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DATE: August 16, 2002
TO: Food and Drug Administration
Docket Officer
FROM: Q.A. Unit
Michigan Community Blood Centers
RE: Medical Devices; Needle-Bearing Devices;
Request for Comments and Information,
Docket No. 01P-0120

Michigan Community Blood Centers (MCBC) would like to thank you for the opportunity to comment on the FDA's proposed rule, Medical Devices; Needle-Bearing Devices; Request for Comments and Information, Docket No. 01P-0120.

MCBC applauds your proposed steps to protect persons from unnecessary exposure to potentially infectious agents. We, too, feel these efforts are very important to the welfare of our staff.

In our search for better, safer equipment, MCBC has found regular glass capillary tubes to be a source of unnecessary exposure risk. The tubes break easily, often leading to blood exposure. We have found the use of *mylar-coated* glass capillary tubes to be an extremely successful alternative. While these tubes are still made of glass, they have an effective, tough outer coating of mylar that protects against exposure if the tube should break. In fact, since our switch, we have had no blood exposures involving these new tubes:

From 1996 – 1998, eleven exposures stemming from glass capillary tubes were reported. In October 1998, MCBC switched to mylar-coated glass capillary tubes for higher risk tasks. Since then (1999 – 2002 to date), we have had *no* exposures involving mylar-coated glass capillary tubes. Although not used often, in that same time frame, we experienced one exposure to a glass capillary tube.

We are aware of other facilities that have switched to *plastic* capillary tubes in a similar effort to reduce the risk of exposure to infectious agents. Although these tubes do not break, they instead pose an altogether new risk of a "splash" exposure. Accidental "flicking" or sharp movement of the plastic tubes causes the contents of the tube to splash out. While not a sharps injury, it remains a blood exposure, often to ocular or other mucous membranes.

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Current trends are to reduce the threat of exposure to potential infectious agents *via sharps equipment*; MCBC has also made it a priority to guard against splashes and other non-sharps exposures. Eliminating the option of utilizing *mylar-coated* glass capillary tubes would defeat this goal.

We recommend a modification to the ban on glass capillary tubes. In an effort to decrease the incidence of all types of blood exposures, we believe mylar-coated glass capillary tubes to be a viable option—perhaps the preferred option.

Thank you again for the opportunity to comment.

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