DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date SEP 11 1997

From Chief, Field Programs Branch, HFZ-306

Subject New Policy Concerning PMA Postmarket Inspections of Contract Sterilizers

To See Addressees

As a result of CDRH's reengineering efforts and a suggestion from a district office, this memo is announcing a new policy regarding Premarket Approval Application (PMA) **Postmarket** Inspections of Contract Sterilizers. This will be implemented as of the date of this letter.

BACKGROUND

Currently all contract sterilizers are routinely inspected in accordance with postmarket inspection assignments. For contract sterilizers with a significant number of customers who manufacture PMA devices, these assignments involve frequent inspections to previously visited sites for district offices.

A review was made of the inspectional assignments, agency databases, and information from district offices. It was determined that in many cases, the contract sterilizers were in compliance with the device Quality System Regulation at the time a new postmarket inspection assignment(s) was issued, and the same sterilization method was covered during the most recent inspection as the one identified in the PMA

NEW POLICY

Due to dwindling resources and CDRH's reengineering assessment of PMA postmarket inspections of contract sterilizers, the Office of Compliance will not issue inspectional assignments for PMA postmarket contract sterilizers when the facility was inspected during the previous two years, and:

1. found to be in compliance with the Quality System Regulation; and
2. the same sterilization method was covered as the one identified in the PMA.

The means to be used by CDRH to determine these factors will be COMSTAT (Compliance Status Information System), PODS (Program Oriented Data System), and district office communication.

The Office of Compliance will continue to issue assignments for PMA postmarket contract sterilizer inspections in cases where:

1. changes in the sterilization process can not be clarified or checked by reviewing sterilization records at the finished device manufacturer;
2. information obtained from the manufacturer discloses a possible problem at the contract sterilizer; and,
3. information needs to be verified.

It is anticipated that this new policy will reduce the number of inspections of contract sterilizers. Therefore, districts are urged to use investigators with experience in conducting inspections of contract sterilizers.

NOTE: This new inspectional policy/strategy is only applicable to PMA postmarket inspections of contract sterilizers. The Office of Compliance will continue to issue PMA **Pre-Approval** inspection assignments for contract sterilizers in accordance with existing policies.

If you have questions concerning this new policy, please contact Allen Wynn at (301) 594-4695.

Marje Hoban

ADDRESSEES:

District Directors
Directors, Investigations Branch