DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 5 2001

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Deputy Director
Public Citizen's Health Research Group
1600 20th Street N.W.
Washington, D.C. 20009

This is in response to your citizen petition submitted on behalf of the Service Employees International Union (SEIU) and Public Citizen, which was filed by the Food and Drug Administration (FDA) on March 7, 2001. In this petition, you request that FDA "(1) remove from the market all unsafe intravenous (IV) catheters, blood collection devices, blood collection needle sets ('butterfly syringes'), glass capillary tubes, and IV infusion equipment, and (2) issue performance standards to ensure that new unsafe devices of these kinds do not enter the market, including a labeling requirement for syringes that do not adequately protect the user from bloodborne pathogens."

FDA is very concerned about the problem of needlestick injuries and has initiated a variety of actions over the past years to address the problem. For the reasons discussed below, FDA is not taking the specific actions requested in your petition at this time. However, as discussed further below, FDA intends to issue an advance notice of proposed rulemaking (ANPRM) to invite interested persons to submit additional information FDA will consider in determining what additional steps the agency should take to address this issue. After FDA reviews the information submitted in response to the ANPRM, FDA may undertake some of the actions you requested in your petition or other appropriate actions. FDA also is taking some additional steps now, as discussed below.

Your Petition

Your petition refers to five design criteria included in a safety alert issued by FDA on April 16, 1992 and requests that FDA take the following three actions in response to your petition:

1) That FDA ban:
   a) IV catheters, blood collection devices (needles and tube holders), and blood collection needle sets ("butterfly syringes") that do not meet the design criteria in the FDA safety alert;
   b) Glass capillary tubes; and
   c) IV infusion equipment that does not use needleless technology or recessed needles.

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2) That FDA issue performance standards based on the five design criteria identified in FDA's safety alert following the procedures set forth in 21 CFR part 861; and

3) That FDA issue a performance standard to require that the labeling for conventional syringes state: "TO PREVENT POSSIBLE EXPOSURE TO HIV AND HEPATITIS, DO NOT USE FOR STANDARD BLOOD DRAWS."

Your petition primarily cites two sources of occupational exposure data, EPINet, coordinated by the University of Virginia, and the Centers for Disease Control (CDC). You state that 52 hospitals with an average daily census of 9,681 patients reported 3,180 sharps injuries to EPINet in 1998. Thirty-three percent of exposures involved syringes, 2% involved needles on IV lines, 8% involved butterfly needles, 6% involved vacuum tube blood collection needles, 6% IV involved catheter stylets, and under 1% glass capillary tubes. The remainder involved other devices. You also state that 29% of the 4,951 sharp object injuries reported to CDC's surveillance system for the period June 1995 to July 1999 involved hypodermic needles, 13% butterfly needles, 6% IV catheter stylets and 4% blood-drawing needles. The remainder involved other devices.

With respect to the health consequences of sharps injuries, your petition states that CDC has reported that there have been 55 documented cases of occupationally acquired HIV among health care workers between January 1985 and June 1999 and that 49 of these documented cases involve needlestick injuries. Your petition also states that CDC reported that approximately 800 health care workers became infected with the hepatitis B virus in 1995, primarily from needlestick injuries. Your petition further states that there has been a 95% decrease in new hepatitis B infections among health care workers, primarily due to OSHA's bloodborne pathogens standard. Your petition also states that the greatest risk from needlestick injuries to health care workers is exposure to hepatitis C virus (HCV). You state that the risk of occupational HCV transmission from sharps injury is estimated at 1.8% and that hundreds of health care workers acquire HCV occupationally in the U.S. each year.

FDA Actions

FDA has taken several actions to address the risk of sharps injuries to health care workers 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 replace hypodermic needles for accessing 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 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 health care facilities.
- FDA has co-sponsored 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), CDC, and OSHA issued a joint safety advisory about glass capillary tubes.
- FDA continually evaluates the adverse experience reports it receives and follows up as appropriate.

FDA and OSHA Cooperative Action

In December 1998 and February 1999, the Assistant Secretary of Labor for Occupational Safety and Health and the Deputy Commissioner for Operations, FDA, exchanged letters (enclosed) in which they outlined the responsibility of each agency in the regulation of unprotected syringes and natural rubber latex gloves. Both agencies agreed that, although these products are medical devices regulated by FDA, instituting workplace controls relating to such devices would remain the responsibility of OSHA.

