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February 24, 1999

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

RE: Citizen Petition re: New Drug Application for
Mixture of Estrogens
Docket Number 98P-0311

Dear Sir or Madam:

We are writing to provide comment regarding the Citizen Petition that has been filed with the Food and Drug Administration regarding approval of a New Drug Application (NDA) for a mixture of "conjugated" estrogens (Cenestin™) submitted by Duramed Pharmaceuticals. The American College of Clinical Pharmacy (ACCP) is a 5,000-member professional and scientific society of clinical pharmacists. Most ACCP members are Pharm.D.-educated and residency or fellowship trained. Most practice in university, community or government hospitals; managed care organizations; or health system affiliated ambulatory clinics. About 25% are certified in one or more of the specialty practice areas recognized by the Board of Pharmaceutical Specialties. The majority of ACCP members regularly teach physicians about appropriate pharmacotherapy. Additionally, within their practice settings, ACCP members are influential contributors to the decision making processes of their local P&T Committees and Institutional Review Boards.

For purposes of declaration, ACCP has previously received unrestricted educational grants from Wyeth-Ayerst Laboratories in support of its conferences. Wyeth-Ayerst also provides support for clinical pharmacy research and research training through the ACCP Research Institute. Please note, however, that our decision to comment on this issue is based on our concern for the patients served by our members. As clinical pharmacists, ACCP members routinely practice both generic substitution and therapeutic interchange when in the best interests of their patients.

98P-0311

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Among the concerns raised by Wyeth-Ayerst is whether adequate safety information exists to warrant approval of the estrogen mixture proposed by Duramed. Because the NDA submitted by Duramed is not available for our direct review, ACCP is obviously not in a position to evaluate the adequacy with which the long-term safety of this product has been documented. We do believe, however, that even if the labeling currently sought by Duramed is limited to short-term use for treatment of vasomotor menopausal symptoms, it is reasonable to assume that many patients will be placed on chronic therapy with this estrogen mixture, as is done now with Premarin™, single-entity estrogens, or estrogen/progestin combinations. We fully trust that FDA will not compromise patient safety if legitimate reasons exist to question the long-term safety of the Duramed estrogen mixture. The FDA should also consider what liability may befall prescribers and pharmacists if, for reasons expanded upon below, patients should be harmed by chronic administration of a product labeled only for short-term use.

We do agree with Wyeth-Ayerst's claim that there is real potential for marketplace confusion between Cenestin and Premarin. Given the current standards of the U.S. Pharmacopeia, both Cenestin and Premarin would qualify to be called "conjugated estrogens USP". A pharmacist presented with an order for "conjugated estrogens" would often be compelled to fill the prescription with a lesser-priced generic equivalent if one exists because of stipulations imposed by the patient's health plan. An unusual dilemma exists here because the FDA has previously determined that the Duramed estrogen mixture cannot be considered a generic equivalent to Premarin. Hence, what preparation is the pharmacist to use in filling the prescription order? At a minimum, the pharmacist would probably need to seek clarification with the prescriber—adding an unnecessary, avoidable burden to the pharmacist, physician, and patient. We believe that the best way to avoid this confusion is to identify the Duramed mixture with a different generic name from that given to Premarin.

Thank you for this opportunity to comment.

Sincerely,



Robert M. Elenbaas, Pharm.D., FCCP
Executive Director