





## The Mentholatum Co., Inc.

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### Submitted by Fax

October 28, 2003

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

Re: October 14, 2003 Comments to Docket No. 78N-0301; External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph

Dear Sir or Madam:

We wish to assure FDA that The Mentholatum Company does not claim any privilege for anything in the material submitted on October 14, 2003. This information is considered part of the public docket.

Sincerely,

*Joyce L. Miller*

Joyce L. Miller  
Director, Regulatory Affairs

***The Mentholatum Co., Inc.***

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**FAX TRANSMITTAL**

**DATE:** October 28, 2003

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**TOTAL PAGES:** 2

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In response to your telephone contact, please see attached letter regarding The Mentholatum Company's comments to Docket No. 78N-0301 on October 14, 2003.

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**The Menthol Company, Inc.**  
**Adverse Experience Reports on Patch/Pad Products**

**Menthol 4.26% and 5%**

<b>Reported Adverse Experiences</b>	1996	1997	1998	1999	2000	2001	2002	2003 (thru Aug.)
Total number of affected individuals (AE may be counted more than once below)	3	7	5	8	21	53	66	28
Total number of individual patches/pads sold <sup>1</sup>	253,770	1,652,345	2,178,740	3,346,115	3,900,710	5,442,395	9,273,300	12,055,630
Stinging, burning, or itching		2	2	1	4	25	9	20
Local irritation, redness, or rash	1	4	2	2	10	37	10	38
Blistering, bruising, swelling, or skin removal	2	1	1	5	4	11	5	20
Other (i.e., dizziness, headache, nausea/upset stomach, diarrhea, difficult breathing, weakness)					5	5	4	11

**Methyl salicylate 10%**

<b>Reported Adverse Experiences</b>	1996	1997	1998	1999	2000	2001	2002	2003 (thru Aug.)
Total number of affected individuals (AE may be counted more than once below)							5	2
Total number of individual patches/pads sold <sup>2</sup>							1,965,816	1,889,712
Stinging, burning, or itching							2	
Local irritation, redness, or rash							2	2
Blistering, bruising, swelling, or skin removal							1	
Other (i.e., dizziness, headache, nausea/upset stomach, diarrhea, difficult breathing, weakness)								

<sup>1</sup> Menthol 4.26% and 5% - 5 individual pads per carton

<sup>2</sup> Methyl salicylate 10% - 6 individual pads per carton