DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 2001P–0120 (Formerly Docket No. 01P–0120)]

Medical Devices; Needle-Bearing Devices; Withdrawal of Advance Notice of Proposed Rulemaking

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of an advance notice of proposed rulemaking (ANPRM) concerning needle-bearing devices. FDA is concerned about the significant health risk posed by needlestick and other percutaneous injuries but FDA believes that the actions it has taken and continues to take along with the actions taken by the Occupational Safety and Health Administration (OSHA) are addressing the issue adequately at this time.

DATES: The ANPRM published at 67 FR 41890 (June 20, 2002), is withdrawn as of September 7, 2005.

ADDRESSES: Responses to petitions and references may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

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 ''HRG/SEIU petition''). The HRG/SEIU 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 an ANPRM inviting interested persons to submit additional data and information to assist FDA in determining a proper course of action.

In the **Federal Register** of June 20, 2002 (67 FR 41890), FDA published an ANPRM on this topic. FDA invited interested persons to submit comments on the HRG/SEIU petition and other matters related to needlestick prevention by September 18, 2002. FDA received more than 50 written and electronic comments from a wide variety of individuals and organizations.

II. HRG/SEIU Petition

The following is a brief summary of the HRG/SEIU petition. The petition and FDA's response are available from the Division of Dockets Management (see **ADDRESSES**). In requesting the petition and response, refer to docket number 2001P–0120.

A. Banning

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

1. Intravenous (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.

B. Performance Standard

The HRG/SEIU petition requested that FDA issue performance standards based on the five design criteria identified in the FDA safety alert following the procedures set forth in 21 CFR part 861.

C. Labeling

Finally, the HRG/SEIU 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.

III. Comments

A. Banning

A few comments supported the ban proposed in the HRG/SEIU petition. One of these comments submitted three studies that showed a significant decrease in needlesticks when safety devices were used. In their comment, HRG objected to FDA's conclusion in the petition response that there was insufficient information to relate injuries to specific devices so as to justify banning them. HRG suggested that FDA should make a greater effort to extract the data from its own records to support a ban. Many comments opposed a ban. Several of these comments suggested that the criteria for banning a device under section 516 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360f) were not met. Many of the comments suggested that a ban would create a critical shortage of necessary devices.

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. 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 continued 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 response to the HRG/SEIU petition, 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 HRG/SEIU 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 has not received any information since publication of the ANPRM that would lead it to reach a different conclusion.

B. Performance Standards

Many of the comments expressed a willingness to participate in the development of a performance standard for needle-bearing devices. Many of these same comments and other comments, however, expressed doubt as to whether a standard could be developed because of the wide range of devices and technologies. No comments proposed any specific parameters for such a standard. FDA has consulted with some standard development organizations. The representatives of these groups expressed some willingness to work with FDA to develop a standard but also acknowledged the difficulty of developing a standard to address so many different devices. FDA will continue to work with these standard development groups to determine if one or more useful standards could be developed.

C. Labeling

Some comments suggested that the labeling statement for conventional syringes proposed in the HRG/SEIU petition may be useful. Many comments suggested that the labeling statement was unnecessary.

In its response to the HRG/SEIU petition, FDA stated that the information in the proposed 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 has not found anything in the comments to suggest a different conclusion.

D. National Association for the Primary Prevention of Sharps Injuries List

The National Association for the Primary Prevention of Sharps Injuries (NAPPSI) requested that FDA post on its Web site and disseminate NAPPSI's Safety Device List. This list includes sharps injury prevention devices. Several comments supported this proposal.

FDA is in favor of health care professionals having access to information that will help them choose safer medical devices. However, FDA believes that it would be difficult to ensure that NAPPSI's Safety Device List was up to date at all times. FDA, nevertheless, encourages health care professionals and others to make use of whatever information is available to choose safe devices.

E. The OSHA Bloodborne Pathogens Standard

Several comments suggested that the OSHA Bloodborne Pathogens (BBP) standard, together with the actions that FDA has been taking, provides sufficient protection.

