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January 17, 2006

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

Re: Docket Nos. 1976-0052N and 1981N-0022
Supplemental Submission

Dear Commissioner:

After Wyeth submitted a letter to FDA dated December 27, 2006, addressing limitations in a study performed in Korea on products containing phenylpropanolamine (the "Korean Study"), an article regarding that study was published on January 9, 2007 in the journal *Neurology*. A copy of the article is attached hereto. 

Notably, the authors of the attached article address one of the limitations identified in Wyeth's December 27, 2006 letter. In agreeing that media coverage about PPA, which occurred during the study, raises doubts about the validity of the study, the authors stated:

This study has limitations. First, the lower rate of PPA exposure than expected can raise doubts regarding the validity of this study. The decrease in the exposure rate may be due to unexpected public concerns regarding PPA that were evoked by the press in the summer of 2003 in Korea. Before September 2003, the exposure rate of PPA was 1.6%; however, since then, it has decreased to 0.6% for combined cases and controls.

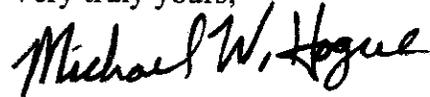
68 *Neurology* at 149. The article, however, does not address the lack of exposed controls identified after the media exposure began in the summer of 2003. Nor does the article address the change in the exclusion criteria for hospital controls, which occurred after about five months of data collection. (See Korean Study Progress Report previously attached).

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Finally, the published article states that one of the eligibility criteria was an "absence of brain lesions that would increase the risk of hemorrhage." Table 14 of the Translation of the Korean study reported, however, that seven (7) of the exposed cases had aneurysms. (Korean Study Translation at 47)

Very truly yours,

A handwritten signature in black ink that reads "Michael W. Hogue". The signature is written in a cursive style with a large, stylized 'M' and 'H'.

Michael W. Hogue

MWH:ns

cc: William W. Vodra, Esq., Arnold & Porter