From the FDA

New drug testing guidelines include women

Under new guidelines for drug testing, women—including those of childbearing age—will no longer be excluded from early clinical trials. All new drug applications will undergo review for the inclusion of women in the drug manufacturers' studies, with the completion of the review process dependent, in part, on this gender inclusion.

Among the provisions detailed in the guidelines are:

- adequate numbers of women subjects must be enrolled in clinical trials to detect clinically significant differences in drug responses between men and women;
- an analysis of how the drug's pharmacokinetics are affected by the effects of the menstrual cycle and menopausal status; the effects of concomitant estrogen supplementation or the use of systemic contraceptive agents; and the drug's effect, if any, on oral contraceptive efficacy; and
- the inclusion of appropriate measures taken to minimize the risk of fetal exposure, with a statement outlining the potential fetal risks to prospective study subjects. Although the agency will review these measures, it is up to the drug sponsor, physicians, patients, and the institutional review boards to make the initial determinations concerning the adequacy of these precautions.

The agency also intends to sponsor public workshops to examine the effects of drugs on pregnant women and their fetuses.

A copy of the *Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs* may be obtained by writing to: Center for Drug Evaluation and Research (HFD-8), Food and Drug Administration, 7500 Standish Pl, Rockville, MD 20855. Interested parties should enclose two self-addressed adhesive labels with each request.

Epilepsy drug approved

Neurontin (gabapentin), manufactured by Parke-Davis Pharmaceutical Research (Morris Plains, NJ), has been approved for use in controlling partial epileptic seizures. In clinical trials involving more than 700 adults, gabapentin has been shown not to interfere with with the metabolism of other antiepileptic drugs. In fact, when combined with other antiepileptic agents, gabapentin reduced the frequency of those partial seizures that progressed to generalized seizures. Dizziness and drowsiness were the main side effects associated with gabapentin in clinical trials.

From HHS

New system to streamline Medicare claims processing

A new system for processing Medicare claim forms will begin on a small scale in 1996. The Medicare Transaction System (MTS) will be a national processing system that will replace the current network of 14 automated systems used by the 72 insurance companies who contract with Medicare.

The standardized system will link regional processing centers with local contractors. Using uniform software, physicians and hospitals will transmit insurance data to MTS. The data bank will include each beneficiary's eligibility, specific insurance coverage, and a history of the beneficiary's Medicare use.

The expected savings of $200 million in administration costs will likely be reinvested in the Medicare system, which is undergoing budgetary cuts, say officials.

GTE Government Systems Corp (Chantilly, Va) will develop the $19 million system, expected to be fully operational by 1998.

Changes in SSI claims for respiratory illness

The Social Security Administration has revised its guidelines for beneficiaries who make claims of disability due to respiratory illness. Regulatory changes are being made in the following areas:

- more specific documentation requirements for various tests, with guidance on when purchasing certain tests may be appropriate;
- treatment guidelines, including what to do when the patient does not receive treatment;
- new evaluation criteria for adults with cystic fibrosis; and
- expanded rules for children to give the same attention to pediatric respiratory disease as that formerly given only to adults.

The complete copy of these regulations appears in the October 7, 1993 issue of the *Federal Register*. ◆