ANIMAL HEALTH INSTITUTE
Representing manufacturers of animal health products

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Re: Docket No. FDA–2012–N–0447; Antimicrobial Animal Drug Sales and Distribution Reporting; Proposed rule

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments to Docket No. FDA-2012-N-0447 intending to amend **21 CFR 514.80; Records and Reports,** to include the administrative practices for sponsors to submit sales and distribution data for antimicrobial drug products sold for food producing animals as required under the Animal Drug User Fee Act of 2008. AHI is the national trade association representing manufacturers of animal health products -- the pharmaceuticals, biological products and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. AHI member companies represent the majority of companies producing antibiotics used in animal production and thus have a keen interest in the request for comments on this proposed regulation.

AHI supports the collection and reporting of useful data on the distribution of antimicrobials from all markets, whether for human medicine, veterinary medicine, or for plant health programs, when there is a clearly stated scientific purpose. As discussed later, we believe that for veterinary uses, a secure and confidential program like the USDA National Animal Health Monitoring System (NAHMS) is a far better vehicle for collecting this information than sales data because sales data do not correlate with antimicrobial resistance or public health. Currently, FDA only requires the reporting of sales data from animal health companies, yet has released commercially-derived data from a private human sales database. This has led to erroneous comparisons and misuse of the information as to the actual amounts and kinds of antibiotics used for people and animals. We appreciate that FDA has cautioned about using these comparisons to make critical judgements on antibiotic use, but unfortunately, the misinformation and exaggerated claims are still reported in both print and social media.

The proposed regulation, if finalized, will only add to the information being misused. FDA knows well the severe limitations on sponsors identifying species in which antibiotic products are administered, yet asks sponsors to provide "estimates." Estimates are not data. The future misuse of this information is entirely predictable. When the proposed regulation

was published, a prominent advocate for eliminating antibiotic use in food animals was quoted as saying "*It puts [livestock producers] in the hot seat…..If the data show that there's one species getting the lion's share of antibiotics versus another … it will allow policy analysts like myself to know where to apply pressure to the food industry."*

Producers and veterinarians should not become "targets" as a result of the release of information by FDA. That is one reason why AHI is concerned with the new requirements being proposed in 21 CFR 514.87 asking antimicrobial drug product sponsors to estimate the percentage of their products sold for the food producing species. Asking drug sponsors to *estimate* sales data will lead to imprecise numbers that will be used as definitive measures of antibiotic use. If one antimicrobial product is labeled for both a cattle and swine, any attempt to estimate the breakdown across species will be nothing more than a guess. Another complication with estimates is that products sold by the sponsor to a distributor may be intended for one species but be used in another. Bad data are worse than no data.

Furthermore, the species of food animal tells only part of the story because there are different production classes within those species (such as feedlot cattle versus dairy cattle, non-lactating dairy cows versus milking cows versus calves, broiler chickens versus breeding hens versus chicks, etc.,) which may receive different amounts of antibiotics for specific purposes.

We refer you to our extensive comments dated October 19, 2012 to the FDA Advance Notice of Proposed Rulemaking on antimicrobial sales and distribution data in which we addressed many of the obstacles in estimating actual sales for different animal species.

The President's National Action Plan for Combating Antibiotic Resistance states that FDA and USDA are to partner on the collection of more detailed on farm usage information through the NAHMS to evaluate the impact of the changes underway as outlined in Guidance for Industry #213. Understanding how antibiotics are being applied at the farm level by veterinarians and producers provides much better information on the link between use and selection of resistant micro-organisms than do sales information, which serves as only a surrogate. How will the data requested in this draft interact with or complement the NAHMS initiative? The draft rule says species-specific estimates "would be important in supporting efforts such as NARMS…" but fails to explain how. We fail to see how *estimates of use* can support the resistant bacteria data collected in NARMS. AHI would prefer that FDA develop a clear and comprehensive strategy on antibiotic data collection rather than expand ad-hoc requests to sponsors to provide estimates of species sales data, which puts them in the position of simply providing best guesses. Scientific decisions leading to risk management decisions should not be based on guesses.

