

Wyeth Pharmaceuticals August 28, 2002

Important labeling update: new information to provide guidance in prescribing PREMPRO<sup>TM</sup>/PREMPHASE<sup>®</sup> (conjugated estrogens/medroxyprogesterone acetate tablets) and PREMARIN<sup>®</sup> (conjugated estrogens tablets, USP)

Dear Health Care Professional:

We are writing to inform you of important new safety information in labeling regarding PREMPRO<sup>TM</sup> (conjugated estrogens/medroxyprogesterone acetate tablets), PREMPHASE<sup>®</sup> (conjugated estrogens/medroxyprogesterone acetate tablets), and PREMARIN<sup>®</sup> (conjugated estrogens tablets, USP). The labeling changes reflect new data, primarily from the Women's Health Initiative (WHI).

The new PREMPRO/PREMPHASE and PREMARIN labels provide additional information with regard to certain risks. Notably, several sections have been modified, including the INDICATIONS and USAGE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and DOSAGE and ADMINISTRATION sections. Please be certain to read both entire labels (enclosed) carefully, as they include changes not reprinted in this letter.

Please note that:

PREMPRO, PREMPHASE, and PREMARIN are not indicated and should not be used to prevent coronary heart disease.

The product indications remain the same. However, because of the potential increased risks of cardiovascular events, breast cancer and venous thromboembolic events, use of PREMPRO, PREMPHASE, and PREMARIN should be limited to the shortest duration consistent with treatment goals and risks for the individual woman, and should be periodically reevaluated. When used solely for the prevention of postmenopausal osteoporosis, alternative treatments should be carefully considered.

Wyeth will continue to work closely with the medical community and regulatory authorities to further refine its product labels for all of its postmenopausal hormone therapies, regardless of the estrogen or progestin used. We are dedicated to communicating new information to you and your patients. If you have additional questions, please call the PREMARIN® Family of Products information line at 1-800-842-1441.

Sincerely,

Victoria Kusiak, M.D.

Vice President, Global Medical Affairs and

North American Medical Director for Wyeth Pharmaceuticals

**Enclosures**