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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 Annual Summary Report Data Tables**

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket No. FDA-2012-N-0447. 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 how antibiotic sales data submitted by those companies is reported and represented.

We previously commented on the Advanced Notice of Proposed Rulemaking that preceded this notice in our filing to the docket on October 19, 2012, where we raised several concerns with a new reporting scheme that FDA might use for the data. The current notice proposes a significantly different breakdown of submitted sales information from previous year summaries.

In developing these new proposed data tables, AHI greatly appreciates the agency’s careful attention to industry’s concerns for the protection of confidential business information as required in ADUFA Section 105. While we understand and support FDA’s desire to make a clear distinction between quantities of actives sold for use in animals that are medically important and those quantities sold for use in animals that are not medically important, we believe, as further detailed below, that splitting the current categories in this manner will cause confidential business information of AHI member companies to be disclosed in violation of the Act.

As the proposal acknowledges, Food, Drug and Cosmetic Act Section 512(l)(3)(E) directs both that drug sales be aggregated and reported by antimicrobial class so that no reported class has fewer than three distinct sponsors, and that such **“data shall be reported in a manner consistent with protecting .... confidential business information.”** 78 Fed. Reg. 59309 (emphasis added). The Act thus acknowledges FDA’s obligation to protect confidential business information, and makes clear that the aggregation and reporting of data in classes with a minimum of three sponsors, by itself, is not sufficient to provide such protection.

The information submitted to FDA by AHI members is commercially sensitive and kept strictly confidential. The compilation of such sales data/information is unique and sensitive to each company and must be protected. Sales data (including the volume of sales for individual drugs) is not available to the public.

The animal health industry has significantly consolidated over the past 20 years, leaving a limited number of companies that produce antimicrobial drugs approved for use in food-producing animals and a small number of drugs used in the industry. The category of Not Individually Reported (NIR) is small and there are only a few drugs that make up the majority of sales classified in this category.

Table 3 purports to report domestic sales and distribution data by medical importance and drug class marketed. AHI is concerned that, with regard to the reporting of aggregate data in the NIR category, separating Medically Important and Not Medically Important products would lead to the disclosure of confidential business information.

There are two ways in which confidential business information would be disclosed through this reporting structure -- even if each category contains the drugs of more than two sponsors. First, if the NIR category is split into Medically Important and Not Medically Important categories and any of the drugs in either of the NIR categories enjoys a significant relative share, competitors will be able to determine the actual sales of the product with most significant sales. When the NIR category is combined, as it is currently today, the relative sales levels of drugs, even of those with significant sales, are aggregated together with other products, making it harder to determine accurately the actual sales level/volume for any one drug. For that reason, FDA should not separately report these categories but should aggregate them together.

Second, future movement of products between the Medically Important and Not Medically Important categories will provide another mechanism for competitors to calculate the sales level/volume for products that move from one category to the other. Appendix A of Guidance for Industry 152, entitled Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern, specifically states that it is the intent of the Agency to reassess the rankings providing in Table A1 (which provides a ranking of medically important antimicrobial drugs or classes of antimicrobials) periodically to confirm that the ranking is consistent with current circumstances. If there is a product in the Not Medically Important NIR category that is moved to the Medically Important NIR category between reporting periods for Year 1 and Year 2, for example, one could use the changes in these NIR categories (the increase from Year 1 to Year 2 for the Medically Important NIR category, and the decrease from Year 1 to Year 2 for the Not Medically Important NIR category), along with recalculated values for previous years, to closely approximate the total sales for the product that has moved. This could put FDA in the awkward position of being unable to report total sales for Medically Important NIR and Not Medically Important NIR, or being unable to present recalculated values for previous years, without violating the statutory directive to preserve confidential

business information in Section 512(l)(3)(E)(ii) of the Act. This specific risk would not exist for product classes that are individually reportable and are reclassified, because such classes are likely to move in their entirety between Medically Important and Not Medically Important.

There is a solution to these two problems. Specifically, we urge FDA to consolidate the NIR categories in Table 3 to provide a single category that includes an aggregate amount for both Medically Important NIR and Not Medically Important NIR.

Finally, the notice seems to indicate that these new tables will also be applied retrospectively, “...to augment the data tables provided in previous Summary Reports.” If the published data from 2009, 2010 and 2011 are to be re-tabulated by these new approaches, how will the agency communicate these changes to the public? The separation of data into categories may have changed over this period due to new product approvals, product indication changes, etc., which could alter year-on-year report totals. There would then be a substantial likelihood that splitting the categories (such as the NIR category into Medically Important and Not Medically Important) would reveal confidential business information.

Thank you for the opportunity to comment on these new proposed tables prior to FDA reporting the data in this format. Should you have any questions, please do not hesitate to contact AHI at (202) 637-2440.

Sincerely,

A handwritten signature in black ink that reads "Richard A. Carnevale". The signature is written in a cursive, flowing style.

Richard A. Carnevale, VMD