

ana's balanced treatment act, which mandates equal treatment of creation science and evolution in the state's public schools, is unconstitutional.

The appeals court, which upheld a ruling delivered earlier this year by Judge Adrian Duplantier (*Science*, 25 January, p. 395), said the law violates the constitutional guarantee of separation of church and state. "We seek simply to keep the government . . . neutral with respect to any religious controversy," the court said.

Two days after the appeals court decision, Louisiana Attorney General William Guste said he would appeal the ruling to the 16-member fifth circuit court to rehear the case.

A similar law in Arkansas requiring the teaching of creation science in that state's public schools was struck down for the same reason in 1982.

—COLIN NORMAN

## Generic Valiums Clear Another Hurdle at FDA

The Food and Drug Administration (FDA) has rejected arguments by Hoffmann-La Roche Inc. that the agency is using the wrong tests to evaluate generic versions of Valium. The decision removes what could have become a major obstacle to agency approval of generic forms of Valium, whose patent expired in February. Several manufacturers have applications pending before FDA to manufacture generic diazepam, the active ingredient in Valium.

Shortly before Valium went off patent, Roche filed a petition asking FDA to use a new method to measure whether generics are indeed equivalent to Valium (*Science*, 26 April, p. 472). The changes, if adopted, would have been more costly and time-consuming for generic companies. In the petition, Roche contended that the agency should require computerized brain-wave tests in addition to blood sampling as a measure of bioequivalency. It based its claims mainly on a company-sponsored study, which, it said, showed that generic diazepam available in Canada and Turkey did not produce the same central nervous effects as Valium.

Harry Meyer, director of the Center for Drugs and Biologics at FDA, said

in a letter to Roche that the company had failed to provide well-documented evidence to support its various claims. Meyer noted that a blood level study, which compared the foreign generics to Valium, was so "seriously flawed" that it "invalidated" the company's argument that the brain-wave tests can distinguish important differences between generics and Valium.

While the agency rejected a majority of Roche's claims, FDA agreed to slight changes in its bioequivalency testing procedures on two counts as a result of the petition. The rate at which diazepam dissolves will be measured at a higher pH, and blood samples will be collected at an earlier stage in testing. Company officials say the revisions that FDA did agree to were a significant victory. "FDA should be appreciative of our petition," Bruce Medd, a Roche scientist said.

A generic company bidding for part of the Valium market says that its product meets the revised guidelines anyway. The changes will not hold up approval, says James Leonard, who is now president of Zenith Laboratories Inc., a generic drug company, and was president of Roche Products for 18 years.

Marvin Seife, director of FDA's division of generic drugs, said that the petition has not held up the agency's review of the generic diazepam and says approval may begin within the next month or two.—MARJORIE SUN

## USDA Smooths Way for Biotech Imports

Biotechnology companies will be able to import cell lines and other biological materials more cheaply and swiftly as a result of an agreement struck last month with the U.S. Department of Agriculture (USDA).

The department quarantines incoming biological materials at its Plum Island facility to prevent the introduction of hoof-and-mouth disease and other livestock diseases foreign to the United States. But companies have complained that the process of clearing USDA quarantine rules and testing procedures can take up to 18 months. The department agreed to changes that will shorten the process to 2 months.

Companies, which expect to import substantially more biological material in the next few years, will now be able to finish the necessary paperwork while their material is being tested. USDA previously required the paperwork be completed entirely before testing could start. In addition, companies can set up escrow accounts to fund the tests. USDA used to bill the firm and require payment before testing could proceed.

The testing process will be less expensive as well. USDA agreed to permit the use of in vitro tests in place of several in vivo tests, which cuts the cost for the companies by \$6000 to \$7000 per test.

The industry also has asked the department to grant exemptions to the rules if the incoming biologics are intended only for human use, but this issue is still under discussion. James Glasser, associate director of the Animal and Plant Health Inspection Service, said that before exemptions would be granted, the agricultural community will have to be "sensitized" to the idea, and criteria defining safeguards would have to be set.

—MARJORIE SUN

## Comings and Goings

**Bernard D. Goldstein**, head of research and development at the Environmental Protection Agency, is resigning effective 2 August to return to the University of Medicine and Dentistry of New Jersey—Rutgers Medical School. Goldstein was recruited 2 years ago by former agency administrator William Ruckelshaus as part of the new crew to set EPA back on course after Anne Burford resigned. Goldstein was recently approached to head the beleaguered Occupational Safety and Health Administration, but declined so that he could return to his family in New Jersey. He will be heading a new graduate program in environmental health. No successor to Goldstein has been named.

**Richard S. Nicholson** has been nominated to be assistant director for mathematics and physical sciences at the National Science Foundation. Nicholson has been staff director of the foundation. His appointment is subject to Senate confirmation, which is expected.—MARJORIE SUN