

September 20, 2002

5 8 3 4 '02 SEP 23 AM 10



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

RE: Docket No. 01P-0120

Dear Sir/Madam:

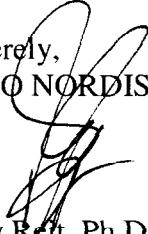
Herein are provided comments on behalf of Novo Nordisk A/S on the advance notice of rulemaking by the Agency (published June 20, 2002) seeking written comments or information regarding additional actions, if any, the Agency should take to protect healthcare workers from needlestick injuries from medical devices. Specifically, the Agency has invited interested persons to submit any information or data addressing the appropriateness of developing a performance standard to address the risk of needlestick injury.

Concerning developing a standard addressing the risk of needle stick injury, we provide the following comments:

- It is possible to make a safe injection with only one hand.
- After injection, the lock of the needle shield can resist a minimum pressure of 50N.
- After injection, a color change at the needle shield indicates that the needle has been used and is locked within the shield.
- The needle shield locks automatically after injection.

These comments are being submitted in duplicate. If there are any questions, please contact Rima B. Nassar, Ph.D., Assistant Director, Regulatory Affairs at (609) 987-5852.

Sincerely,
NOVO NORDISK PHARMACEUTICALS, INC.


Barry Reft, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance

01P-0120

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FROM: NOVO NORDISK PHARM INC.
HODIWALA
100 COLLEGE ROAD WEST
PRINCETON, NJ
08540 UNITED STATES

ACCT: 781623069
Shippers REF:
REGULATORY-781623069
DATE: 09-20-02

TO: DOCKETS MANAGEMENT BRANCH
HFA-305
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE
ROOM 1061
ROCKVILLE, MD
20857 UNITED STATES

DESCRIPTION:

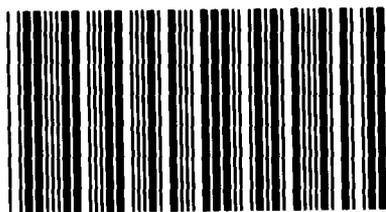
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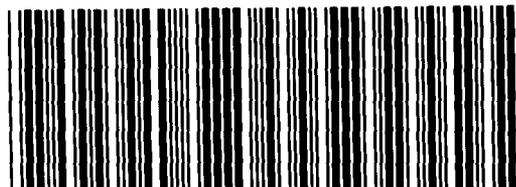
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