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.

GUIDANCE ON THE

CONTENT AND FORMAT OF

PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

FOR SHARPS CONTAINERS

October 1993

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of General and Restorative Devices
Infection Control Devices Branch

A. Scope

This document pertains to sharps containers and secondary sharps containers. A secondary container holds the sharps container, if leakage is possible (refer to OSHA regulation 29 CFR 1910.1030(d)(4)(iii)(A)(3)).

B. Introductory Information

1. The labeling or promotional material for the sharps container may not state that the device is FDA approved or cleared. The applicant may be able to claim the device meets OSHA regulations on Bloodborne Pathogens, 29 CFR 1910.1030, if such a statement is permitted under OSHA regulations and statutes.

2. FDA 510(k) clearance does not preclude OSHA from finding the device and/or its use to be violative under OSHA regulations. If the design is found deficient by OSHA, subsequent to a finding of substantial equivalence by FDA, and it is modified to render it acceptable to OSHA, then a new 510(k) should be submitted noting the modifications.

3. FDA and OSHA are working together to implement adequate infection control practices to reduce the risk of bloodborne infections. FDA is not enforcing the OSHA regulations, per se. Rather, FDA evaluates whether a sharps container has features that are consistent with current good infection control practices, for instance, as expressed in the OSHA Bloodborne Pathogen regulations related to engineering and work practice controls. OSHA engineering controls are controls that isolate or remove the bloodborne pathogens from the workplace. OSHA work practice controls are intended to help ensure that sharps containers are used in a manner that will reduce the likelihood of an exposure to infectious material by altering the manner in which sharps disposal is performed (e.g., recapping contaminated sharps only when no alternative is feasible or when such action is required by a specific medical procedure, placement of containers, and routine replacement).

4. This document is fashioned in a checklist format for use by FDA reviewers, and it is also a guide for applicants. In the blank spaces next to the requested information the FDA reviewer should indicate "Y" when the information is acceptable, "N" when not acceptable, and "NA" when not applicable. Applicants may wish to reproduce portions of the guidance and include it in

the 510(k) application, with supporting information, to facilitate the review process.

5. The applicant should respond to each of the items in the guidance. Provide the information requested, state why the information is not applicable, or provide alternative information that is commensurate with the data requested.

6. Be advised that FDA has determined that devices which remove sharps off the needle hub, typically by means of an electrical charge or heat, present a new type of safety and effectiveness issue (potential for toxic emissions), and are therefore not substantially equivalent devices. The devices are Class III products requiring premarket approval, or reclassification to Class I or II before they may be marketed.

C. Standards

There are no FDA regulatory standards for sharps containers. The applicant may choose to indicate that the device meets a standard. The following are examples of standards and reference information that are relevant to sharps containers:

1. Occupational Safety and Health Administration - Occupational Exposure to Bloodborne Pathogens; final rule (29 CFR 1910.1030; Federal Register 1991 December 6; 56, No. 235:64175-82.

2. British Standard Institution - Specification for Sharps Containers (BS 7320:1990)

3. Australia Standard - Non-Reusable Containers for the Collection of Sharps Medical Items Used in Health Care Areas (AS 4031 - 1992, 1992)

4. American Society for Testing and Materials (ASTM) - Standard for puncture resistance being considered (ASTM Task Force F04.65.01)

5. Canadian Standard being considered (CAN/CSA Z316.6)

6. Health Devices, August-September 1993, ECRI, Vol. 22 Nos. 8-9.

D. **Cover Letter**

State at the top of the cover letter "510(k) Notification"

____ 1. Trade/Proprietary Name (Model Name and Number):_____

____ 2. Common/Usual Name:Sharps container and/or secondary container should be noted, as applicable.

3. Classification name (select one):

____ accessory to hypodermic needle

____ accessory to blood collection device (if dedicated to that use)

____ other: describe

4. Reason for Submission

____ new device

____ modified device

____ other: describe

____ 5. Classification: Class II for accessories noted in item 3 above.

____ 6. Panel/Procode: 80 FMI for a needle accessory

____ 7. Registration #: _____

E. **Labeling**

Provide copies of labels, labeling, and promotional material. All claims will be closely scrutinized for supportive information (e.g., disease prevention claims, comparative performance claims).

_____ Biohazard labels with visible location on device

_____ General Labeling Information required under 21 CFR 801 (e.g., manufacturers name and address)

_____ Disposal Procedures

_____ Assembly/Mounting Instructions

_____ Operating Instructions

F. **General Description**

Provide a detailed description of the sharps container.

