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# ARNOLD & PORTER

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September 9, 2002

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

Re: Docket No. 94P-0429: Withdrawal of Petition

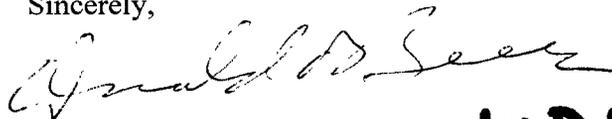
Dear Sir or Madam:

At the request of the Food and Drug Administration, Wyeth has agreed to withdraw the above-referenced Petition. This withdrawal is based on the understanding that FDA will require any generic version of conjugated estrogens to contain delta<sup>8,9</sup> dehydroestrone sulfate in the same quantities present in Wyeth's conjugated estrogens (Premarin®), and will work with the United States Pharmacopeia to assure that the monographs for conjugated estrogens drug substance and drug product require inclusion of that important estrogen. Wyeth continues to have the some concerns about issues raised in the above-referenced Petition. In particular, Wyeth believes that FDA's current proposal to the United States Pharmacopeia for a revised conjugated estrogens monograph is inadequate. In addition, Wyeth continues to urge FDA to require a specific assay for determination of delta<sup>8,9</sup> dehydroestrone levels in any bioequivalence study for a potential generic conjugated estrogens product.

Wyeth will continue to pursue its position with respect to these and other issues relating to conjugated estrogens. Based on the Agency's future responses, Wyeth may again file a citizen petition requesting resolution of the applicable scientific and regulatory issues. Accordingly, this withdrawal is without prejudice to the pursuit of such issues and to the incorporation by reference of some or all of the record of this docket in the record of any future citizen petition.

Nevertheless, in the interest of cooperation with the FDA, and in recognition that several of the significant objectives of the petition have been met, we are hereby withdrawing this petition.

Sincerely,



Donald O. Beers

94P-0429

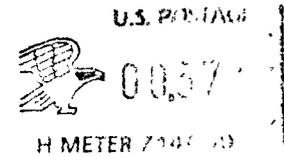
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