

ARNOLD & PORTER

Donald O. Beers
Donald_Beers@aporter.com
202.942.5012
202.942.5999 Fax
555 Twelfth Street, NW
Washington, DC 20004-1206

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VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Nos. 94P-0429 and 94P-0430: Response to Request to Withdraw Petitions

Dear Sir or Madam:

We have carefully considered Jane Axelrad's letter of December 11, 2001 and have ultimately concluded that it is inappropriate for us to withdraw the above-referenced petitions at this point. The relief requested by the petitions was amended by subsequent submissions, see, e.g., our submission of December 9, 1996, and there remain some important issues outstanding. We recognize, however, FDA's need to address these petitions and are prepared to discuss the issues and to work with FDA to reach an appropriate resolution.

Sincerely,



Donald O. Beers

cc: Jane A. Axelrad, Esq.

94P-0429

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