____ Pictures or detailed drawings (labeling may suffice)

____ Volume

____ Dimensions

____ Empty Weight

Describe the materials and form of construction

_____ Description of Materials (type of plastic, metal, cardboard, etc)

_____ Thickness of Materials (provide variations in thickness that may exist in different parts of device, and tolerances)

_____ How Device is Formed (molded, glued edges, etc.)

_____ Reusable (labeling and design must address safe disposal of sharps per OSHA regulations, i.e., no manual processing)

_____ Clarity of Material (clear, opaque, etc.)

____ Intended Location for Use (OR, patient room, etc.)

____ Describe any unique features in detail.

G. **Design Features of Containers for Contaminated Sharps**

Indicate if the device meets the following design features, when applicable. The basis for the list is the OSHA regulations.

____ 1. Closable

____ 2. Puncture resistant

____ 3. Leakproof on the sides and bottom

4. Labeled or color-coded:

____ a. BIOHAZARD warning label

fluorescent orange or orange-red or predominantly

so, with lettering or symbols in a contrasting color

____ b. affixed as close as possible to the container by string, wire, adhesive, or other method that prevents loss or unintentional removal

____ c. red container may substitute for labels

____ 5. Capable of maintaining stable, upright position

____ 6. No feature to bend, break, or shear needle (includes blunting and melting of needle).

____ 7. OSHA Compliance Directive On Needle Unwinders

Feature to recap the needle, or remove the needle off the hub of the syringe (i.e., an unwinder as characterized by OSHA) provides for a one-handed technique (i.e. does not require holding container with the free hand).

Container with unwinder is designed so that it is stabile (secured to a wall, table, or tray) to prevent slipping during use.

The unwinder is designed to provide for a secure capture.

____ 8. Container for reusable sharps shall not be designed to require employee to reach by hand into the container to retrieve the contaminated reusable sharps.

____ 9. Container is designed to easily and safely determine if the container is full.

10. Optional features/accessories:

____ locked enclosure

____ holder to secure to wall, table, etc.

H. **Design Features of Secondary Containers**

Indicate if the device meets the following design features, when applicable. The basis for the list is the OSHA regulations.

____ 1. Closable

____ 2. Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping

____ 3. Labeled or color-coded as above in G.4.

I. **Specifications of Design Features**

State the specifications for each of the following features. The specification should be objective and quantitative, when appropriate (e.g., puncture resistance). Refer to any standard the specification meets.

____ Impact Resistance

____ Puncture Resistance (base, sides, closure, top)

____ Overfill Detection

____ Leak Resistance (sides and bottom)

____ Sharps Access and Closure

____ Stability (maintaining upright position)

____ Mounting Accessories and any Locking Mechanism

____ Handling (safe transportation features)

____ Capacity

____ Feature to Minimize Aerosolization

____ OTHER (as applicable, e.g., electrical):

J. **Design Validation Test Methods**

Summarize the test methods for each of the specifications noted in item I above. The protocol must indicate pass-fail criteria and the safety and effectiveness basis for the criteria (e.g., a standard). There are tests methods indicated in the referenced standards.

K. **Comparison to a Legally Marketed Sharps Container**

Persons submitting 510(k)s must compare their device to a legally marketed device. FDA has recently decided to actively regulate sharps containers. FDA formal announcement of this initiative is imminent and it may provide a grace period for submission of 510(k)s.

There will be a period of time during this transition in regulatory control where some currently marketed containers are still pending FDA clearance, making confirmation of legality of a predicate device problematic in the short term. Still, the applicant should provide a comparison of their device to ones available on the market and to available standards noted in item C above.

Provide a side by side comparison of design features and specifications of containers that most closely match the device being submitted for clearance.

L. **Safe Medical Devices Act 510(k) Statement of Safety and Effectiveness or 510(k) Summary of Safety and Effectiveness**

____ Provide either the statement or summary as required under 21 CFR 807.92 or 807.93 (see attached).

M. **Address**

Submit duplicate copies (two copies) to the following address:

FDA
Document Mail Center
HFZ-401
1390 Piccard Dr.
Rockville, MD 20850

N. **Contact for Questions**

If there are any questions, please call:

Branch Chief
Infection Control Devices Branch
(301) 594-1307

O. **Attachment**

21 CFR 807.87 - 807.94.