-130), 12420 Parklawn Drive, Rockville, MD 20857 or via e-mail to the Director, DDFI. You can also e-mail IOM@FDA.HHS.GOV. If you are recommending a change or revision, please use the IOM Change Request Form available from DDFI’s web site.

Thank you for your continued hard work and dedication in protecting and promoting the health and well-being of the American people.

/Dara A. Corrigan/

Dara A. Corrigan, Associate Commissioner for Regulatory Affairs

FDA/Office of Regulatory Affairs