DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Ms. Jeane Westin
United Animal Nations
5892A South Land Park Drive
P. O. Box 188890
Sacramento, CA 95818

Re: Docket No. 01P-0083/CP1

Dear Ms. Westin:

This letter is in response to your petition, dated February 21, 2001, asking the Food and Drug Administration (FDA) to require full and clear disclosure of the source of the drug Premarin on all information inserts, repackaged bottles, boxes, and other containers issued by pharmacies for Premarin prescriptions. For reasons that I will try to explain below, the Agency must deny your petition.

As you know, Premarin, conjugated estrogens tablets, USP, is a hormone replacement drug containing estrogens derived from pregnant mares' urine. In your petition, you describe the results of a survey of 847 women age 40 and older indicating that most women are unaware of the source of Premarin and that most physicians do not discuss other options for hormone replacement with their patients. In addition, you explain that the Premarin package insert contains only a one-line reference to the fact that Premarin comes from pregnant mares' urine and that this reference is in the fine print intended for physicians and not included in the "Information for the Patient" section. You state your belief that tens of thousands of pregnant mares are exploited and thousands of foals slaughtered annually to produce Premarin. You also say that you believe women have a right to make an informed choice about hormone replacement therapy and should know that Premarin contains estrogens derived from pregnant mares' urine. To this end, your petition asks FDA to require the clear disclosure of Premarin source information on various containers and inserts.

Generally, the Agency has no objection if a company wishes to include source information in a product's materials. However, when FDA *requires* a manufacturer to include certain information in its product materials, the Agency does so on the basis of existing statutory and regulatory provisions. For instance, if a product contains an ingredient to which some people may be allergic, FDA can require that this information appear prominently in the product's materials on the basis that adequate warnings are needed when a product's use may be dangerous to the public health (see 21 U.S.C. 502(f)). In the case of source information, there is no statutory or regulatory basis for a requirement to include such information in a product's materials.

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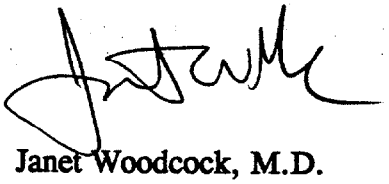
I understand that you find the source of Premarin objectionable. However, many drugs come from unusual sources. For example, menotropins are extracted from the urine of postmenopausal human females; some thyroid products are prepared from fresh, desicated animal thyroid glands. Any or all of these sources may be objectionable to some people, but that is not reason enough to impose a regulatory requirement. The Agency must be very careful when it imposes regulatory requirements, keeping foremost in sight its responsibility to protect the public health. Accordingly, your petition is denied.

Sincerely yours,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research