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
Radiological Health
2098 Gaither Road
Rockville MD 20850

FEB 3 1994

TO: MANUFACTURERS AND INITIAL DISTRIBUTORS OF SHARPS CONTAINERS AND DESTROYERS USED BY HEALTH CARE PROFESSIONALS:

The purpose of this letter is to clarify the regulatory status of devices which serve as Sharps Containers and/or Sharps Destroyers (sharps devices). These products are devices as that term is defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). In the past, FDA has exercised enforcement discretion, and has not actively enforced marketing clearance, registration and listing, and manufacturing requirements for these devices. This document shall serve to clarify all past correspondence and outline all requirements which need to be complied with to lawfully market these devices.

Because of increasing concern about transmission of disease associated with needle sticks, e.g., HIV, Hepatitis B, and other blood born agents, we are exercising our discretion to now require manufacturers and initial distributors of sharps devices to comply with all applicable requirements of the Act, including registration and listing, obtaining appropriate marketing clearance, assuring conformance with the Good Manufacturing Practices for medical devices regulation (GMP), and to appropriately label the devices to assure they provide adequate directions for safe use.

If your firm introduced sharps devices into commercial distribution for the first time after May 28, 1976, the date of enactment of the device amendments to the Act, or if your firm has significantly modified any device which was commercially marketed prior to that date, you must submit a premarket notification [510(k)], pursuant to the requirements of 21 CFR 807.81(a)(1).

If the type of sharps device submitted in your 510(k) submission is found to be not substantially equivalent (NSE) to a predicate device, your device will automatically be classified in Class III, in accordance with the requirements of section 513(f) of the Act, thereby requiring the submission of an application for premarket approval (PMA). PMA submissions are based on the collection and review of preclincial, clinical, and where appropriate, engineering data collected in accordance with the Investigational Device Exemption (IDE) requirements to establish the safety and efficacy of the device being reviewed.

Sharps devices shall be labeled with an appropriately colored biohazard warning label, or be red in color and appropriately labeled with a biohazard warning. In addition, these devices should be designed so that they are closable, puncture resistant, and leak proof on their sides and bottom.

FDA is allowing manufacturers and initial importers a discretionary period to continue marketing sharps devices which are already in commercial distribution, providing the following requirements are fulfilled. Within 180 days of the date of this letter, manufacturers and initial distributors of currently marketed sharps devices are to file appropriate premarket notification submissions with the Agency for each different type of device currently being marketed. Firms will also be required to register their firms and list the products being manufactured and/or distributed in accordance with Sections 510(b) and/or (c), and (j) of the Act respectively. Although encouraged to do so, foreign firms are not required to register with FDA, however, they are required to list their devices. During this 180 day period, manufacturers and initial distributors should review all current labels and labeling for the sharps devices in distribution to assure they provide adequate directions for safe use, as described above. All necessary labeling modifications should be made as soon as possible, and certainly within the 180 day timeframe. Firms should also assure the integrity of the devices being marketed to assure they are puncture resistant and do not leak. Appropriate procedures and controls should be in place as required by the GMP to assure the consistent manufacture of quality devices.

Firms which have complied with the provisions outlined above will be able to continue marketing their devices until FDA determines whether or not their device(s) are substantially equivalent to a predicate device. Those found "substantially equivalent (SE)" may continue to be lawfully marketed.

Should FDA render a "not substantially equivalent (NSE)" decision, to your 510(k) submission, an approved application for premarket approval (PMA) will be required before you may legally continue to market your device. In that instance, current marketing of your device must stop. Firms choosing to "investigate" the use of their device as a means to collect data to establish the safety and efficacy of their device may do so under an Investigational Device Exemption (IDE), and label their devices appropriately.

Sharps devices in commercial distribution before May 28, 1976, which have not been changed significantly (see 21CFR 807.81), and

satisfy the labeling, registration and listing requirements, and are manufactured in accordance with the GMP, may continue to be marketed without submission of a 510(k).

Failure to comply with the requirements of this letter in the timeframe specified may result in the distribution of violative devices.

Devices not yet being marketed must comply with these requirements now. New, additional models of devices should not be introduced into the marketplace without obtaining premarket clearance prior to their introduction into interstate commerce. Such devices will be considered misbranded and adulterated in accordance with Sections 502(o) and 501(f)(1)(B) accordingly.

You may obtain a free booklet on how to prepare a premarket notification submission [510(k)] by calling our Division of Small Manufacturers Assistance at 1-800-638-2041.

Should you have any questions regarding this policy or the contents of this letter, please contact Mr. Tim Wells, Acting Branch Chief, Gastro/Urology and General Hospital Devices Branch at this address, or you may call him at (301) 594-4616.

Thank you for your cooperation.

Sincerely yours,

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