the total mix of information in the report; and

(b) The report would be misleading to a reasonable investor if the information was omitted from the report.

Date: _____

_____

[Signature] [Title]

* Provide a separate certification for each principal executive officer and principal financial officer of the registrant. See Rules 13a–14 and 15d–14.

* * * * *

12. By amending Form 10–KSB (referenced in § 249.310b) by revising General Instruction C.2. and by adding a Certifications section after the Signatures section and before the reference to ''Supplemental information to be furnished with reports filed pursuant to Section 15(d) of the Act by registrant which have not registered securities pursuant to Section 12 of the Act'' to read as follows:

Note: The text of Form 10–KSB does not, and this amendment will not, appear in the Code of Federal Regulations.

Form 10–KSB

* * * * *

General Instructions

* * * * *

C. Signature and Filing of Report

1. * * *

2. Who must sign. The small business issuer, its principal executive officer or officers (who also must provide the certification required by Rule 13a–14 (17 CFR 240.13a–14) or Rule 15d–14 (17 CFR 240.15d–14)), its principal financial officer (who also must provide the certification required by Rule 13a–14 (17 CFR 240.13a–14) or Rule 15d–14 (17 CFR 240.15d–14)), its controller or principal accounting officer and at least a majority of the board of directors or persons performing similar functions. If the small business issuer is a limited partnership, then the general partner and a majority of its board of directors if a corporation must sign the report. Any person who occupies more than one of the specified positions must indicate each capacity in which he or she signs the report. See Rule 12b–11 concerning manual signatures under powers of attorney.

* * * * *

Signatures

* * * * *

Certifications *

I, [identify the certifying individual], certify that:

1. I have read this annual report on Form 10–KSB of [identify small business issuer];

2. To my knowledge, the information in this report is true in all important respects as of [specify last date of the period covered by the report];

3. This report contains all information about the company of which I am aware that I believe is important to a reasonable investor as of [specify last date of the period covered by the report]; and

4. I have reviewed the results of the evaluation of the procedures maintained by the company to collect, process and disclose, in a timely manner, the information required to be disclosed in the company's quarterly and annual report.

For purposes of this certification, information is ''important to a reasonable investor'' if:

(a) There is a substantial likelihood that a reasonable investor would view the information as significantly altering the total mix of information in the report; and

(b) The report would be misleading to a reasonable investor if the information was omitted from the report.

Date: _____

_____

[Signature] [Title]

* Provide a separate certification for each principal executive officer and principal financial officer of the small business issuer. See Rules 13a–14 and 15d–14.

* * * * *

Dated: June 14, 2002.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 02–15571 Filed 6–19–02; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 01P–0120]

RIN 0910–ZA20

Medical Devices; Needle-Bearing Devices; Request for Comments and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this document to invite interested persons to submit information to assist the agency in determining what additional actions, if any, the agency should take to protect healthcare workers from needlestick injuries from medical devices. FDA is taking this action because it is concerned about the significant health risk posed by needlestick and other percutaneous injuries. The agency is also responding to a petition.

DATES: Submit written comments or information by September 18, 2002.

ADDRESSES: Submit written comments or information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION: Blood and other potentially infectious materials have long been recognized as a potential threat to the health of employees who are exposed to these materials by percutaneous contact (penetration of the skin). Injuries from contaminated needles and other sharps have been associated with the increased risk of disease from infectious agents. The primary agents of concern are the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). (Ref. 1)

I. Previous FDA Actions

FDA has taken several actions to address the risk of sharps injuries to healthcare workers and others from devices and continues to monitor this issue.

- On April 16, 1992, FDA issued a safety alert warning of the risk of needlestick injuries from the use of hypodermic needles as a connection between two pieces of intravenous (IV) equipment. The safety alert urged that needleless systems or recessed needle systems be used in place of hypodermic needles to access IV lines. The agency noted that hypodermic needles should only be used in situations where there is a need to penetrate the skin. FDA also outlined various device characteristics that have the potential to reduce the risk of needlestick injuries.
- In March 1995, FDA issued a guidance document entitled ''Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices With Sharps Injury Prevention

Features.'' This guidance was intended to: (1) Make it easier to prepare and submit 510(k) applications for devices incorporating a sharps injury prevention feature so as to encourage the development of more of those types of devices, (2) promote consistency in the content of 510(k)s in order to facilitate review by FDA, and (3) guide FDA review staff in conducting and documenting the review of 510(k)s for devices with sharps injury prevention features.

