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2400 Bernville Road
Reading, PA 19605

(610) 378-0131
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June 26, 2001

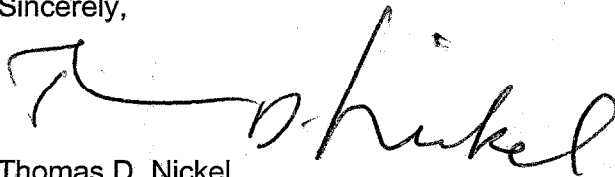
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 01D-0202 – Medical Devices: Draft “The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles;” Availability

Dear Sir or Madam:

We find the draft guidance document dated May 3, 2001 to be acceptable as written, and congratulate CDRH on a job well done.

Sincerely,



Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

ltr

FOR INFORMATION OF THE OFFICE OF THE ATTORNEY GENERAL
AND THE OFFICE OF THE ATTORNEY GENERAL
AND THE OFFICE OF THE ATTORNEY GENERAL

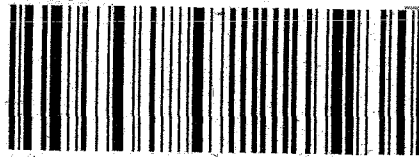
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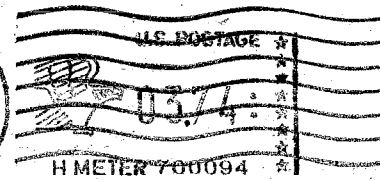
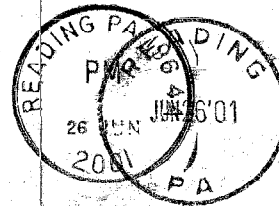
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PLACE STICKER AT TOP OF ENVELOPE
TO THE RIGHT OF RETURN ADDRESS
FOLD AT DOTTED LINE



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Rockville, MD 20852

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