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Rockville, MD 20852

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Comments of Consumers Union on the Food and Drug Administration (FDA) Proposed Rule "Antimicrobial Animal Drug Sales and Distribution Reporting" Docket No. FDA-2012-N-0447

Consumers Union (CU), the public policy and advocacy arm of Consumer Reports,[1] welcomes the opportunity to comment on the Food and Drug Administration's (FDA) proposed rule on antimicrobial animal drug sales and distribution reporting. We commend FDA for working to address the problem of overuse of antibiotics in food animals, which has created a serious global public health problem for both humans and animals. We also thank FDA for proposing regulations for the administrative practices and procedures for animal drug sponsors who must report on animal antimicrobial sales as part of the Animal Drug User Fee Amendments (ADUFA) of 2008. In particular, we appreciate that FDA has noted a main problem with section 105 of ADUFA (ADUFA 105), namely that it does not require sponsors of animal antimicrobials to disclose an estimate of the total amount of each approved active ingredient sold or distributed for each food-producing species, and for proposing requiring data on such uses.

In 2011, the U.S. Government Accountability Office (GAO) recommended that FDA collect "more detailed data on antibiotic use in food animals, including the species in which antibiotics are used and the purpose of their use" so as "[t]o track the effectiveness of policies to curb antibiotic resistance, including FDA's voluntary strategy to reduce antibiotic use in food

[1] Consumers Union is the public policy and advocacy arm of Consumer Reports. Consumers Union is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. It conducts this work in the areas of food and product safety, telecommunications reform, health reform, financial reform, and other areas. Consumer Reports is the world's largest independent product-testing organization. Using more than 50 labs, auto test center, and survey research center, the nonprofit organization rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications.

animals."[2] We strongly agree – and have long agreed – with GAO's recommendations and have pushed for FDA to both collect more data on antibiotic sales and use in livestock, poultry and aquaculture and report those data to the public so as to determine if the FDA's voluntary guidance approach, e.g., Guidances for Industry (GFI) # 209[3] and # 213,[4] is achieving its goals of reducing injudicious antimicrobial use and having the desired public health outcome of minimizing antimicrobial resistance development.

While we wholeheartedly agree with FDA on the need for requiring species-specific data on antimicrobials sold or distributed for use in food-producing animals, we do not think that FDA's proposal—requiring companies to provide a species-specific ***estimate*** of the percentage of each new animal drug product containing an antimicrobial active ingredient that was sold or distributed domestically for use in just cattle, swine, chickens, or turkeys—will result in the most accurate data. Rather, the sponsors should be required to report, as accurately as possible, the exact percentages of annual product sales that are sold or distributed domestically for use in both major and minor food-producing species (e.g., not just for cattle, swine, chickens, or turkeys). In addition, as explained more fully below, more accurate information on the precise amounts of antimicrobials used in food-producing animal species can be obtained from the annual reporting of data regarding antimicrobial drugs added to animal feed, already being required as part of the recently finalized Veterinary Feed Directive[5] (VFD) rules, by veterinarians and feed mills in a standardized format. Since some 74% (e.g., 6,828,506 kg out of 9,196,803 kg) of all medically important antimicrobials used in food-producing animals in 2013 were distributed via feed,[6] requiring that the data gathered as part of the VFD be turned over to FDA and made part of the annual data reported to the public is actually the single most important step FDA could take at this time to gain the most accurate data on species-specific use of antimicrobials.

Specific comments on the issues raised by FDA in the Proposed Rule are as follows:

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[2] Pg. 46 in Government Accountability Office (GAO). 2011. ANTIBIOTIC RESISTANCE: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals. GAO-11-801. At: http://www.gao.gov/new.items/d11801.pdf

[3] FDA. 2012. Guidance for Industry (GFI) #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals. 26 pp. At: http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf

[4] FDA. 2012. Draft Guidance for Industry (GFI) #213: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209. 18 pp. At: http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf

[5] 80 Fed. Reg. 31708. 2015. At: http://www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13393.pdf

[6] See Table 11a in FDA. 2015. 2013 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. At: http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM440584.pdf

Sales and Distribution Data by Species

We commend FDA for now recognizing the importance of species-specific data on antimicrobial use for understanding, monitoring and managing antimicrobial resistance. As the Proposed Rule notes, "Collecting species-specific data is expected to assist FDA in assessing antimicrobial sales trends in the major food-producing animal species and examining how such trends may relate to antimicrobial resistance. Having improved data would also support this Agency's ongoing efforts to encourage the judicious use of antimicrobials in food-producing animals to help ensure the continued availability of safe and effective antimicrobials for animal and humans."[7]

However, we do not agree with FDA's proposal to require that the drug sponsor provide ***estimates*** of species-specific use data, since such estimates are not an accurate substitute for the actual collection of species-specific antimicrobial drug use data. First, FDA has not provided any evidence that the drug sponsors have the information to make accurate estimates. Indeed, as the Generic Animal Drug Alliance (GADA) noted in its comments on the ANPR, "it is impractical to obtain and provide such additional sales estimates and distribution data by individual species with any reasonable degree of accuracy … once the product is sold by the drug manufacturer (i.e., drug sponsor) to the primary customer, there is no practical means for the drug sponsor to further trace the ultimate use of the product to an individual animal species."[8]

Second, FDA already has evidence that the drug sponsors are not accurate in reporting antimicrobial sales and distribution data. Presently, as part of ADUFA 105, drug sponsors report the numbers of each drug product sold as well as the amount of antimicrobial active ingredients associated with such product(s). FDA reports that drug sponsors seem to have a problem with accurately converting their product sales data into active ingredient sales data. Since the drug sponsor data on total amount of antimicrobial active ingredients sold per year is so inaccurate, FDA has proposed that the drug sponsors only submit data on sales of each drug product, and allow the FDA to calculate the total amount of antimicrobial active ingredients for each such drug product. As FDA notes, "our experience has shown great variability in reporting accuracy when sponsors are asked to convert product sales data into active ingredient sales data. … Therefore, FDA believes this approach [drug sponsor only submits product sales data and allows FDA to calculate total amount of antimicrobial active ingredient in those products] will … greatly increase the accuracy of the final results." If the companies have such difficulty in accurately transforming product sales data into total amount of antimicrobial active ingredient use (i.e., multiplying the number of units of the specific drug product sold by the amount of each active ingredient in that specific drug product), how can we expect them to accurately estimate the species-specific use of each antimicrobial active ingredient?

