

 Association of the
Nonwoven Fabrics Industry

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November 25, 2002

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

RE: Docket No. 00D-0053, "Determining Hospital Procedures for Opened-but-Unused, Single-Use Medical Devices; Request for Information"(67 FR 167 pp. 55269-55270)

Dear Dockets Management Branch Officer:

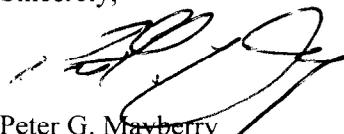
I am writing on behalf of INDA, Association of the Nonwoven Fabrics Industry in response to FDA's request for information regarding hospital usage of opened-but-unused, single-use medical devices. INDA's basis for comment rests on the fact that nonwovens are a primary component in the manufacture of numerous single-use medical devices such as bandages, dressings, disposable surgical drapes and disposable surgical gowns widely used in hospitals throughout the United States.

With respect to the issue at hand, INDA believes single-use medical devices manufactured with nonwoven fabrics that have been opened but not used should not be re-sterilized, due to concerns about the effects of un-validated sterilization processing on the safety and efficacy of the device.

As you likely know, those companies involved in the manufacture of medical devices develop specific sterilization procedures tailored to their particular product to ensure that the device maintains its efficacy and to validate that the device is safe for distribution and use. Hospital re-sterilization, therefore, is highly problematic because the sterilization procedures used may not be appropriate for a particular device, and hospitals are not equipped to validate the safety of a re-sterilized device, thereby raising the possibility that patients, healthcare care workers and/or users may utilize devices that, potentially, could be unsafe.

On behalf of INDA, Association of the Nonwoven Fabrics Industry, I thank you for the opportunity to submit these comments. Please feel free to contact me should you have any additional questions or concerns.

Sincerely,



Peter G. Mayberry
Director of Government Affairs

00D-0053

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