

# COOK®

**Cook Incorporated**

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September 10, 2002

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

Re: Docket No. 01P-0120—June 20, 2002 Advanced Notice of Proposed Rulemaking, Needle-Bearing Devices

Dear Sir or Madam:

Thank you for the opportunity to comment on the advanced notice of proposed rulemaking, Docket No. 01p0120. Please accept the following comments concerning what actions the agency should take, if any, to protect healthcare workers from needlestick and other percutaneous injuries.

While we fully recognize the elimination of workplace exposure to needlesticks and other percutaneous injuries would be a laudable goal of regulatory actions, we would expect a more structured and cooperative approach than that of an outright ban on devices. We would recommend the FDA continue their work with OSHA, and also involve industry, in an effort to systematically eliminate those risks. This can be accomplished by further efforts in the field of Guidance documents and product or performance standards.

Many advances in technologies for vascular access and fluid administration have resulted from past efforts, such as the 1992 Safety Alert and the Bloodborne Pathogens Standard. These are the types of efforts that should be continued and advanced. Banning devices without first allowing for necessary planning on the part of both manufacturers and users would be detrimental to the level of patient care sought by our system of healthcare.

First and foremost, all needle-bearing devices need to be categorized by their intended use and then prioritized, by risk, for further action. Many needle-bearing devices, although contacting blood or contaminated fluids, do not pose the same risks as others, due to the methods of use and the clinical setting in which they are utilized. Both the petitioners and FDA have recognized this and excluded those devices from their actions. However, simply grouping products by slang nomenclature, as was done in the petition, leads to confusion within both the user and manufacturing groups. Manufacturers have experienced this confusion on the part of users, who often expect safer alternatives to devices not addressed by the safety alert or the Bloodborne Pathogens Standard.

Once appropriate categorization and risk analysis work has been done, efforts should be undertaken to create product/performance standards and timelines for compliance to

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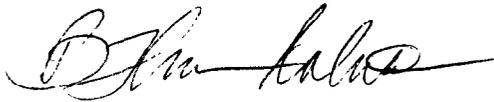
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those standards. Industry has proven the ability to meet recognized standards, especially when those standards are linked to product marketing approvals, as is the system for CE marking devices in Europe.

We ask the FDA, OSHA and industry to continue towards elimination of needlestick injuries, but we ask that a structured program be developed to accomplish this goal. Given appropriate guidelines and time to implement changes, manufacturers will comply with product standards. If they do not, then those non-compliant devices could be the focus of further regulatory actions.

Sincerely,

Cook Incorporated

A handwritten signature in black ink, appearing to read "B. Thomas Roberts". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

B. Thomas Roberts  
Vice President, Quality Assurance

Cc: Kem Hawkins, President, Cook Group Incorporated  
Steven L. Ferguson, Executive Vice President Regulatory and Legislative Affairs,  
Cook Group Incorporated  
April Lavender, RAC, Vice President Regulatory Affairs, Cook Incorporated

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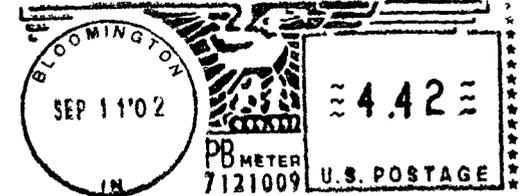
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**Address Service Requested**

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