September 27, 1999

Dear Members,

I am writing to you as the new Executive Secretary of the Advisory Committee for Reproductive Health Products (yes, another re-shuffling within our office). Hopefully, this will be the last change for the time being.

The **October 18, 1999, meeting of the Advisory Committee for Reproductive Health Drugs** is still on track. As Karen Somers described in her letter to you dated August 24th, the meeting will be a single day, open session. I will forward a final agenda to you under separate cover. The primary purpose of the meeting is to seek your guidance and input on four draft guidances that are in development within the Division of Reproductive and Urologic Drug Products.

The morning session will consist of brief presentations on the functions and activities of the FDA Pregnancy Labeling Task Force and the Pregnancy Labeling Subcommittee. We will follow these presentations with a discussion of the first two of the four draft guidances, "Reviewer's Guidance, Evaluation of Human Pregnancy Outcome Data" and "Guidance for Industry, Establishing Pregnancy Registries." These guidances were released for public comment in June of this year, were published in the Federal Register and are attached here as Attachments 1 and 2. A solicitation for comments from the public was included in the Federal Register notice.

The afternoon session will be primarily taken up by a discussion of two additional draft guidances. The first is titled, "Labeling Guidance for Non-Contraceptive Estrogen Drug Products—Prescribing Information for Health Care Providers, and Patient Labeling." We expect this guidance to be made available to the public by the date of the advisory committee meeting. The draft and the 1992 version it replaces are included here (Attachments 3a and 3b). The fourth and final draft guidance, tentatively entitled, "Guidance for Clinical Evaluation of Combination Estrogen/Progestin-containing Drug Products used for Hormone Replacement Therapy of Postmenopausal Women" remains a work in progress within the agency. Although the revised draft guidance is not included, the 1995 document it would replace is attached here (Attachment 4).

For the purpose of enlisting your assistance in the development of these draft guidances, under separate cover and within the next week or so, I will forward to you a series of general questions related to each of these draft guidances. We would like the committee to address each of the questions during the relevant portion of the meeting.

Finally, we plan to end the meeting by providing you with an update regarding the activities and upcoming meetings of the Urology subcommittee.

As a reminder, the meeting will be held at the Holiday Inn, located at 2 Montgomery Village Avenue in Gaithersburg, Maryland beginning at 9:00 a.m. and ending no later than 5:00 p.m. By now you should have received both travel and hotel room reservation information from Vonda Carter of this office.

Prior to the meeting, if you have any questions about this package or the meeting itself, please do not hesitate to contact me at 301-827-6766.

Sincerely,

Jayne E. Peterson, R.Ph., J.D.
Executive Secretary

Pharmacy Compounding Advisory Committee
Advisory Committee for Reproductive Health Drugs

Enclosure

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Attachment 1
Pregnancy Registries