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

Re: Docket No. FDA-2012-N-0447; Antimicrobial Animal Drug Sales and Distribution Reporting, Advance Notice of Proposed Rulemaking

These comments are made on behalf of the American Feed Industry Association (AFIA) by AFIA's legal counsel, Olsson Frank Weeda Terman Matz, PC. AFIA is the world's largest organization devoted exclusively to representing the business, legislative and regulatory interests of the United States animal feed industry and its suppliers. Founded in 1909, AFIA also is the recognized leader on international industry developments. AFIA represents the total feed industry, and its members include more than 575 domestic and international companies and state, regional and national associations. Member companies are livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, equipment manufacturers and companies which supply other products, services and supplies to feed manufacturers.

AFIA is pleased to respond to the proposed rulemaking on antimicrobial animal drug sales and distribution reporting, 80 Fed. Reg. 28,863 (May 20, 2015) (the Proposed Rule). AFIA appreciates FDA's desire to monitor the use of antibiotics within the animal agriculture industry as part of its efforts to understand and prevent antibiotic resistance. However, FDA must undertake these efforts within the bounds of its existing authority prescribed by Congress. While AFIA welcomes the proposed changes that would reduce duplicative reporting requirements, AFIA strongly contests the wisdom and FDA's legal authority to require new animal drug sponsors to report species-specific estimates of product sales.

FDA Lacks the Legal Authority to Require New Animal Drug Sponsors to Report Species-Specific Distribution Estimates

While FDA is charged with the responsibility of monitoring and preventing antibiotic resistance, it must do so within the confines of its statutory authority. In the Proposed Rule, FDA proposes requiring new animal drug sponsors to submit estimates of antimicrobial ingredient sales by species. These estimates would be submitted as part of the annual distribution reports required by § 105 of the Animal Drug User Feed Amendments of 2008 (ADUFA). However, Congress has not provided FDA the authority to require reporting of these estimates.

Section 105 of the ADUFA clearly delineates the information that drug sponsors are required to disclose in their annual distribution reports. Specifically, ADUFA § 105(a)(3) amended § 512(l) of the FD&C Act in the following manner:

> (A) In the case of each new animal drug described in paragraph (1) that contains an antimicrobial active ingredient, the sponsor of the drug shall submit an annual report to the Secretary on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product.
>
> (B) Each report under this paragraph shall specify the amount of each antimicrobial active ingredient –
>
> (i) by container size, strength, and dosage form;
>
> (ii) by quantities distributed domestically and quantities exported; and
>
> (iii) by dosage form, including, for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approval label of the product.

Here, Congress made clear the information that must be contained in the annual distribution reports. Section 105 makes no mention of any requirements to report species-specific estimates. AFIA is, appropriately, perplexed at FDA's inclusion of such a provision in the Proposed Rule when it is not supported by any modicum of congressional intent.

There is ample Supreme Court jurisprudence indicating that FDA does not have the authority to mandate additional reporting requirements pursuant to the ADUFA. As a federal regulatory agency, FDA is aware of the *Chevron* two-part test, which governs the deference provided to a federal agency in interpreting statutes it is charged with administering. *See Chevron U.S.A. v. NRDC,* 467 U.S. 837 (1984). The first question posed in the *Chevron* test is "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. As the Supreme Court noted, "[i]f the intent of Congress is clear, that is the end of the matter, for the court, as well as the agency." *Id*. at 842-43. Here, Congress made clear in § 105 the type of distribution data the agency should collect pursuant to the ADUFA. The Proposed Rule's

species-specific estimate data is not included in the statute. Per *Chevron*, its absence in the text of the ADUFA should proscribe its inclusion in the Proposed Rule.

Reading § 105 of the ADUFA to allow for a species-specific estimate reporting mandate is an impermissible construction of the statute. *See 62 Cases, More of Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951) ("[O]ur problem is to construe what Congress has written. After all, Congress expresses its purpose by words. It is for us to ascertain – neither to add nor to subtract, neither to delete nor to distort."); *Ayes v. U.S. Dep't of Veterans Affairs,* 473 F.3d 104, 108-11 (4th Cir. 2006) ("We must presume that 'Congress says in a statute what it means and means in a statute what it says'") (internal quotation marks omitted)).