FDA 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.*). 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 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 this 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.

IV. Conclusion

FDA has cleared several hundred devices with needlestick prevention features. FDA continues to work with manufacturers to assist in the clearance of devices with needle-free technology or needlestick prevention features.

On November 12, 2002, FDA issued a guidance document entitled ''Needlesticks Medical Device Reporting Guidance for User Facilities, Manufacturers, and Importers.'' This guidance document outlines 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 continues to work with health care professionals on educational issues concerning the safe use of needle-bearing devices.

As noted previously, FDA is working with consensus standards development groups to determine whether standards could be developed to address the issue of needlesticks related to medical devices.

FDA believes that these actions, in conjunction with the actions taken by OSHA under its BBP standard, are sufficient to address the risk of needlestick injuries related to the use of needle-bearing medical devices. FDA, therefore, does not intend to take any of the specific actions requested in the HRG/SEIU petition at this time and is withdrawing the ANPRM published in the **Federal Register** of June 20, 2002.

V. References

The following references have been placed on display in the Division of Dockets Management (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. 2001P–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: August 29, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–17733 Filed 9–7–05; 8:45 am]

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 4, 24, and 27

[Re: Notice No. 51]

RIN 1513–AB00

Certification Requirements for Imported Natural Wine (2005R–002P); Correction

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB), Treasury.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: On August 24, 2005, TTB published a notice of proposed rulemaking in the **Federal Register** regarding the certification requirements for imported natural wine. We also published a temporary rule on the same subject in the same issue. In that notice of proposed rulemaking, a cross reference contains an incorrect CFR section number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Gail Davis, International Trade Division, Alcohol and Tobacco Tax and Trade Bureau, telephone 202–927–8110.

SUPPLEMENTARY INFORMATION: On August 24, 2005, TTB published a notice of proposed rulemaking, Notice No. 51, in the **Federal Register** entitled ''Certification Requirements for Imported Natural Wine'' (70 FR 49516). Notice No. 51 was cross-referenced to a temporary rule on the same subject, which was published in the same issue as T.D. TTB–31 (70 FR 49479). Notice No. 51 contains a cross reference with an incorrect CFR section number.

Therefore, in the **Federal Register** of August 24, 2005, on page 49518, in the first column, in paragraph number (7), the cross-reference instruction should read as follows:

[The text of proposed § 27.140 is the same as the text of § 27.140 as set forth in the temporary rule published elsewhere in this issue of the **Federal Register**.]

Dated: June 1, 2005.

Francis W. Foote,

Director, Regulations and Rulings Division.

[FR Doc. 05–17756 Filed 9–7–05; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG–2005–22363] [Formerly CGD08–05–049]

RIN 1625–AA09

Drawbridge Operation Regulation; Lafourche Bayou, Lafourche Parish, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking; change of address and docket number for comments.

SUMMARY: On September 2, 2005, the Coast Guard published a notice and requested comments on a proposed change to regulations governing six drawbridges across Bayou Lafourche, south of the Gulf Intracoastal Waterway, in Lafourche Parish, Louisiana. The proposed rule would change bridge schedules so that they would remain closed to navigation at various times on weekdays during the school year to facilitate the safe, efficient movement of staff, students and other residents within the parish. That notice was signed August 26, 2005, before Hurricane Katrina struck New Orleans and caused that city to be flooded. We have changed the address and docket number where comments on the proposed rule should be sent because of flood conditions in New Orleans.

DATES: Comments and related material must reach the Coast Guard on or before November 1, 2005.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2005–22363 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Web site: *http://dms.dot.gov.*

(2) Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Washington, DC 20590–0001.

(3) Fax: 202–493–2251.

(4) Delivery: Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(5) Federal eRulemaking Portal: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Roger Wiebusch, Bridge Administration Branch, telephone 314–539–3900, ext. 2378.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (USCG–2005–22363), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.