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FDA cites cancer links in seeking to withdraw approval of antibiotic used in pigs

By Ed Silverman Nov. 7, 2023
Reprints

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After years of trying, the Food and Drug Administration is again seeking to withdraw approval of an antibiotic that is widely used by farmers to control diarrhea in their pigs, but has generated controversy over links to cancer.

At issue is carbadox, which, since the 1970s, has been added to livestock feed to combat diarrhea in young pigs after they are weaned from their mothers, as well as to promote growth. But evidence suggests the antibiotic is a carcinogen that can cause tumors in lab animals, which has raised concerns that harmful traces of the medicine can find their way into humans through the food supply.

The FDA previously moved to withdraw approval of the antibiotic in 2016 over carcinogenicity, but the manufacturer, Phibro Animal Health, fought the effort by arguing, in part, that its drug is medically necessary. In addition to once again attempting to withdraw approval, the agency is also saying there is no reliable method for determining how much drug residue may be found in the tissue of pigs and hogs, according to a pair of Federal Register notices (see this and this).

The move caps a long-running effort to withdraw the antibiotic from the food supply chain in the U.S., after it was banned some years ago in the European Union, Canada, and Australia. In 2020, in fact, the FDA first proposed revoking the method used for detecting drug residue in swine tissue. After sparring with Phibro in various hearings, the agency is following through on that approach.

Carbadox is generating attention for a key reason — the drug is the one remaining animal feed additive still approved under a provision of U.S. law allowing carcinogenic drugs to be given to animals under the strict condition they do not cause carcinogenic residues in edible animal tissues, according to Food Animal Concerns Trust, a nonprofit that seeks to limit antibiotic use in food-producing livestock.

"With the withdrawal of the method, the drug is no longer in compliance with requirements for carcinogenic animal drugs," explained Steven Roach, who heads the safe and healthy food program at the nonprofit. "If this drug stays on the market, it would allow a carcinogen to remain in the food supply and increase the risk of developing cancer among everyone who eats pork."

Data from the U.S. Department of Agriculture regularly show that the amount of carbadox residue can be found in about 1% of the roaster pigs tested, according to the nonprofit. Although 1% may appear to be a small number, about 650,000 roaster pigs are slaughtered each year, which translates into roughly 6,500 pigs or 390,000 servings of pork with carcinogenic drug residue each year.

As of June, there were 72.4 million hogs and pigs on U.S. farms, according to USDA data. But the agency only samples roaster pigs, not market hogs, which means it is difficult to determine how many pigs may have unsafe carbadox residue levels, Roach explained. Given the limits on methodology for detecting drug residue, he argued the amount of carcinogenic meat is likely significantly underestimated.

For its part, Phibro issued a statement saying the company is "extremely disappointed in the actions taken by the FDA and believes fully in the safety" of its drug. "Today's steps are the latest in a long history of attempted measures taken by the FDA relating to carbadox that we do not believe are based on solid science."

The company added that it previously provided the FDA with "extensive and meticulous research and data" — including at a March 2022 hearing — that demonstrated carbadox is safe and should not be removed from the market. Phibro added removal would have an "adverse effect" on its finances. Carbadox generated about $20 million in sales in the year ended June 30 (see page 18). The company, which boosted production four years ago, indicated in a recent regulatory filing it would seek a hearing to preclude the FDA move.

On a broader scale, the National Pork Producers Council last year warned in a letter to the FDA that, "if carbadox is removed from the market, it is estimated that the total cost to the U.S. pork industry in the first year could be as high as $500 million dollars, driven by the higher level of disease and death losses. This could drive further pork production consolidation and force more independent producers out of the industry."

The FDA move comes after years of efforts to reduce the use of antibiotics in food-producing livestock, primarily over mounting evidence that widespread usage contributes to antibiotic resistance in humans. A key challenge is the ability of farmers to produce sufficient livestock — typically, cattle, pigs, poultry, and sheep — to meet consumer demand, but at the same time, address public health concerns.

The issue has engulfed regulators and farmers in a growing number of countries and led to certain restrictions on the use of antibiotics. For instance, certain types of antibiotics that may be used to treat both humans and animals may not be administered to livestock in order to boost their weight, which makes them more valuable.

An FDA program begun in 2017 has shown mixed results. The sale of medically important antibiotics given to food-producing livestock declined by less than 1% overall in the U.S. in 2021, according to the latest available data. In particular, the sale and distribution of tetracycline, which accounted for 65% of the medically important antibiotics, fell by only 1%.

On the other hand, the FDA data showed a 38% decrease in the sale of medically important antibiotics given these food-producing animals since 2015, when sales of such medicines peaked. The report also noted that sales fell by 33% from 2012, when data were first being collected in response to concerns that antibiotic resistance was worsening, in part, due to the medicines given livestock.

Carbadox, however, can still be promoted by the manufacturer for weight gain. Why? The antibiotic is only approved for veterinary use and when the FDA banned growth-promoting uses, it was only for drugs that are also used in humans, Roach explained. But

carbadox is among another set drugs that may be used to promote weight gain in livestock, because they are not given to humans.

Consequently, the FDA is not supposed to look at animal health needs when evaluating human health risks, Roach said. And in his view, this means that the arguments made by Phibro are not actually relevant to the FDA decision-making process. "The FDA doesn't do a risk-benefit analysis to determine the risk to pigs and the value to humans when making such decisions," he told us.