



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAR 2 2000

Peter G. Mayberry,  
Director of Government Affairs  
INDA, Association of the Nonwoven Fabrics Industry  
7799 Leesburg Pike  
Suite 900N  
Falls Church, VA 22043

Re: Docket No. 99N-4784

Dear Mr. Mayberry:

This letter responds to your letter of February 25, 2000, requesting the Food and Drug Administration (FDA) to extend for an additional 60 days the comment period of docket number 99N-4784, the proposed rule entitled "Pre-market Notification; Requirement for Redacted Version of Substantially-Equivalent Pre-market Notification." Your letter states that an additional 60 days is needed by INDA, Association of the Nonwoven Fabrics Industry (INDA) to submit comments and that an extension of the comment period will not have a significant impact on public health. FDA has evaluated your request. Your reasoning that the comment period should be extended an additional 60 days is not persuasive.

FDA has decided to grant a 28 day extension of the comment period. This means comments on docket number 99N-4784 must be submitted by April 19, 2000. The extension of the comment period is intended to allow additional time to comment for the members of INDA and other persons. As required by 21 CFR 10.40(b)(3)(ii), FDA will file this letter with the Dockets Management Branch.

Sincerely yours,

Linda S. Kahan  
Deputy Director for  
Regulation and Policy  
Center for Devices and  
Radiological Health

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