9. Because of the effects of estrogens on epiphyseal closure * * * should be used judiciously in young patients in whom bone growth is not complete.
10. The age of the patient constitutes no absolute limiting factor, although treatment with * * * may mask the onset of the climacteric.
11. The pathologist should be advised of * * * therapy when relevant specimens are submitted.

ADVERSE REACTIONS OBSERVED IN PATIENTS RECEIVING ORAL CONTRACEPTIVES

A statistically significant association has been demonstrated between use of oral contraceptives and the following serious adverse reactions:

Thrombophlebitis
Pulmonary embolism

Although available evidence is suggestive of an association, such a relationship has been neither confirmed nor refuted for the following serious adverse reactions:

Cerebrovascular accidents
Neuro-ocular lesions, e.g., retinal thrombosis and optic neuritis

The following adverse reactions are known to occur in patients receiving oral contraceptives (Consult the clinical section.)

Nausea
Vomiting
Gastrointestinal symptoms (such as abdominal cramps and bloating)
Breakthrough bleeding
Spotting
Change in menstrual flow
Amenorrhea during and after treatment
Edema
Chloasma or melasma
Breast changes: tenderness, enlargement and secretion
Change in weight (increase or decrease
Changes in cervical erosion and cervical secretions
Suppression of lactation when given immediately post-partum
Chloestatic Jaundice
Migraine
Rash (Allergic)
Rise in blood pressure in susceptible individuals
Mental depression

Although the following adverse reactions have been reported in users of oral contraceptives, an association has been neither confirmed nor refuted:

Anovulation post treatment
Prementrual-like syndrome
Changes in libido
Changes in appetite
Cystitis-like syndrome
Headache
Nervousness
Dizziness
Fatigue
Backache
Hirsutism
Loss of scalp hair
Erythema multiforme
Erythema nodosum
Hemorrhagic eruption
Itching

The following laboratory results may be altered by the use of oral contraceptives (see sections on clinical laboratory):

Hepatic function: Increased sulfobromophthalein and other tests
Coagulation tests: increase in prothrombin Factors VII, VIII, IX and X
Thyroid function: increase in PBI, and butanol extractable protein bound iodine and decrease in T^3 values
Metyrapone test
Pregnanediol determination

ANIMAL STUDIES

This should include results of acute, chronic toxicity and reproduction studies using the compounds present in the product. Significant laboratory and pathologic findings should be mentioned.
Endocrine and metabolic screening. State results on dose per weight basis.