In the *Federal Register* of December 6, 1991 (56 FR 64004), OSHA issued its Bloodborne Pathogens (BBP) Standard (29 CFR §1910.1030). The provisions of the standard were based on 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 input and comment to OSHA during the drafting of the standard.

On November 6, 2000, President Clinton signed the Needlestick Safety and Prevention Act, Pub. L. 106-430. The Act required OSHA to revise the BBP standard in certain specific ways within six months of the statute's enactment. In addition, Congress and the President directed OSHA, as the agency responsible for worker safety, to initiate regulatory action on this issue. 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 drafting of the amended BBP standard. The amended BBP standard added new requirements to the annual review and update of a facility's Exposure Control Plan. Specifically, each facility subject to OSHA's rule must document the extent to which it uses, or has considered using, products that will minimize workplace exposure to needlesticks.

Another amendment to the BBP standard requires that the health care facility actively solicit input concerning the identification, evaluation, and selection of effective engineering and work practice controls from non-managerial employees who are responsible for direct patient care and who are potentially exposed to contaminated sharps in the workplace.

Finally, the rule amends the BBP standard to require that health care facilities maintain a sharps injury log to serve as a tool to identify high risk areas and to better evaluate the risks associated with particular devices.

The revised OSHA bloodborne pathogen standard specifically mandates consideration of safer needle devices as part of the re-evaluation of appropriate engineering controls during the annual review of the employer's exposure control plan. It calls for employers to solicit frontline employee input in choosing safer devices. New provisions require employers to establish a log to track all needlesticks, rather than only recording those cuts or sticks that actually lead to illness. The standard also directs employers to maintain the privacy of employees who have suffered these injuries.

In March 2000, the Centers for Disease Control and Prevention estimated that selecting safer medical devices could prevent 62 to 88 percent of sharps injuries in hospital settings. In order to assist health care facilities to choose safer devices, FDA is working with NIOSH to make available a list of devices with needlestick prevention features that it has cleared. FDA intends to link that list to the other relevant guidances and safety alerts it has issued on sharps safety. The University of Virginia currently provides a list of "safer sharps" products at its EPINet web site.

FDA believes that the OSHA rule, when fully implemented, could reduce needlestick injuries significantly. It may be premature to take additional federal regulatory measures to control the use of these kinds of devices without first evaluating the effect of the amended OSHA rule on injury rates.

Banning

The criteria for banning a device are set out in section 516 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360f), as follows:

SEC. 516. [360f] (a) Whenever the Secretary finds, on the basis of all available data and information, that -

(a) (1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and
(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period; he may initiate a proceeding to promulgate a regulation to make such device a banned device.

In the regulations implementing section 516, FDA states that, in determining whether the risk of illness or injury is substantial, FDA will consider whether the risk is important, material, or significant in relation to the benefit to the public health from the continued marketing of the device (21 CFR 895.21(a)(1)).

The information and data that you have submitted show that there is a significant problem with respect to needlestick injuries related to devices. However, FDA believes that it still does not have sufficient information upon which to base a conclusion that any of the specific devices you identified presents an unreasonable and substantial risk of illness or injury within the meaning of section 516 of the act such that it should be banned. In the ANPRM that FDA intends to publish, FDA will invite interested persons to submit additional information and data to assist FDA to determine whether banning particular devices or types of devices is warranted.

Performance Standard

You also request that FDA develop a performance standard for these devices based on the five design criteria in FDA's 1992 safety alert using the procedures set forth in FDA regulations at 21 CFR Part 861, which implements section 514 of the Act (21 U.S.C. 360d).

FDA declines to develop a performance standard incorporating the five design criteria at this time. Instead, in the ANPRM, FDA intends to invite interested persons to submit any information that may assist FDA to develop such a standard or to work with any standards organization that wants to undertake developing a standard. FDA also invites you, as it has done in the past, to contact these standards organizations to encourage them to develop a standard.

Labeling

Finally, you request that FDA issue a regulation to require that the labeling for conventional syringes state: "TO PREVENT POSSIBLE EXPOSURE TO HIV AND HEPATITIS, DO NOT USE FOR STANDARD BLOOD DRAWS."

FDA believes that this warning is commonly known to health professionals licensed by law to use these devices. As such, FDA ordinarily does not require such a statement to be included in the labeling for syringes (21 CFR 801.109(c)). In the ANPRM that FDA intends to issue, FDA will invite additional comments on whether this labeling statement or other labeling statements may be necessary to reduce the risk of accidental needlesticks.

