

CLINICAL DATA

Efficacy—This should include the number of cycles completed. Breakdown by number of patients completing a specific number of cycles should also be mentioned. State number of pregnancies in number per 100 woman years. Pearl's formula or life table technique should be used. The following statement is permitted if applicable: "Virtually 100% effective when used according to directions."

Adverse Reactions Clinical Laboratory Results—This should include liver, thyroid, renal functions, coagulation tests, endocrine function as well as routine hematology and cytology.

DOSAGE AND ADMINISTRATION

This should include routine administration and specific instructions on handling problems such as breakthrough bleeding, amenorrhea, etc.

AVAILABILITY

BIBLIOGRAPHY

Reference, not a complete bibliography.

May 10, 1968 / Food and Drug Administration / U.S. Department of Health, Education, and Welfare / Washington, D.C. 20204.