Reuse of Medical Disposable Devices Policy

DEPARTMENT OF HEALTH & HUMAN SERVICES - Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

December 27, 1995

American College of Healthcare Executives
North Franklin Street, Suite #1700
Chicago, Illinois 60606-3491

Dear Mr. President:

The Food and Drug Administration (FDA) has become aware that an increasing number of firms are reprocessing single use medical devices for health care facilities. This letter is to notify your trade association and others of the FDA's policies that may apply to the reuse of single-use or disposable medical devices and to request your assistance in disseminating this information to your members. The FDA has two existing Compliance Policy Guides (CPG), *Reuse of Medical Disposable Devices* (CPG 300.500), which covers reprocessing of disposable devices by health care facilities, and Reconditioners/Rebuilders of Medical Devices (CPG 300.200), which covers reconditioning or rebuilding of medical devices by a person or firm that takes ownership of used medical devices for the purpose of resale. The FDA is presently working to revise CPG 300.200 regarding the refurbishing or remanufacturing of medical devices to remove the requirement of ownership for the policy to apply. The revised policy is intended to take effect sometime in the next 6 - 12 months. Note that FDA is evaluating those situations in which submission of a 510(k) or PMA supplement would be required for reprocessing of devices. This information would be included in any revised policy regarding device reprocessing.

We wish to clarify at this time that consistent with existing regulations, any person or firm that reprocesses medical devices for health care facilities **and engages in repackage relabeling, or sterilization activities (including any associated.processing operations; e.g., cleaninq,** are required to comply with the Good Manufacturing Practice (GMP) and device labeling requirements of the Federal regulations, 21 CFR Parts 820 and 801, respectively.

Information regarding compliance with the GMP and device labeling requirements can be obtained from our Division of Small Manufacturers Assistance (DSMA) by calling 1-800-638-2041.

Similarly, copies of the March 1995 edition of the FDA's *Compliance Policv Guides* document can also be obtained from DSMA. If you have any questions or require further clarification, please feel free to contact Larry Spears at 301-796-5500.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and Radiological Health

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)