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FDA Denies Citizen Petitions on Animal Antibiotics

Agency Claims Withdrawing Drugs Is Too Hard; Will Rely on Drug Companies to Self-Regulate

Chicago - On Monday, in a disappointing move, the U.S. Food and Drug Administration (FDA) denied two citizen petitions that asked the Agency to ban certain uses of antibiotics in food animals. The petitions, filed in 1999 and 2005, urge the FDA to withdraw the approvals for antibiotics given to animals in feed or water for purposes other than disease treatment if the antibiotics are also used in human medicine. The petitions were filed by Environmental Defense, Center for Science in the Public Interest, Food Animal Concerns Trust, and the Union of Concerned Scientists along with other groups because of evidence showing that using antibiotics in this way in food animals can lead to the spread of difficult to treat resistant infections in humans.

The response to these long-standing citizen petitions came after several of the petitioners filed suit in May against the FDA for not responding. In addition to demanding the FDA respond to the citizen petitions, the lawsuit asks that the FDA take action on the Agency's own safety findings from 1977 and withdraw approval for most uses of penicillin and tetracyclines in animal feed.

In denying the petitions, the FDA did not challenge the need to reduce antibiotic use, but instead argued that the withdrawal process itself was too expensive and resource intensive. Rather than implementing its formal process for taking drugs off the market, the Agency stated that it plans "to work with sponsors who approach FDA and are interested in working cooperatively with the Agency to phase out production uses of medically important antimicrobials." FDA has released a draft version of a document that describes its plan to reduce use through the voluntary withdrawal by pharmaceutical companies of currently marketed uses of antibiotics in feed.

"Instead of adhering to its mission to protect consumers, the FDA is waiting for the drug companies to voluntarily do what the Agency is legally mandated to do. There is absolutely no reason to believe that drug companies will voluntarily reduce sales of antibiotics and act against their own financial self-interest. Without reductions in antibiotics used it is impossible for there to be any public health benefit." said Steven Roach, FACT's Public Health Program Director. "For this reason we do not see the FDA's plan as an answer to the petitions or the problem of antibiotic resistance."

In addition to bringing suit against the FDA, FACT also supports the Preservation of Antibiotics for Medical Treatment Act. This federal legislation, if passed, would require the FDA to address non-therapeutic antibiotic use and make it easier for the Agency to withdraw animal antibiotics that are found to be unsafe from an antibiotic resistance standpoint.

“Reducing antibiotic overuse is essential for making sure antibiotics will keep working for years to come – to treat our sick children, families and animals. It is outrageous that the FDA considers voluntary self-regulation by drug companies to be enough. It is clearly not,” said FACT’s Executive Director Richard Wood.

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Food Animal Concerns Trust (FACT) is a Chicago based non-profit that promotes humane and healthy farms through science-based advocacy, consumer education, and support for humane farmers. For more information visit www.foodanimalconcerns.org.