Consumer Federation of America

November 7, 2016

The Honorable Robert M. Califf, M.D.,
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: FDA-2016-N-1896 Direct Final Rule; New Animal Drugs for Use in Animal Feed; Category Definitions

Dear Commissioner Califf:

Consumer Federation of America (CFA) appreciates the opportunity to submit these comments on the U.S. Food and Drug Administration's proposed direct final rule to modify how FDA categorizes animal drugs used in medicated feeds. The rule change responds to concerns that recent FDA actions to phase out antibiotic use for growth promotion will result in fewer treatment options for minor species other than horses, dogs, cats, cattle, pigs, turkeys, and chickens. In our comments submitted jointly with other members of the Keep Antibiotics Working coalition, we point out that FDA's categories for animal drugs in medicated feed are arbitrary and capricious, that the agency has not adequately explained its rationale for short-circuiting public comment through a direct final rulemaking, and that the agency should categorize animal drugs in medicated feeds based on risk. We write separately to underscore the need for risk-based regulation of animal drugs to protect consumers.

The current categorization scheme dates back to recommendations made in 1978 by FDA's Medicated Feed Task Force. The Task Force recommended that the agency's "control of feeds" containing animal drugs be "based upon the degree of risk from use of the drug, either in terms of the toxicity of the drug itself or the concentration of the drug."[1] Both of these factors—toxicity and concentration—relate to the risk of poisoning consumers through excessive residue levels. In response, the agency "concluded that the drugs used in animal feeds should be placed into categories based on their likelihood of producing unsafe residues in the edible products of treated animals."[2] The agency did not conclude that it should categorize drugs used in animal feeds based on their likelihood of giving rise to antibiotic resistant bacteria. To advance the limited objective of protecting consumers from antibiotic residues, the agency determined that

[1] FDA. "New Animal Drugs for Use in Animal Feeds; Definitions and General Considerations; Revised Procedures Re Medicated Feed Applications." 48 *Fed. Reg.* 34574 (July 29, 1983).
[2] *Id.*

where it maintained a "zero tolerance" for a drug's residues, or required an animal to undergo some withdrawal period following its last ingestion of a drug at the lowest approved use level, the agency would allow only federally licensed feed mills to handle the drug. All other drugs can go through licensed and unlicensed feed mills alike.

FDA should devise a new basis for deciding which drugs must go through licensed feed mills. The agency's 1978 Medicated Feed Task Force was right to conclude that FDA should regulate animal drugs in feed "based upon the degree of risk from use of the drug." The current regulatory scheme, however, poorly accomplishes that objective for at least two reasons. First, it fails to account for what we now understand to be a critical risk associated with the use of antibiotics in animal agriculture: development of bacteria resistant to medically important drugs. Second, it fails to effectively target the factors most likely to result in consumers' exposure to unsafe drug residue levels.

To address the first deficiency, FDA should bring its regulation of medicated animal feeds in line with its initiatives to ensure judicious use of medically important antibiotics in animal agriculture. Specifically, FDA guidance outlines a methodology for assessing resistance risk in new animal drugs. The methodology asks whether use of a new drug is likely to lead to an animal harboring resistant bacteria, whether humans are likely to ingest that bacteria from "the relevant food commodity," and whether human exposure to the resistant bacteria is likely to result in adverse health consequences.[3] Similar considerations should guide the agency's decision of whether to allow unlicensed feed mills to handle an existing drug. The ultimate risk assessment scheme could take many forms, but it should deemphasize drugs' lowest approved use levels. A continued focus on lowest approved use will create further disruptions as FDA turns its attention from growth promotion claims to preventive uses of antibiotics. It will also continue to create perverse incentives for drug manufacturers to market drugs for use among large groups of animals at longer durations, contributing to a higher risk of antibiotic resistant bacteria.

To better protect consumers from drug residues, FDA should develop a risk assessment scheme that more directly takes exposure risk into account. Factors such as a drug's established tolerance levels, observed tissue residue depletion rates, and the incidence of residue violations, should inform whether the agency allows unlicensed feed mills to handle the drug. In its rule establishing the current scheme, the agency claimed that "it is highly unlikely that the use of [exempt "Category I" drugs] would result in drug residues in the edible products of food-producing animals, even under conceivable conditions of misuse."[4] Yet as the notice points out, exempt "Category I" drugs include penicillin, which accounted for 306 or 22% of the violative samples collected by USDA Food Safety Inspection Service (FSIS) Inspectors in FY2014 under the National Residue Program.[5] Category I includes several other drugs, such as amprolium,

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[3] FDA. Guidance for Industry #152 (Oct. 23, 2003) *available at*: http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf

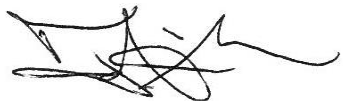
[4] 48 *Fed. Reg.* 34574.

[5] USDA Food Safety Inspection Service. National Residue Program for Meat, Poultry, and Egg Products. FY 2014 Residue Sample Results (Dec. 2015) *available at*: http://www.fsis.usda.gov/wps/wcm/connect/2428086b-f8ec-46ed-8531-a45d10bfef6f/2014-Red-Book.pdf?MOD=AJPERES

chlortetracycline, dichlorovos, erythromycin, lasalocid, lincomycin, oxytetracycline, and tylosin, whose residues FSIS routinely tests for.

In conclusion, FDA should take action now to begin developing a risk-based classification of animal feed drugs that protects consumers more effectively and efficiently. Public comment should inform the agency's deliberations and help to strike a balance between minimizing risks associated with these drugs and ensuring access to all producers.

Sincerely,



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