

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1651]

OMB

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**Devices—Inspections of Medical Device Manufacturers Compliance Program
Guidance Manual, CP 7382.845; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance program (CP) entitled “Inspection of Medical Device Manufacturers.” This CP is intended to help FDA components and industry comply with FDA’s internal inspection and compliance processes concerning quality system/good manufacturing practice (QS/GMP) inspections of manufacturers of medical devices.

DATES: Submit written comments on this CP at any time.

ADDRESSES: Submit written requests for single copies of CP 7382.845 “Inspections of Medical Device Manufacturers” to the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Copies of the CP may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs (ORA) home page includes the CP and may be accessed at <http://www.fda.gov/ora>. The CP will be available on the compliance references page for ORA. Submit written comments on the CP to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Technical questions concerning inspections of medical device manufacturers: Denise D. Dion,
Division of Emergency and Investigational Operations (HFC-130), Office of Regional

Operations, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5645, FAX 301-443-6919.

Questions concerning regulatory actions and all comments: Wes W. Morgenstern, Division of Program Operations (HFZ-305), Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-4699, FAX 301-594-4715.

SUPPLEMENTARY INFORMATION: FDA has renumbered CP 7382.830 as CP 7382.845 and revised it to reflect a change in the guidance on how a QS/GMP inspection of a medical device manufacturer should be conducted. The new inspectional method is known as the quality systems inspection technique. The revision to the CP also reflects changes in when FDA may consider a firm out of compliance with the medical device quality system regulation (21 CFR part 820).

The CP is intended to provide policy and regulatory guidance to FDA's field and headquarters staff with regard to medical device manufacturer inspections. It also contains information that may be useful to the regulated industry and to the public.

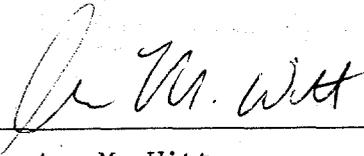
The CP is being issued as a guidance document and represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. FDA published a notice making a draft of the CP available for public comment in the **Federal Register** (64 FR 44024, August 12, 1999).

The agency has adopted good guidance practice (GGP) regulations (65 FR 56468, September 19, 2000) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This CP is issued as a level 1 guidance consistent with GGP's.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the CP entitled "Inspections of Medical Device Manufacturers" at any time. Two copies of any comments are to be submitted, except individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the CP and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 22, 2001
January 22, 2001.



Ann M. Witt,
Acting Associate Commissioner for Policy.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



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