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January 10, 2005

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

Re: Docket No. 78N-0301

Dear Sir or Madam.

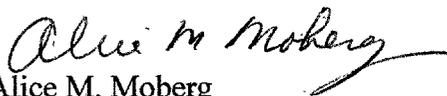
I am writing in regard to the recent reopening of the Administrative Record and Amendment of Tentative Final Monograph on external Analgesic Drug Products and Over-the-Counter Human Use (21 CFR Part 348) on July 17, 2003.

Our small company has been making the same poultice product (Numotizine Cataplasm) for human applications for 100 years (since 1905). Numotizine Cataplasm is our primary product. We have many testimonies from customers who have been using Numotizine for 30 to 50 years as an external analgesic. Numotizine is used for both human and veterinary applications.

Numotizine contains a small amount of methyl salicylate, less than 1% by weight (0.3%) as an active ingredient. Our company has no reports of poisoning or human skin irritation problems in our 100 year history. We certainly view the use of this ingredient as a very low safety risk.

We are trying to get information on the status of this Tentative Final Monograph and the proposed changes to it. We were not aware of the July 17, 2003 reopening until now. We look forward to hearing from you regarding any changes as our human poultice is one third of our yearly sales and very important to us.

Sincerely yours,


Alice M. Moberg
President
Hobart Laboratories, Inc.

78N-0301

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