A cannon of statutory construction that is instructive in this case is *expressio unius est exclusio alterius*. *See Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993). This principle means "the expression of one thing is the exclusion of another," stands for the proposition that if Congress undertakes to delineate specific provisions in a statute, the agency is not free to supplement the statutory prescriptions with additional requirements. Here, Congress specifically outlined the required provisions that animal drug sponsors must report pursuant to § 105 of the ADUFA. Congress' language did not include species-specific estimate reporting requirements. Thus, FDA is not permitted to require this information from new animal drug sponsors.

AFIA anticipates that FDA may assert that its authority is derived from its general authority to require recordkeeping and reporting by new animal drug sponsors under FD&C Act § 512(l)(1). However, any reliance on this provision is misplaced. It is a well-established precept of statutory construction that "specific terms prevail over the general in the same or another statute which otherwise might be controlling." *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222, 228-29 (1957). While § 512(l)(1) may provide FDA with the general authority to require recordkeeping and reporting, this authority is constrained by § 512(l)(3) (amended by ADUFA § 105). Section 512(l)(3) restricted the general authority provided in § 512(l)(1) with regard to FDA's recordkeeping and reporting authority of antimicrobial distribution data. Unlike the general authority provided in § 512(l)(1), § 512(l)(3) specifically delineates the required information to be included in annual antimicrobial active ingredient reports. It is impermissible for the agency to read additional requirements into these reports on the basis of its general authority.

Even assuming *arguendo* that FDA's statutory authority is ambiguous (which it is not), the legislative history of the ADUFA demonstrates that Congress did not contemplate a species-specific estimate reporting requirement when it considered the Act. For example, the House of Representatives Committee on Energy and Commerce report on ADUFA contains no mention of species-specific estimate reporting requirements. The E&C Committee's report described the distribution data reporting requirements in the following manner:

> Each report shall specify the amount of each antimicrobial active ingredient by container size, strength, and dosage form; by quantities distributed domestically and quantities exported; and by dosage form, including, for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product. Each report shall be submitted not later than March 31 of each year, shall cover the period of the preceding calendar year, and shall include separate information for each month of such calendar year.

H.R. Rep. 110-804, 14, 2008 U.S.C.C.A.N. 1287, 1295.

This report is consistent with the plain language of § 105 of the ADUFA, which clearly outlines the reporting requirements authorized by that Act. Notably, there is no mention of species-specific estimate reporting requirements. This absence is indicative that Congress did not consider Section 105 of the ADUFA as providing FDA the authority to require new animal drug sponsors to provide species-specific estimates as part of their distribution data reports.

New animal drug sponsors do not maintain sales distribution records by destination species. Many of these antimicrobials are sold as premixes to distributors and licensed feedmills. At this point, new animal drug sponsors lose control over the antimicrobials and have no ability to document which species ultimately receive these products. Congress recognized this marketplace reality and did not require new animal drug sponsors to track species-specific data in § 105 of the ADUFA because it would be impossible.

Species-Specific Estimate Reporting Would Not Result in Useful Data

Bad data should not be preferred over a lack of data. Animal drug sponsors do not maintain records of sales by species. This information would be impossible to monitor because drug sponsors do not maintain control over antimicrobials throughout the supply chain. Without actual data, an estimate is nothing more than a guess. FDA has not demonstrated how gathering a series of "guesses" regarding antimicrobial use will support its monitoring efforts under programs, such as the National Antimicrobial Resistance Monitoring System (NARMS). Scientific decisions should not be based on wholly inadequate and unreliable data.

The President's National Action Plan for Combating Antibiotic Resistance requires FDA and USDA to cooperate and develop a plan to collect more detailed farm-level data on antimicrobial usage through the National Animal Health Monitoring System (NAHMS). The information gathered under the NAHMS project will gather much more useful information about how antimicrobials are being used at the farm level by veterinarians and livestock producers. Actual data, such as the data that will be gathered under NAHMS, will be more helpful at determining any linkages that may exist between the use of antimicrobials and resistant organisms. Species-specific estimates by sponsors would be a poor substitute for actual data. The likely result from any reliance on these estimates would be confusion and misuse.

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AFIA Supports FDA's Proposals That Will Simplify Annual Reporting Requirements

AFIA supports the provisions contained in the Proposed Rule that would allow sponsors the option to exclude annual antimicrobial distribution data from the annual drug experience reports. This eliminates unnecessary, duplicative reporting requirements for sponsors.

AFIA also supports FDA's proposal that would allow sponsors to report antimicrobial sales by unit instead of volume of active ingredients. This greatly simplifies the distribution reporting process and removes a tedious recordkeeping burden.

AFIA appreciates the agency's consideration of our views.

Sincerely,

John G. Dillard
Counsel for American Feed Industry Association