NATIONAL MILK PRODUCERS FEDERATION

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Division of Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

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

To whom it may concern:

The National Milk Producers Federation (NMPF) submits these comments to Docket No. FDA-2012-N-044 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 Amendments of 2008[1]. The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

NMPF supports the collection and reporting of useful data on antimicrobial sales from all markets of antimicrobial drug products whether for human medicine, veterinary medicine, or for plant health programs when there is a clearly stated scientific purpose. Currently the Food and Drug Administration (FDA) only requires sales data collection from animal health companies yet the Agency 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 versus animals. While FDA has attempted to caution about using data for these comparisons to make critical judgements on antibiotic use, misinformation and exaggerated claims are still reported in both print and social media.

Unfortunately, the current draft proposal will only add to the information being misused. FDA should be well aware of the severe limitations on drug sponsors identifying species in which antibiotic products are administered; yet the Agency proposes that sponsors provide "estimates." Unfortunately estimates are not data and 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."*[2]

Dairy farmers and veterinarians should not become "targets" as a result of the release of information by FDA. That is one reason why NMPF is concerned with the new requirements being proposed in 21 CFR 514.87 asking antimicrobial drug product sponsors to ***estimate*** the

[1] http://www.gpo.gov/fdsys/pkg/FR-2015-05-20/pdf/2015-12081.pdf
[2] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM456284.pdf

percentage of their products sold for the food-producing species. Requesting drug sponsors to ***estimate*** sales data will lead to imprecise numbers that will unfortunately be used as ***definitive*** measures of antibiotic use. When an antimicrobial product has both a cattle and swine label, 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 and end up in another (such as through veterinary prescribed extra-label drug use). Bad data is worse than no data.

Furthermore, the species of food animal tells only part of the story, since there are different production classes within those each of 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, as well as different types of antibiotics, for specific purposes. For example, sulfaquinoxaline is approved for treatment of a variety of bacteriological infections: for dairy cattle, but not for lactating dairy cows; for calves, but not for veal calves; for chickens, but not for those laying eggs for human consumption; and for turkeys, but for not those laying eggs for human consumption[3] FDA is aware of the many obstacles in estimating actual sales for different animal species as detailed in the extensive Animal Health Institute's October 19, 2012 comments to the FDA Advance Notice of Proposed Rulemaking on antimicrobial sales and distribution data.[4]

The President's National Action Plan for Combating Antibiotic Resistance[5] states that FDA and U.S. Department of Agriculture (USDA) will partner on the collection of more detailed on-farm usage information through the National Animal Health Monitoring System (NAHMS) to evaluate the impact of the changes underway as outlined in FDA Guidance for Industry #213. Understanding how antibiotics are being applied at the farm level by veterinarians and dairy producers provides far better information on the potential link between use and selection of resistant micro-organisms than estimated sales information by species. 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 resistance bacteria data collected in National Antibiotic Resistance Monitoring System (NARMS). NMPF would prefer that FDA, in consultation with other appropriate federal agencies, develop a clear and comprehensive strategy on antibiotic data collection rather than expanding ad-hoc requests to drug sponsors to provide estimates of species sales which puts them in the position in many cases of simply providing best guesses. Scientific decisions leading to risk management decisions should not be based on a guess.

Additionally, the proposed requirement for drug 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 cannot therefore 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 require the maintaining of records and making reports relative to species-specific estimates.

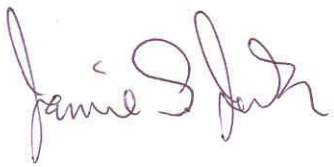
In the proposal, FDA indicates the following justifications for the proposed species-specific estimates: "intended to *enhance* FDA's understanding of antimicrobial animal drug sales intended for use in specific food-producing animal species"; "*assist* FDA in assessing

[3] http://www.accessdata.fda.gov/scripts/animaldrugsatfda/details.cfm?dn=006-891
[4] http://www.regulations.gov/contentStreamer?documentId=FDA-2012-N-0447-0014&attachmentNumber=1&disposition=attachment&contentType=pdf
[5] https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf

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. [emphasis added]" None of these rise to the level of the statutorily required finding that the proposed 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 isn't even plausibly related to the withdrawal provisions. This aspect of the proposed rule does not have the requisite statutory authority for promulgation.

NMPF supports both transparency and good data, but reiterate that having drug sponsors simply estimate species percentage of use will not provide useful information to further the goal of identifying causes of and mitigation interventions for antimicrobial resistance. FDA and its federal partners should present a comprehensive plan for antibiotic use data collection complete with justifications and goals rather than incomplete, ad-hoc approaches that only confuse the issue. We believe that working with USDA Animal and Plant Health Inspection Service to gather on-farm use data under the NAHMS program combined with the USDA Agricultural Research Service on-farm pilot programs to correlate use and resistance are superior to collection of estimated sales by species.

Sincerely,



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