MDC MEETING

HELPFUL HINTS FROM THE FDA COMMISSIONER

BOSTON—"The biggest trap that you can fall into is improper validation," warned U.S. Food and Drug Administration (FDA) commissioner Frank E. Young at the Massachusetts Biotechnology Council annual meeting held here recently. "Consult with us early in order to design and carry out your studies well," he suggested. "A responsible sponsor submits no application before its time."

Making the keynote speech before a group consisting largely of top-level biotech executives, Young outlined several pitfalls for firms to avoid while navigating the sometimes turbid waters of FDA's drug-approval process. The Commissioner cautioned companies against overblowing their research findings, whether for the purpose of raising capital, attracting scientists, or simply impressing the public. And he stressed that commercial concerns must make the effort to understand the way the FDA bureaucracy works.

According to Young, "Just as FDA won't discriminate against a product with burdensome requirements because it results from biotechnology,

neither will we cut corners to 'fast track' a product just because of its origin or potential market appeal. We will continue to treat biotechnology products the same as others." The bottom line is one of balance: "Researchers can't neglect safety aspects of biotechnology products because they believe their products to be innately superior. Nor can society afford to stifle research and bury biotechnology's potential for changing our lives for the better."

The FDA commissioner believes that the general public has now accepted the use of biotechnology to make new drugs, and he likewise believes that FDA is adequately prepared to deal with the expected onslaught of biotech-derived applications in this area. In the case of AIDS, Young pledged that FDA would return to industry with an opinion on a drug within 180 days of submission. "FDA is in a war on AIDS," he concluded. "I look at us as a munitions factory."

While admitting that the emphasis on AIDS might slow the review of non-AIDS related applications,

Young expressed real concern over FDA's ability to handle one particular biotech area that is expected to blossom with applications over the next few years: food. He cited a recent FDA study pointing to more than 800 food technologies already being developed through biotech. He reported that almost half these products and processes "are already technically feasible," and that perhaps half could be commercialized by the year 1990. But unless FDA gets additional funding to bulk up its effort in this area, the agency will have difficulty dealing with upcoming applications in a timely manner.

Nevertheless, Young vowed to make sure that the first such commercial proposals are "done incredibly carefully." Using the example of a tomato engineered to produce *Bacillus thuringiensis* toxin as an insecticide, Young stressed the difficulty of convincing an often skeptical public about the wonders of biotech. Will the man on the street believe agbiotech's battle cry of "Don't worry, it only kills the worm"?

—Arthur Klausner

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LC 85-11036 CIP
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