- On August 9, 1996, FDA issued a guidance document entitled ''MDR Guidance Documents and Exemption-No. 3-Needlesticks and Blood Exposure-E1996003.'' This guidance document outlined FDA's policy for determining when an event involving needlesticks and blood exposure is reportable as a serious injury and when it is reportable as a malfunction.
- On March 2, 2001, FDA issued a guidance document entitled ''Premarket Approval Applications (PMA) for Sharps Needle Destruction.'' This document provides guidance to manufacturers on the types of issues and areas of concern that need to be addressed when submitting a PMA for sharps needle destruction devices intended for use in healthcare facilities.
- FDA has cosponsored several national meetings on needlestick prevention issues.
- FDA has worked with consensus standards development groups on needleless injectors.
- FDA has cleared several hundred devices with needlestick prevention features.
- In February 1999, FDA, in conjunction with the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control and Prevention (CDC), and the Occupational Safety and Health Administration (OSHA), issued a joint safety advisory about glass capillary tubes.

II. FDA Cooperation With OSHA

FDA also has been working together with OSHA to reduce the risk of sharps injuries to healthcare workers and others. FDA regulates medical devices, including those containing sharps under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (the act). OSHA maintains authority to regulate workplace controls for the protection of employees (Refs. 2 and 3).

In the **Federal Register** of December 6, 1991 (56 FR 64004), OSHA issued its Bloodborne Pathogens (BBP) Standard (29 CFR 1910.1030). The standard reflects OSHA's determination that a combination of engineering and work practice controls, personal protective equipment, training, medical surveillance, hepatitis B vaccination, signs and labels, and other requirements would minimize the risk of disease transmission. FDA provided extensive input and comment to OSHA during the development of the standard.

On November 6, 2000, President Clinton signed the Needlestick Safety and Prevention Act (Public Law 106–430). This statute required OSHA to revise several aspects of the BBP standard within 6 months. In the **Federal Register** of January 18, 2001 (66 FR 5318), OSHA published a final rule amending the BBP standard. The final rule went into effect on April 18, 2001. Again, FDA provided input and comment to OSHA during the development of the amended BBP standard.

The amended BBP standard added new requirements to the annual review and update of a covered employer's exposure control plan. Specifically, under these new requirements, each covered employer must document the extent to which it uses, or has considered using, products that will minimize workplace exposure to needlesticks and other percutaneous injuries. The annual update and review of each covered employer's plan must also reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens and document consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure. Each employer subject to the rule is also required to solicit input from nonmanagerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls. The employer must document the solicitation in the exposure control plan.

III. HRG/SEIU Petition

On March 6, 2001, FDA received and then filed a petition that had been submitted jointly by Public Citizen's Health Research Group (HRG), a consumer advocacy group, and the Service Employees International Union (SEIU). The petition requested that FDA take certain actions to further reduce the risk of needlestick injuries to healthcare workers. On September 5, 2001, FDA issued a response to this petition. In its response, FDA stated that it did not have sufficient information to take the actions requested by the petitioners, but that FDA would publish this advance notice of proposed rulemaking inviting interested persons to submit additional data and information to assist FDA in determining a proper course of action. The HRG/SEIU petition and FDA's response are available from the Dockets Management Branch (see **ADDRESSES**). In requesting the petition and response, refer to docket number 01P–0120.

In the following paragraphs, FDA summarizes the actions requested by HRG and SEIU and invites interested persons to submit additional data and information to support these actions or any other action that the commenter may consider appropriate.

A. Banning

The HRG/SEIU petition requested that FDA ban the following:

1. IV catheters, blood collection devices (needles and tube holders) and blood collection needle sets (''butterfly syringes'') that do not meet the criteria identified in FDA's April 16, 1992, safety alert. This safety alert says that needle-bearing devices should have a fixed safety feature that meets all of the following criteria:

(1) It provides a barrier between the hands and needles after use;

(2) It allows or requires the worker's hands to remain behind the needle at all times;

(3) It is an integral part of the device, and not an accessory; and

(4) It is in effect before disassembly, if any, and remains in effect after disposal.

The safety alert also suggests that the device should be simple and easy to use requiring little training.

2. Glass capillary tubes; and

3. IV infusion equipment that does not use needleless technology or recessed needles.

The petitioners stated that they identified these particular devices as devices that should be banned because they meet at least two of the following three criteria:

(1) Their use creates a high risk of exposure to bloodborne pathogens,

(2) Their use is common in healthcare today, and

(3) There is currently available FDA-cleared technology to minimize exposure.

