



**Corporate Regulatory and Quality Science**

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September 18, 2002

Dockets Management Branch (HFA -305)  
Food and Drug Administration  
5630 Fishers Lane - Room 1061  
Rockville, MD 20852

**RE:** *Medical Devices; Needle-Bearing Devices [Docket 01P-0120]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA's advance notice of proposed rule making (ANPRM) on needle-bearing devices, published in the Federal Register on June 20, 2002 at 67 FR 4189.

Abbott applauds FDA's efforts to seek public comment and obtain additional data and information regarding needle-bearing devices. We endorse the efforts of OSHA and the Joint Committee on Accreditation of Healthcare Organizations (JCAHO) to reduce needle-stick injuries. Abbott supports the development of voluntary consensus standards developed with expertise from FDA, manufacturers, users, and standards organizations.

We note the Agency has banned only one device to date. Therefore, we recommend the Agency thoroughly consider the risk and benefits of needle-bearing devices, available controls, and methods to optimize safe use in its decision-making process. Further, we recommend any review of this issue consider personal use devices separately.

Thank you for the opportunity to provide these comments. Should you have any questions, please contact April Veoukas at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

A handwritten signature in black ink that reads 'D L Sporn'.

Douglas L. Sporn  
Divisional Vice President  
Corporate Regulatory Affairs, Abbott Laboratories

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