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February 1, 2002

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VIA HAND DELIVERY

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

RE: Docket No. 97N-0325 – Continuation of Hearing Request

Dear Sir or Madam:

This letter responds to the Food and Drug Administration's ("FDA's") January 3, 2002 letter regarding Duramed Pharmaceutical, Inc.'s September 8, 1997 request for a hearing (filed by Charles J. Cooper on behalf of Duramed). Duramed, which is now a wholly-owned subsidiary of Barr Laboratories, Inc., has retained Kirkpatrick & Lockhart, LLP to represent the company with respect to this matter, and the undersigned will serve as the contact person for all future correspondence concerning Duramed's request.

Duramed believes that the issues surrounding the denial of its abbreviated new drug application ("ANDA") for synthetic conjugated estrogens have not been sufficiently resolved. Specifically, the company continues to believe that the legal positions taken by FDA when denying ANDAs for synthetic conjugated estrogens lack the requisite statutory support. Accordingly, Duramed, by and through this correspondence, preserves its legal rights in this matter and thereby maintains its September 8, 1997 request for a hearing. In support of Duramed's continuing request, the company incorporates by reference the issues raised in Duramed's October 6, 1997 letter to this docket.

Thank you for your attention to this matter.

Sincerely,



Kathleen D. Jaeger

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