The proposed draft claims that public disclosure of any summary data would be limited by the current confidentiality and national security protections in existence under section 105 of the Animal Drug User Fee Act (ADUFA), and under the exemptions to the Freedom of

Information Act (FOIA). We agree with FDA that these data (both at the company-specific level and when aggregated but in a manner that company-specific data can be derived when coupled with other information) are confidential under both of these provisions. However, as FDA is well aware, that position is currently being challenged in the courts by third parties who seek public disclosure of confidential sales data. Collection activity should not be expanded until those legal challenges are resolved. The release of "estimated" sales data (species specific, class specific or route specific), if not considered confidential business information, could reveal to third parties (including competitors) the total sales of specific company products, thereby providing the third party with accurate information about the market demand for another company's products. Using publicly available information on prices, a third party would be able to calculate the revenues generated by the sale of certain products, thereby providing it with accurate information on the demand for specific products in dollars and use that information to decide to introduce its own product in the same route and class, competing directly with the sponsor without regard to the time, money and years of investment the company has made to supporting its product. We have strong objections to being required to provide estimates that can be misused and that, if subject to public disclosure, would, as FDA acknowledges, lead to the release of confidential business information.

The proposed requirement for sponsors to submit species-specific estimates of product sales as a percentage of total sales is not supported by law. The reporting of species-specific estimates is not among the data reporting requirements established by ADUFA § 105 and inserted into the Food, Drug and Cosmetic Act at Section 512(l)(3), which therefore cannot be utilized to support this aspect of the proposed data collection. Neither does the general Records and Reports provision at Section 512(l) (1) of the Act support this aspect of the data collection. The provision at Section 512(l)(1) allows FDA to require a sponsor to maintain records and make reports "***on the basis of a finding that such records and reports are necessary***" in order to enable or facilitate a determination of whether there may be grounds for invoking the withdrawal provisions in 512(e) or 512(m)(4).

FDA has made no finding to support the proposed requirement to mandate the maintenance of records and submission of reports relative to species-specific estimates. In the proposal, FDA indicates the following justifications for the proposed species-specific estimates: "*intended to enhance FDA's understanding of antimicrobial animal drug sales intended for use in specific food-producing animal species"; "assist FDA in assessing antimicrobial sales trends in the major food-producing animal species and examining how such trends may relate to antimicrobial resistance"; "support this Agency's ongoing efforts to encourage the judicious use of antimicrobials in food-producing animals"; "supporting efforts such as NARMS"; "useful to better understand how the use of medically important antimicrobial drugs in food-producing animals may contribute to the emergence or selection of antimicrobial resistant bacteria"; "this information could inform microbial food safety risk assessments"; "could further enhance FDA's ongoing activities related to slowing the*

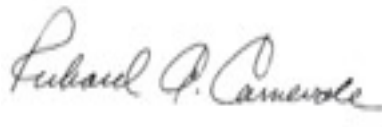
development of antimicrobial resistance and is consistent with the recommendations in guidance recently issued by this Agency." None of these rise to the level of the statutorily-required finding that the proposed estimation of species-specific data is necessary to enable or facilitate a determination of whether there may be grounds for invoking the withdrawal provisions of 512(e) or 512(m)(4). Indeed, most of the stated rationale is not even colorably related to the withdrawal provisions. This aspect of the proposed rule does not have the requisite statutory authority for promulgation.

We do support two other provisions of the proposed rule. The proposal to allow sponsors to opt to exclude the duplicative reporting of units sold at the time of the annual drug experience reports under 514.80 is a welcome change for the industry, and AHI supports this change. AHI also supports that sponsors be allowed to report units of antimicrobial products sold and not be required to calculate the amount of active ingredient in kilograms those units represent. This will be consistent with the current reporting requirements for other animal drugs under 514.80 and relieve the burden on each sponsor of the necessity of tedious calculation on an active ingredient basis. We ask that these calculations be shared with individual reporting sponsors on a collaborative basis to ensure accuracy.

AHI companies have responsibly complied with the request for sales data mandated under ADUFA §105 to the limits of the law and their ability to fully know where their products are distributed and used. Even prior to the ADUFA requirement, AHI voluntarily collected this information from their members and made the data publicly available. However, we have always noted in our comments to the agency that sponsors are quite limited in their knowledge of the exact extent of use in each labeled species for many of the products with multi-species labels. We support both transparency and good data, but reiterate that having sponsors simply estimate species percentage of use will not provide useful information to further the goal of mitigating antimicrobial resistance and will put the sponsors, individually and collectively, in jeopardy of misinformation and disclosure. FDA and its federal partners should present a comprehensive plan for antibiotic use data collection complete with justifications and goals rather than incomplete, one-off, ad-hoc approaches that only confuse the issue.

We believe that working with USDA APHIS to gather on-farm use data under the NAHMS program combined with the USDA ARS on-farm pilot programs to correlate use and resistance are superior to the collection of estimated sales data which, at best, serve as a surrogate for use.

Sincerely,



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