The legal standard to be applied by FDA in deciding whether it is appropriate to ban a device is set out in section 516 of the act (21 U.S.C. 360f). In short, this section states that FDA may ban a device if it finds that the device presents a ''substantial deception or an unreasonable and substantial risk of illness or injury.'' The regulations implementing section 516 state that, in determining whether the risk of illness

or injury is substantial, FDA will need to consider whether the risk posed by continuing marketing of the device is important, material, or significant in relation to the benefit to the public health from continued marketing (21 CFR 895.21(a)(1)).

In its petition response, FDA stated that it did not have sufficient information to conclude that there is a legal basis for banning the devices identified in the petition. In support of their petition, the petitioners refer to occupational exposure data obtained from the Epinet database coordinated by the University of Virginia (Ref. 1). The Epinet data show that 52 hospitals with a total average daily census of 9,681 patients reported 3,180 sharp object injuries in 1998. Syringes accounted for 33 percent of these injuries; needles on IV lines, 2 percent; butterfly needles, 8 percent; vacuum tube blood collection needles, 6 percent; IV catheter stylets and glass capillary tubes, less than 1 percent.

The petition also cited similar data from the Centers for Disease Control and Prevention (CDC). The CDC reported that, for the period from June 1995 to July 1999, there were 4,951 sharp object injuries reported to its surveillance system. Of these reported injuries, 29 percent involved hypodermic needles, 13 percent butterfly needles, 6 percent IV catheter stylets, and 4 percent blood drawing needles. The petition also stated that 8 percent of exposures with hollow bore needles were categorized as IV line-related.

Although the petition addressed the number of injuries related to generic types of devices, it did not show: (1) Which specific devices were used; (2) how many devices of that type were used during the relevant time period; (3) what the design characteristics of those devices were or (4) whether the devices met any or all of the design criteria listed. In the absence of such information about specific devices, FDA was unable to conclude that any particular device presented a ''substantial deception or an unreasonable and substantial risk of illness or injury.'' FDA invites interested persons to submit data and information that would provide insight on the basis for banning one or more of these devices.

B. Performance Standard

The petition requested that FDA issue performance standards based on the five design criteria identified in the FDA safety alert (listed in section III.A of this document) following the procedures set forth in 21 CFR part 861. The petition listed the criteria but did not discuss how FDA could apply these criteria to specific devices in the context of a mandatory performance standard; or how such a standard would provide reasonable assurance of the safety and effectiveness of these devices.

In its response, FDA stated that it did not have sufficient information to develop a standard to address the risk of needlestick injury. FDA believes that these criteria are a good starting point to develop a standard, but FDA needs additional information to determine how best to apply these criteria to specific devices in the context of a standard.

FDA invites interested persons to submit any information or data addressing the appropriateness of developing a performance standard, based on these criteria or others. FDA is also prepared to enter into discussions with any organization that wishes to develop a voluntary consensus standard for one or more of these devices that FDA may adopt or recognize in some form.

C. Labeling

Finally, the petition requested that FDA require that the labeling for ''conventional syringes'' state: ''TO PREVENT POSSIBLE EXPOSURE TO HIV AND HEPATITIS, DO NOT USE FOR STANDARD BLOOD DRAWS.'' The petitioners stated that current labeling for syringes does not contain adequate warning of the hazards that the device presents.

In its response, FDA stated that the information in this statement is well known to healthcare professionals who use these types of devices and, therefore, under 21 CFR 801.109(c), FDA would not ordinarily require such a statement in the labeling. FDA invites interested persons to comment on whether the proposed labeling statement or any other labeling requirement is necessary to provide reasonable assurance of the safety and effectiveness of these devices.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on this document by September 19, 2002. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the name of the device and the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Public Citizen, Health Research Group and the Service Employees International Union (Docket No. 01P–0120) and FDA's response dated September 5, 2001.

2. Letter from Dr. Michael A. Friedman, Deputy Commissioner for Operations, Food and Drug Administration, to Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, dated December 18, 1998.

3. Letter from Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, to Dr. Michael A. Friedman, Deputy Commissioner for Operations, Food and Drug Administration, dated February 8, 1999.

Dated: January 31, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–15493 Filed 6–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 301 and 602

[REG–106871–00 and REG–209813–96]

RIN 1545–BA83 and RIN 1545–AU15

Reporting for Widely Held Fixed Investment Trusts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Proposed rulemaking and withdrawal of previous notice of proposed rulemaking.

SUMMARY: This document contains the withdrawal of proposed regulations (REG–209813–96), published on August 13, 1998 in the **Federal Register** (63 FR 43354). This document also contains new proposed regulations that define widely held fixed investment trusts, clarify the reporting obligations of the trustees of these trusts and the middlemen connected with these trusts, and provide for the communication of necessary tax information to beneficial owners of trust interests.