Inspection of Medical Device Manufacturers Final Guidance for Industry and FDA

Document issued on: February 7, 2001

This document supersedes "Draft Compliance Program Guidance Manual: Inspection of Medical Devices" released on August 12, 1999.



U.S. Department Of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health

> Field Programs Branch Division of Program Operations Office of Compliance

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Walter W. Morgenstern at (301) 594-4699 ext. 102 or email www.gov.gov.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/ora/cpgm/default.htm or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1702 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Inspection of Medical Device Manufacturers Final Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Link to Document in WORD, HTML and PDF