Conclusion

For the reasons discussed above, FDA is denying the specific actions you requested in your petition at this time but FDA may undertake one or more of those actions in the future, after reviewing information submitted in response to the ANPRM described below. FDA believes that the most effective risk reduction efforts will result from user education and training on sharps safety, increased use of products that incorporate risk reduction features, and compliance with OSHA's bloodborne pathogens standard. As previously stated, FDA does intend to take the following actions in the near future:

1) Issue an advance notice of proposed rulemaking (ANPRM) that will invite all interested persons to submit additional data and information on the following issues:
   a) Whether FDA should ban certain devices that lack needlestick prevention features and, if so, which devices and why;
   b) Whether FDA should establish a standard for those devices that may cause sharps injury and, if so, what type of standard should be developed and what should be the standard's parameters;
   c) Whether FDA should require the specific labeling statement on "conventional syringes" as you have requested in your petition, or whether FDA should instead consider requiring a different labeling statement on any device that presents a risk of needlesticks; and

d) Whether there are any other actions that FDA should take to reduce the risk of needlestick injuries.

2) During or following the comment period on the ANPRM, FDA will hold an open public meeting to gather information from various stakeholders on this subject.

3) FDA will review its previous safety alert to health care workers on the risk of injuries from needlesticks to determine whether FDA should revise it and reissue it.

4) FDA will revise and reissue its guidance, "MDR Guidance Document No. 3 - Needlestick & Blood Exposure."

5) FDA will work with NIOSH to make available on its web site a list of devices with needlestick prevention features cleared by FDA and provide links to other relevant agency documents.

We invite your comments on the ANPRM and your participation at the upcoming public meeting. We look forward to continuing to work with you to address this issue in the most effective manner possible.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices and Radiological Health

Food and Drug Administration
Rockville MD 20857

December 18, 1998

Charles N. Jeffress,
Assistant Secretary of Labor for Occupational Safety and Health
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Dear Mr. Jeffress:

On November 12, 1998, representatives of the Food and Drug Administration (FDA) and the Occupational Safety and Health Administration (OSHA) met to discuss technical, policy, and legal areas of cooperation relative to latex gloves and unprotected sharps. In part, the November 12th meeting was held in response to the September 24, 1998 letter from Senators Enzi, Jeffords and Frist requesting FDA and OSHA to address potential jurisdictional conflicts in the regulation of unprotected syringes and natural rubber latex gloves

FDA and OSHA recognize the potential for jurisdictional overlap in regulating the use of latex patient examination and surgeon's gloves, and unprotected sharps. We acknowledge the desirability of discussing, clarifying and harmonizing regulation development by the two Federal agencies. We also agreed that latex patient examination and surgeon's gloves, and unprotected sharps are medical devices regulated by FDA that are used by health care workers in workplaces regulated by OSHA. FDA intends to focus its regulatory activities on aspects pertaining to the products, such as labeling requirements that ensure safe and effective use, test methods for glove protein content, and efficacy of barrier properties. We will not, however, require facilities to have written standard operating procedures for selecting and evaluating the distribution of gloves or sharps among employees, and to control airborne particulate matter. FDA defers such workplace controls to OSHA.

Sincerely yours,

Michael A. Friedman, M.D.
Deputy Commissioner for Operations

U.S. Department of Labor

Assistant Secretary for
Occupational Safety and Health
Washington, D.C. 20210

FEB 8 1999

Dr. Michael A. Friedman
Deputy Commissioner for Operations
Food and Drug Administration
Rockville, Maryland 20857

Dear Dr. Friedman:

Thank you for your letter of December 18 concerning the November 12, 1998 meeting between representatives from the Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA) on latex allergy and unprotected sharps. OSHA believes that this was a productive meeting during which our agencies reached agreement on several issues.

As you stated in your letter, OSHA and FDA understand that latex patient examination and surgeon's gloves, and unprotected sharps, are medical devices regulated by FDA and used by healthcare workers in workplaces regulated by OSHA. We also understand that FDA would not require facilities to have written standard operating procedures for selecting and evaluating the distribution of gloves or sharps among employees, or for controlling airborne particulate matter, and that such workplace controls would remain OSHA's area of responsibility.

We appreciate the spirit of cooperation shown by FDA on this issue and look forward to continued coordination between OSHA and FDA in addressing jurisdictional issues.

Sincerely,

Charles N. Jeffress
Assistant Secretary