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U.S. Tightens Rules on Antibiotics Use for Livestock

By GARDINER HARRIS

Farmers and ranchers will for the first time need a prescription from a veterinarian before using antibiotics in farm animals, in hopes that more judicious use of the drugs will reduce the tens of thousands of human deaths that result each year from the drugs' overuse.

The Food and Drug Administration announced the new rule Wednesday after trying for more than 35 years to stop farmers and ranchers from feeding antibiotics to cattle, pigs, chickens and other animals simply to help the animals grow larger. Using small amounts of antibiotics over long periods of time leads to the growth of bacteria that are resistant to the drugs' effects, endangering humans who become infected but cannot be treated with routine antibiotic therapy.

At least two million people are sickened and an estimated 99,000 die every year from hospital-acquired infections, the majority of which result from such resistant strains. It is unknown how many of these illnesses and deaths result from agricultural uses of antibiotics, but about 80 percent of antibiotics sold in the United States are used in animals.

Michael Taylor, the F.D.A.'s deputy commissioner for food, predicted that the new restrictions would save lives because farmers would have to convince a veterinarian that their animals were either sick or at risk of getting a specific illness. Just using the drugs for growth will be disallowed and, it is hoped, this will cut their use sharply. The new requirements will also make obtaining antibiotics more cumbersome and expensive.

"We're confident that it will result in significant reductions in agricultural antibiotic use," Mr. Taylor said. "That's why we're doing this."

Just how broadly farmers use antibiotics simply to promote animal growth is unknown. About 80 percent of antibiotics used on farms are given through feed, and an additional 17 percent are given in water. Just 3 percent are given by injection.

The F.D.A. believes that veterinarians will be far less likely to endorse indiscriminate drug uses. While doctors have the power to use drugs in ways not approved by the F.D.A., veterinarians are allowed to give a prescription for antibiotics in feed and water only if such uses are approved by the F.D.A.

Dr. Christine Hoang of the American Veterinary Medical Association said that her organization supported the new rules, although she said that some remote or small farmers might have trouble abiding by the rules since there are fewer than 10,000 large-animal veterinarians in the United States.

Antibiotics were the wonder drugs of the 20th century, and their initial uses in humans and animals were indiscriminate, experts say. Farmers were impressed that antibiotics led to rapid animal growth and began to add the drugs to feed and water, with no prescriptions or sign of sickness in the animals.

By the 1970s, public health officials had become worried that overuse was leading to the development of infections resistant to treatment in humans. In 1977, the F.D.A. announced that it would begin banning some agricultural uses. But the House and Senate appropriations committees — dominated by agricultural interests — passed resolutions

even convinced some in the agricultural community that action was needed.

The new rules generated mixed reactions from both public health advocates and agricultural trade associations. Laura Rogers of the Pew Campaign on Human Health and Industrial Farming called the new rules “the most sweeping action the agency has undertaken in this area,” while Caroline Smith DeWaal of the [Center for Science in the Public Interest](#) criticized them as “tragically flawed” because they relied too much on voluntary industry efforts.

The [Animal Health Institute](#), an association of animal drug makers, welcomed the new rules. But R. C. Hunt, president of the [National Pork Producers Council](#), said that small farmers and ranchers would have a hard time following the new rules, which “could eliminate antibiotic uses that are extremely important to the health of animals.”

Initially, the F.D.A. is asking drug makers to voluntarily change their labels to require a prescription; federal officials said that drug makers had largely agreed to the change. If some fail to impose the restrictions, the agency will consider a more forceful ban, Mr. Taylor said.

The reason for the reliance on voluntary efforts is that the F.D.A.’s process for revoking approved drug uses is lengthy and cumbersome, officials said. The last time the F.D.A. banned an agricultural use of a medically important antibiotic against the wishes of its maker, legal appeals took five years. In this case, hundreds of drugs are involved, each with myriad approved uses in various animals.

“You and I and our children would be long dead before F.D.A. could restrict all of these uses on its own,” Ms. Rogers said.

Last month, Judge Theodore H. Katz of the Southern District of New York [ordered the F.D.A.](#) to begin the process to ban indiscriminate agricultural uses of penicillin and tetracycline because of dangers to human health. The agency hopes that the rules it announced Wednesday achieve the same result.

This year, the Obama administration announced restrictions on agricultural uses of cephalosporins, a critical class of antibiotics that includes drugs like Cefzil and Keflex, which are commonly used to treat pneumonia and strep throat.

For most drug makers, there are compelling reasons to cooperate. Many of the companies manufacture both animal and human drugs but earn the vast majority of their profits in the human sphere. Any company seen to undermine human health could earn doctors’ disapproval and potentially hurt their most important business.

But Ms. DeWaal of the science center said that she believed the industry would not follow through on its promises but would instead await the next election in hopes of an administration friendlier to its interests. She condemned the F.D.A. for failing to restrict these drug uses outright. “The agency is afraid to use its authority,” she said.