

FDA PROPOSES NEW EXPANSIVE ANIMAL DRUG ANTIMICROBIAL REPORTING REGULATIONS

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FDA Alert

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On May 20, 2015, the Food and Drug Administration ("FDA") proposed new regulations implementing the annual reporting requirements that were originally enacted by Congress in section 105 of the Animal Drug User Fee Amendments of 2008 ("ADUFA 105"). 80 Fed. Reg. 28,863 (May 20, 2015) (proposing new 21 C.F.R. § 514.87). These new regulations, if finalized, would require new animal drug application ("NADA") sponsors for antimicrobial animal drugs to report species-specific estimates of the percentage of product sold for use in cattle, swine, chickens, or turkey to the FDA. It is unclear whether animal drug sponsors have access to sufficient information to accurately provide these estimates. It is also unclear whether ADUFA 105 provides FDA with the legal authority to require the species-specific estimates.

ADUFA 105 amended section 512 of the Federal Food, Drug, and Cosmetic Act ("FDCA") to require certain sponsors of approved or conditionally approved NADAs to maintain records and submit annual reports to FDA. The statute requires sponsors of antimicrobial animal drugs approved for use in food-producing animals to annually report to FDA the amount of each antimicrobial active ingredient sold or distributed for use in food-producing animals. FDA is authorized to require reporting: (i) by container size, strength, and dosage form; (ii) by quantities distributed domestically and exported; and (iii) for each dosage form, a listing of the target animals, indications, and production classes that are specified in the approved product label. In addition to the ADUFA 105 annual reports, FDA's current regulations require NADA sponsors to submit annual reports with sales and distribution data. 21 C.F.R. § 514.80(b)(4)(i)(A).

The proposed rule would permit sponsors to avoid duplicative reporting under both the ADUFA 105 and Section 514.80 reporting provisions, provided certain requirements are met. If the rule is finalized, sponsors will need to carefully review those requirements before deciding whether to adopt a single reporting approach. On the positive side, the rule would allow sponsors to make their ADUFA 105 reports to FDA in terms of product units rather than calculating the amount of antimicrobial active ingredients associated with the product sales, as is the current practice of most sponsors.

The most controversial part of the proposed regulation is the requirement for reporting a species-specific estimate of the percentage of product sold for use in cattle, swine, chickens, or turkey. Percentages for each species must be provided, but only if the product is labeled for the species. The total percentage must add up to 100%. If the animal drug is used in minor species or companion animals (non food-producing), the estimate for that use is to be reported as "other species/unknown."

FDA states that the species-specific estimate "provision is not intended to require animal drug sponsors to conduct studies of on-farm drug use practices." However, it is unclear how sponsors are expected to obtain the information necessary to compile a reasonably accurate estimate. FDA merely states that it "believes that animal

drug sponsors have access to information obtained in the ordinary course of their business (for example, through marketing activities) to estimate the percentage of annual product sales that are sold or distributed domestically for use in any of these four major food-producing species that appear on the approved product label." Given that many sponsors sell product to distributors or feed mills rather than end-users, it is unclear how FDA came to this conclusion.

K&L Gates LLP's FDA practice group is following these developments and would be pleased to assist any sponsors with an evaluation of the ADUFA 105 proposed regulations.

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