FDA Publishes Bovine Growth Hormone Data

In an attempt to quell a furor, the FDA is releasing safety data on a drug intended to boost milk production in cows

IN AN UNPRECEDENTED MOVE, the U.S. Food and Drug Administration is publishing data on the safety of a drug before it has been approved for use. The drug, recombinant bovine growth hormone (rbGH), has been the subject of a hot controversy over health effects. But in this issue of *Science* (see page 875), two FDA researchers publish a review of 30 years of studies on the hormone by its manufacturers and independent scientists and conclude that it presents "no increased health risk to consumers."

In spite of the fact that the FDA isn't expected to rule on use of rbGH for a year, the agency felt it couldn't wait to publicize the data. "There's this public concern about the safety and economics, and a lot of congressional interest," says Gerald Guest, director for the FDA's Center for Veterinary Medicine and the man who will decide whether to approve the drug for use in dairy cows. "We'd like to get our side of the story out, to show why we're comfortable with the safety. We'd like for people to know that it's a thoughtful process, and we want it to be open and credible."

Safe as milk. *Greg Guyer of the FDA.*

Both the congressional scrutiny and the consumer pressure are intense. The FDA is undergoing two congressionally mandated audits of the 10-year process by which it evaluated the health and safety effects of rbGH, which is intended to make cows produce more milk. At the same time, consumer groups are threatening to boycott milk from the cows that will be given the hormone if the drug is approved.

So it's understandable that the FDA wants to calm the waters. But the move may not get them what they want. Critics charge that publishing the article makes the agency a backer of the drug rather than a neutral evaluator. To Samuel S. Epstein, physician and professor of occupational and environmental medicine at the University of Illinois College of Medicine, what's "unprecedented" about the FDA action is that the agency is acting "as a booster or advocate for an animal drug that hasn't yet been approved."

Epstein, a vocal environmentalist, has joined ranks with genetic engineering critic Jeremy Rifkin in criticizing the FDA and the four companies that make rbGH: American Cyanamid, Elanco (a subsidiary of Eli Lilly), Monsanto, and Upjohn. Earlier this year Epstein published a paper in the little known (and non-peer-reviewed) *International Journal of Health Services* charging that the FDA had abdicated its regulatory responsibility by relying on research done by industry and industry's "indentured academics."

Epstein has done no experimental studies on rbGH, but reviewing studies by others convinced him, he says, that there are unresolved questions, including whether rbGH stimulates premature growth in infants and

Europe: Bovine Growth Hormone in a Political Maze

Although the U.S. Food and Drug Administration is touting the safety of recombinant bovine growth hormone (rbGH), in Europe the hormone faces a tough road. Here, nations are skeptical about the need for rbGH—partly in defense of small farmers, whose livelihood could be threatened by agribusiness' use of the expensive drug. And even if a European country approved rbGH, the hormone couldn't be licensed yet because the pan-European body that must approve all new drugs for veterinary use hasn't rendered a verdict.

The bureaucratic maze in which rbGH is trapped is best exemplified by what is now happening in Britain. Monsanto, maker of one version of rbGH, applied to the U.K. Veterinary Products Committee (VPC) for approval and was provisionally turned down late last month. The committee agreed that rbGH was effective and posed no risk to human health or the environment. But, the committee said, it "was not completely satisfied on the basis of the data with some pharmaceutical aspects of the product or with aspects of the safety of the treated animals." Neither the committee nor Monsanto would offer further details.

If all goes as scheduled, the VPC will confirm its decision not to grant a license on 13 September. When it does, Monsanto may appeal. But even if the VPC had decided in favor of rbGH, the hormone could not have been given a license in Britain—because the European Committee for Veterinary and Medical Products (CVMP) hasn't given an opinion. After the CVMP decides, countries may disagree, but until then no license can be granted.

And CVMP's verdict won't be coming for a while. Last year the European Parliament instructed the CVMP not to decide about rbGH before November 1991. That moratorium, the parliament said, was needed to give time for assessing the complex issues surrounding use of the hormone.

One issue is whether its use might have harmful social consequences. Under current European law, new medicines for people or animals must be safe, effective, and have no undue impact on the environment. Under pressure from small farmers, the European Commission last year debated amending a new veterinary products law to add another criterion: socio-economic effects. Though the amendment was dropped, agricultural experts in the EC are drafting a new version. If adopted, it would almost certainly block approval of products such as rbGH.

Francis Adriaens, a Monsanto product development specialist for the U.K., condemned these political moves for applying "subjective criteria" to scientific issues. Companies would be "uncertain and insecure" about developing products if the ultimate adoption of those products depended on political whims 15 years down the line. "A product should prove itself in the market," Adriaens said, "and not in theoretical considerations of need." But for the moment, Adriaens' argument—like the future of rbGH—is likely to remain trapped in the Alice-in-Wonderland maze of Europolitics. ■ JEREMY CHERFAS