This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
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2098 Gaither Road
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To: All Device Manufacturers/Repackers Using Cotton

Since August 1993, the Center for Devices and Radiological Health (CDRH) has become aware of several instances where devices made of Chinese cotton have been found to be contaminated with mold, even though the devices were labeled as sterile. Devices containing cotton include, but are not limited to laparotomy sponges, surgical sponges, surgical drapes, operating room towels and wound dressings. To date, we have not noted problems regarding cotton grown in other countries, including the United States. As a precaution, the following information should be considered regardless of the cotton's origin.

The prevalent mold which has been identified thus far is Pyronemia domesticum, which belongs to the class Ascomycetes and is believed to be nonpathogenic.

Several companies who have experienced problems with mold have changed their sterilization practices. One manufacturer has determined that P. domesticum is resistant to standard ethylene oxide (EO) sterilization cycles and to standard gamma radiation doses. The manufacturer is using a standard steam sterilization cycle followed by a standard EO sterilization cycle. Other companies have instituted a standard EO sterilization cycle followed by a standard gamma radiation cycle, or vice versa.

CDRH is not advocating any of the above methods, but is recommending that you conduct appropriate, adequate and thorough validation studies of each sterilization cycle in use. The sterilization validation studies should not only focus on bacterial contamination, but should also include molds and yeasts. The following points should be included as part of your sterilization validation:

1. Bioburden of the incoming cotton device. The bioburden assessment must include bacteria, molds and yeasts using established test methods. The entire device must be submerged in the culture media. Bioburden should be assessed as part of sterilization cycle development, and then periodic bioburden assessment should be performed once the cycle has been validated.

2. Sterilization cycle development studies should include inoculated product using P. domesticum and any other microorganisms found during initial bioburden assessment. The inoculated product should be placed in the hardest to sterilize locations within the chamber. Standard methods

should be utilized for inoculation, recovery and culture techniques. Again, the entire device must be submerged in the culture media. If gamma radiation is used to sterilize the device, our experience has shown that incubation up to 30 days may reveal slow growing microorganisms which were not found at the traditional 14 day incubation period.

Use of inoculated product should not preclude the use of biological indicators and/or dosimeters during validation and during routing processing.

3. During validation, sterility testing of the sterilized cotton should be performed using established test methods. The testing regimen should include identification of bacteria, molds and yeasts. Again, the entire device must be submerged in the culture media. Traditionally, FDA does not require that routine sterility testing be conducted on each sterilization load, provided that the sterilization process has been properly validated. However, for cotton devices, it is recommended that at least periodic sterility testing be performed to assess that the cycle is adequate.

If you have any questions regarding this letter, you may contact John Samalik of the General Surgery Branch at the above address or at (301) 594-4595.

Sincerely yours,

Ronald M. Johnson
Director
Office of Compliance
Center for Devices and
Radiological Health