CORRESPONDENCE/

To the editor:
We noted with interest the list of "Biotechnology Medicines in Development," compiled by the Pharmaceutical Manufacturers Association (PMA) (*Bio/Technology* **9**:947-50). However, we were disturbed by some of the accompanying commentary about the projected rate of approval of marketing of new biotech products by the Food and Drug Administration's (FDA) Center for Biologics Research and Review (CBER).

PMA calculates the "rate" at which FDA approves new biotechnology products by dividing the total number of products approved by the total time elapsed since the first product was approved (in 1982), which yields a value of some 1.6 approvals per year. They then conclude that because their survey reports 21 products now awaiting approval (though FDA's records indicate the number is closer to 30), it would take FDA's CBER 13 years to approve these products. The fallacy of this mathematical sleight-of-hand is that it ignores the fact that for much of the past decade there were very few products in the pipeline and that they were approved rapidly after the marketing applications were received by FDA. PMA's approach is rather like concluding that if the average production of television sets during 1945-47 was 5000/year, it would require 10,000 years to produce enough to supply each of 50 million American households with one.

A drastically different conclusion can be drawn from the PMA's own data. They note in the *Biotechnology Medicines in Development* report that "FDA required an average review time of 21.4 months to approve biotechnology drugs for their original and additional indications," and their *New Drug Approvals in 1990* informs us that the mean approval time for new drugs (new molecular entities) 1982-90 was *31.8 months*. Thus, one might conclude that FDA is, in fact, approving new biotech products an average of ten months more quickly than for other non-biotech drugs, with all of the advantages to manufacturers—and patients—that implies.

Having said that, FDA *is* concerned about the potential for lengthening approval times for new biotechnology products. The increasing demands of new Congressionally mandated responsibilities for the Agency without commensurate increases in resources have placed unprecedented stresses on FDA, and they will be an important determinant of FDA's ability to keep up with the biotechnology workload. But as the number of new biotech products at all stages of the testing pipeline has increased, the Agency has taken a number of steps to improve its ability to perform high-quality, timely reviews. These steps have included the establishment of a new Division of Cytokine Biology and a new Biological Response Modifiers advisory committee, and the addition of scientists with expertise in the new biotechnology to reviewing and administrative positions. In addition, CBER has continued to issue "Points to Consider" documents to provide guidance to manufacturers on biotechnology-related issues and FDA has just concluded an agreement reconciling differences in regulatory practices between CBER and the Center for Drug Evaluation and Review (CDER) for combination products or others whose jurisdiction is in doubt. Efficient management of the product approval processes has been a top Agency priority during the past year and is receiving personal attention from FDA Commissioner David Kessler; the sweeping reforms in the drug approval process announced in November are ample evidence of this.

We believe that during the past decade our record on the evaluation and approval of new biotech products has been good, and we are striving to improve it, even in a resource-constrained environment. We look forward to shouldering our part of the burden to, in PMA's words, "realiz[e] the potential of this new area of pharmaceutical research—for the people whose lives depend on the treatment and cures biotechnology can bring."

Henry I. Miller, M.D.
Director, Office of Biotechnology
Food and Drug Administration
Department of Health & Human Services
Rockville, MD 20857 U.S.A.