We also disagree with FDA's proposal to only require species-specific antimicrobial use estimates for four food-producing animals: cattle, swine, chickens, and turkeys. As part of this

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[7] Pg. 28864 in 80 Fed. Reg. At: http://www.gpo.gov/fdsys/pkg/FR-2015-05-20/pdf/2015-12081.pdf

[8] Comment to ANPR by Generic Animal Drug Alliance. At: http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-0447-0036

proposal, FDA proposes a fifth category for "other species/unknown." Thus, FDA would lump data on minor food animal species with data on companion animals and data from unknown sources. This proposal does not allow for the public to distinguish between minor food-producing species, companion animals and unknown sources. As an example, FDA refers to an antimicrobial product that is approved for use only in cattle, sheep and dogs, and the sponsor estimates that 50% of annual sales were for cattle, 10% for sheep and 40% for dogs. This would be reported as cattle 50% and species/unknown 50%. Consequently, we wouldn't know that the 50% unknown was actually 10% a minor food animal species (sheep) and 40% for companion animal, and 0% unknown species. Thus, **we urge FDA to at least require reporting for other/minor food species, in addition to data on cattle, swine, chickens or turkeys.**

FDA should require reporting of data from Veterinary Feed Directives (VFDs)

Given the facts that many of the drug companies say they cannot practically or accurately estimate the species specific sales data and that FDA has said the companies cannot accurately estimate/calculate the total amount of antimicrobial active ingredients from the total sales of each separate drug product, we believe that FDA's proposal to allow the drug sponsors to estimate the species-specific data is flawed and will not provide the most accurate or reliable data.

There is an alternative to estimation as a way to obtain accurate species-specific data on antimicrobial use in food-producing animals. That alternative can be found within FDA's existing authority in the recently finalized Veterinary Feed Directive (VFD) rule.[9] A VFD drug is an approved animal drug for use in or on animal feed, and must be used under the professional supervision of a licensed veterinarian.[10] All VFD drugs can only be manufactured by a feed mill that has a medicated feed mill license, which has to be obtained from the FDA. The finalized VFD rule allows for electronic requests and record keeping, and transitions new animal drug products containing medically-important antimicrobial drugs from an over-the-counter status to a status that requires veterinary oversight.

The VFD rule requires that both the veterinarian and the feed mill retain copies of the VFD which includes, among other things, the name of the animal drug, the animal species, the number of animals to be treated/fed the medicated feed, the location of the animals, the date of treatment, and the indication for which the VFD was issued. Since some 74% (e.g., 6,828,506 kg out of 9,196,803 kg) of all medically important antimicrobials used in food-producing animals in 2013 were distributed via feed,[11] requiring that the data gathered as part of the VFD be turned over to FDA and made part of the annual data reported to the public is actually the single most important step FDA could take at this time to gain the most accurate data on species-

[9] 80 Fed. Reg. 31708. 2015. At: http://www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13393.pdf

[10] FDA. 2009. Guidance for Industry #120. Veterinary Feed Directive Regulation Questions and Answers. 11 pp. At: http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf

[11] See Table 11a in FDA. 2015. 2013 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. At: http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM440584.pdf

specific use of antimicrobials. This would enable a meaningful analysis of those factors related to the development and spread of antimicrobial resistance as a result of use of antimicrobials of importance in human medicine.

Since VFD orders include information on the location of the animals to be treated, it will be possible to exclude intermediate distributors and identify what feed was actually sent to farms. Also, given that there are already over 1,300 VFD feed distributors and FDA projects 300 additional distributors each year, it will be relatively easier to maintain the confidentiality of the drug distribution information, compared to the situation under ADUFA 105 where there were only 23 companies that sell these antimicrobial drugs.

Presently, VFD users are required to maintain records and share them among farms, feed distributors, and veterinarians, and make them available to FDA on request. We simply recommend that such records are required to be shared with FDA. To reduce the reporting and analysis burden and analysis on the FDA and feed mill distributors, FDA could require only larger distributors to submit data or could collect data from a selected sample of distributors.

VFD-related data from feed mills would provide accurate data on the amounts of antimicrobials mixed in feed, not estimates. Thus, **FDA should require annual reporting of VFD data by feed mills in a standardized format. FDA should also aggregate those data into a publicly available registry that reports data for each separate food-producing animal species, by use.**

Conclusion

The collection of antimicrobial drug use data is crucially needed to track the effectiveness of policies to curb antimicrobial resistance, including FDA's voluntary strategy to reduce antimicrobial use in food animal species. FDA's proposal to have drug sponsors simply estimate the amount of antimicrobials used in each food animal species, while a small step forward, is not likely to produce the accurate data that is needed. We thus recommend that FDA require the annual reporting of VFD-related data, which would create a system that actually collects data on antimicrobials distributed for use in feed.

Thank you for consideration of our comments.

Respectfully submitted,

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