



Mayer, Brown, Rowe & Maw LLP
1909 K Street, N.W.
Washington, D.C. 20006-1101

Main Tel (202) 263-3000
Main Fax (202) 263-3300
www.mayerbrownrowe.com

Alvin J. Lorman
Direct Tel (202) 263-3350
Direct Fax (202) 263-5350
ajlorman@mayerbrownrowe.com

August 13, 2004

***By Facsimile &
First Class Mail***

Wayne H. Mitchell (HFD-7)
Office of Regulatory Policy
Center for Drug Evaluation and Research
Food and Drug Administration
5515 Security Lane, Room 1101
Rockville, MD 20852

Re: January 21, 1993 Citizen Petition filed by the
American Homeopathic Pharmaceutical Association

Dear Mr. Mitchell:

This letter responds to your recent telephone call to me concerning the January 21, 1993 Citizen Petition filed by the American Association of Homeopathic Pharmacists which sought to amend 21 C.F.R. § 206.7 to categorically exempt homeopathic drugs in the form of medicated pellets or tablet triturates from the imprinting requirements of 221 C.F.R. § 206.10.

You asked two questions: whether the American Homeopathic Pharmaceutical Association was still in existence, and, if so, whether the relief requested in 1993 was still required.

Since the filing of the 1993 Petition, the American Homeopathic Pharmaceutical Association has merged membership with the American Association of Homeopathic Pharmacists. The latter organization has represented the interests of homeopathic drug manufacturers for over 80 years.

The Board of Directors of the American Association of Homeopathic Pharmacists requests that it be substituted as the named petitioner in this matter as successor in interest to the American Homeopathic Pharmaceutical Association because it believes that the facts and circumstances enumerated in the 1993 petition are still valid today. Accordingly, the association does not wish to withdraw the petition. Indeed, it would welcome a response from FDA.

94P-0018

LET 2

Brussels Charlotte Chicago Cologne Frankfurt Houston London Los Angeles Manchester New York Palo Alto Paris Washington, D.C.
Independent Mexico City Correspondent: Jauregui, Navarrete, Nader y Rojas, S.C.

Mayer, Brown, Rowe & Maw LLP operates in combination with our associated English limited liability partnership in the offices listed above.

Wayne H. Mitchell (HFD-7)

August 13, 2004

Page 2

Please do not hesitate to call me if you have any additional questions.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Alvin J. Lofman', with a long horizontal flourish extending to the right.

Alvin J. Lofman
Attorney for the American Association of
Homeopathic Pharmacists

cc: Mark S. Phillips, AAHP