

reared undisturbed and then mated. After their litters were born, the prematurely separated and normally separated mothers were switched so that each litter had a foster mother with a different separation experience. Each litter was separated at normal time (day 21) from its foster mother, restrained, sacrificed and examined for ulcers. The incidence of ulcers in rats born to normally separated mothers but reared by prematurely separated mothers was only 24 percent, whereas the incidence in rats born to prematurely separated mothers but reared by normally separated ones was 66 percent — a highly significant difference.

Thus, "increased restraint-induced gastric erosion susceptibility associated with premature separation is transmitted to the first generation of female rats by prenatal factors," the researchers concluded.

But what prenatal factor might transmit increased ulcer susceptibility? As Skolnick told *SCIENCE NEWS*, "It is really hard to speculate." Do the findings support Lysenko's theory? "I wouldn't say that," he replied. But he pointed out that the theory "hasn't been totally discredited" and that it is possible that inheritance might be passed on not only through genes but through some other, as yet undiscovered ways as well. □

## Drug lag or no drug lag?

The title says it all: "FDA Drug Approval — a Lengthy Process that delays the Availability of Important New Drugs." The just-released General Accounting Office report says approval of an important drug takes 20 months, which is far longer than drug approval times in Canada, Switzerland or the United Kingdom. "The lengthy approval process delays the benefits important drugs can provide to the public," the report says.

The drug approval process must balance speed with protection, counters the Food and Drug Administration. In commentary on the GAO report, The Department of Health and Human Services says the GAO did not consider adequate scientific testing of new drugs, therapeutic needs of patients and property rights of drug manufacturers. The GAO contends, however, that the focus of its report was on the means by which test results and other application information are reviewed and processed.

"The FDA is strangling in its own bureaucratic bog," says Rep. James H. Scheuer (D-N.Y.), a member of the Subcommittee on Science, Research and Technology, the group that requested the GAO report. Scheuer told reporters that the FDA's problem has two components. One is the attitude of FDA employees who are reluctant to approve drugs. The second is poor work management. "It is simply pitiful and absurd that a drug can be delayed for four months or more while chemists' evaluations of New Drug [Applications] and letters to manufacturers are waiting to be typed and sent. Meanwhile the sick suffer and die," Scheuer says.

The FDA has already initiated a program of changes that are intended to reduce the approval time for important drugs by 25 percent over a three-year period. The GAO points out that even if the program is successful, drug approval will still take about 15 months.

The GAO and FDA sharply disagree about the extent of the dreaded lag. According to the GAO the United States falls years behind other countries in drug approval. The FDA disagrees. "The few significant new

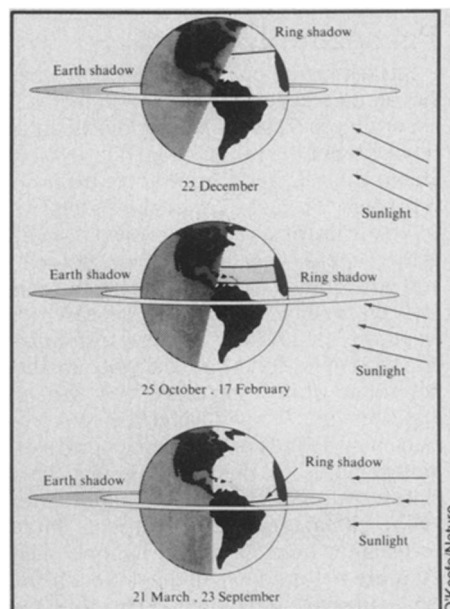
drugs that represent major advances in therapy tend to be introduced in most developed countries at roughly the same time," says FDA's Wayne L. Pines. "There is no evidence that the United States lags significantly behind other countries in the introduction of major new medical advances."

The GAO bases its opinion on a list of 14 selected drugs; the FDA provides a catalog of 13 drugs to back up its contention. Each group claims its roster includes the most important recent therapeutic drugs, but only three drugs appear on both lists. The GAO tally goes back to drugs introduced in 1963; the FDA has selected drugs dating from 1972. In addition to the different drugs on the lists, four of the six countries included in the comparison differ. The GAO compares dates of drug introduction into the United States, United Kingdom, Canada, Norway, Sweden and Switzerland. The FDA includes the United States, the United Kingdom, Germany, France, Italy and Japan.

No drugs on the GAO list were introduced first in the United States, and only two were introduced here the same year as their earliest availability elsewhere in the sample. The rest became available here one to twelve years later. In contrast, on the FDA list seven drugs were introduced in the United States first or in the same year as their earliest use in any country examined and all but one were introduced within two years. "The isolated examples cited [by the GAO] of drugs available in Europe but not in the United States are not evidence of anything except the known phenomenon that different countries often have different drugs," says HHS.

The GAO report makes several specific recommendations to speed up the FDA, including use of expert committees and paraprofessionals, clarification of policy on acceptance of foreign data and development of a program for post-marketing surveillance of new drugs. The FDA points out, however, that many of these recommendations already are in pending legislation. □

## Ring around earth terminates Eocene



As the angle of incoming sunlight changes with the seasons, the ring's shadow moves, making winter hemisphere colder.

It had to happen. For a long time the rings of Saturn were unique in the solar system. Then other major planets began to exhibit rings, as sharper observations became possible. Now there is a suggestion that there may once have been rings around the earth.

The suggestion comes from John A. O'Keefe of the NASA Goddard Space Flight Center in Greenbelt, Md., and appears in the May 28 *NATURE*. O'Keefe starts with the "terminal Eocene event," a catastrophe that occurred about 34 million years ago. Winters became much colder (although summer temperature was not much affected), and there was a widespread extinction of the small animals called radiolaria. Dust in space could have shadowed the earth to produce the climate change, O'Keefe points out.

The date of the terminal Eocene event coincides with the age of the North American strewn field, the largest field of tektites. Tektites are small bits of glass that are found scattered over wide regions of the surface of the earth. It is usually assumed that tektites fell from space. The instantaneous production of so much homogeneous glass out of common rock and soil over such an area — the "North American field" runs from the Caribbean to the Indian Ocean — is hard to imagine. A single distant source, a volcanic blast on the moon perhaps, would be better. Part of a spray of debris from such an event would hit the earth, O'Keefe suggests, but part would miss and go into orbit. That part would settle into a ring, and the dynamics are such that it might have lasted a few million years. □