WIDE-RANGING DISCUSSION

FDA CONTINUES TO FAVOR BIOTECH

WASHINGTON, D.C.—Despite a general hiring freeze at the Food and Drug Administration (FDA, Bethesda, MD), Commissioner David Kessler says the agency will soon meet its promise of hiring 50 new staff members to review new biotech drugs. During a recent press briefing, Kessler also said that the agency will not “back off” from its biotechnology food policy described earlier this year.

FDA announced a hiring freeze in June, as agency officials anticipated a mismatch between budgeted salary requirements and the fiscal year 1993 congressional appropriation for the agency. Nonetheless, Kessler says that “even in a freeze, we need to have a strategy, and we are committed to hiring biotech reviewers.” Thus, areas deemed to be of high priority, such as review of new drugs and enforcement, will continue to build staff. “This is not a shell game,” he adds, meaning that new staff members are being added, not merely drawn from other positions elsewhere within the agency.

“The biotechnology industry could be in trouble if the agency gets hung up

here,” says Kessler. He points again to user fees as a potentially important source of relief for the current tight agency budget. Such fees, which many small companies contend would be burdensome, have been recommended in the last few presidential budgets but have been rejected by Congress.

“It’s absolutely critical to have user fees. The agency can’t survive in the long run without them,” Kessler says. “But we will have to use them so the industry gets value and sees them as in its interest. I have no strong preference for how it’s done, but user fees should go into areas that industry wants supported.”

In other efforts to improve overall performance, FDA is continuing to change some of its management practices and review procedures, Kessler and other agency officials point out. For instance, there is an effort to streamline decision making by delegating more responsibilities to officials at the middle management level, instead of leaving the bulk of those responsibilities with a few center directors.

Another effort involves coming to earlier decisions on what information

should go on labels for new drugs. Sometimes such negotiations between companies and the agency are “protracted,” Kessler notes.

On the matter of foods being developed by biotechnology companies, Kessler admits there are “some tricky issues” that have arisen following the announcement of the agency’s policy on such foods (*Bio/Technology* 10:740, July ’92). “It’s not accurate to say there will be no labeling” of such foods, he says, referring to a widely circulated criticism of the new policy. “If there are any changes in nutrition content, that will be noted. People have a right to know what a product is—what’s in the food. But, currently, we don’t put whether a product was derived through cross breeding on the label.”

Although Kessler says the agency is not backing off its new food policy, some questions appear to remain open as comments from the public continue to come into FDA. “We put out policy guidelines, but the issue is not over,” he says. “We need to hear more. We’re not going to hide anything in food.”

—Jeffrey L. Fox

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