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September 13, 2001

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

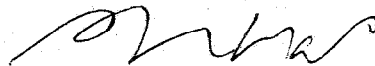
Re: Docket No. 01N-0196

Dear Sir or Madam:

KV Pharmaceutical Company hereby requests a hearing on the proposal to withdraw approval of prescription and over-the-counter drug products containing phenylpropanolamine and to apply the conclusions related thereto to prescription drug products containing phenylpropanolamine marketed without an approved new drug application based on their exclusion from the definition of "new drug," notice of which was published in the Federal Register of August 14, 2001 under the above referenced docket.

As required by the notice, data and information in support of this request for hearing will be submitted no later than October 15, 2001.

Respectfully submitted,



Peter R. Mathers

Counsel for KV Pharmaceutical Company

01N-0196

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