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

RE: Number FDA-2011-N-0656: Proposed Recommendations for the
Reauthorization of the Animal Drug User Fee Act (ADUFA III).

Dear Commissioner Hamburg:

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to offer comments on the Food and Drug Administration’s (FDA) Proposed Recommendations for the Reauthorization of the Animal Drug User Fee Act in the 113th Congress (ADUFA III). CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. CSPI is supported principally by over 800,000 U.S. members and subscribers to our Nutrition Action Healthletter and by foundation grants.

CSPI, individually, and as part of the Keep Antibiotics Working (KAW) coalition, has worked extensively on the issue of antibiotic resistance stemming from the overuse of antibiotics in food animal production. CSPI is deeply concerned with the public health implications of the rise of antibiotic-resistant pathogens in the food supply, and we have taken measures through foodborne illness outbreak analysis to highlight when cases, hospitalizations and deaths occur. CSPI has long recognized the urgency needed to address the issue of antibiotic resistant foodborne pathogens. CSPI previously asked that FDA ban all subtherapeutic use of antimicrobial agents that are used in human medicine or might select for cross resistance to antibiotics used in human medicine. And we strongly supported the FDA’s ban of fluoroquinolone antibiotics in poultry. We are in the midst of a public health crisis; steps taken by FDA to address this critical public health issue must be firm and authoritative. The actions outlined in the draft ADUFA III recommendations of December 5th in the Federal Register notice are far from adequate.

Section 105 of the Animal Drug User Fee Act (ADUFA) of 2008 required the first-ever collection and public reporting of certain data regarding the sales and distribution of approved antimicrobial new animal drugs intended for use in food-producing animals (codified at 21 U.S.C. §360b(l)(3)). We commend FDA for seeking public comment on how to improve this data collection and reporting, in order to improve monitoring of antibiotic use and the resulting public health threat of antibiotic resistance. We recommend the FDA pursue much more robust data collection and public reporting of such data.

Public Law 110-316 (ADUFA II) sets out specific procedures that FDA must follow in developing and making its recommendations to Congress. The procedures require FDA to consult with stakeholders other than the regulated industry. ADUFA requires FDA to consult
with the following specific groups: scientific and academic experts, veterinary professionals, and representatives of patient and consumer advocacy groups. In addition, FDA must consider the comments of members of the public.

ADUFA requires that FDA take comment from these stakeholders at specific points. First, the FDA has to have public input prior to beginning negotiations with regulated industry, including a public meeting and through an open comment period. Secondly, FDA must gain insight from stakeholders through periodic consultation during the regulated industry’s negotiations. And, finally, a public meeting and comment period must be held once the FDA has developed proposed recommendations. CSPI has repeatedly gone to organizational expenses, spending both our valuable time and money, to travel to the Center and to continually provide FDA specific suggestions for enhancements to the ADUFA. Dishearteningly, FDA recommendations include not one of the priorities identified by consumer stakeholders and fail to even acknowledge the considerable suggestions offered to the agency. Instead, the revised recommendations take an approach that will weaken the Agency’s authority over veterinary drug compounding and the need for conditional veterinary approval; in essence making it less expensive and less burdensome for industry to increase the combinations of drugs being given to food animals.

In the reauthorization of ADUFA III, CSPI asks that collected fees be directed to post marketing safety reviews of antimicrobial drugs for which premarket review was not done. We also urge that ADUFA III direct FDA to collect antimicrobial use data from feed mills, thus allowing species specific data to be made public.

Finally, we ask that ADUFA III require FDA to provide more detail in public reports related to antimicrobial sales and distribution data collected as required by ADUFA II. Capturing and disseminating additional data is essential for measuring trends of antibiotic usage, and to determine the effectiveness and impact of Agency guidances. In making certain that usage for growth promotion is curbed, and not just a shell game of hiding old practices behind new labels, more granular data is needed. It is impossible for the agency to attempt to rein in usage, without having a meaningful baseline and trend analysis on which to build policy. More granular sales data is readily available. The Agency already collects information on how the drugs are sold for administration: in feed, water, or by injection. As well, the Agency does collect monthly information. This data should be made available to the public.

Specifically the annual summaries should be transparent in the information that they share publically.

1. Report the dose of antibiotics both in total and by drug class (e.g. route of administration, such as by injection, in feed and water etc.). Although route of administration is not necessarily a surrogate marker for the indication of end use of the drug, it tends to separate individual from group drug purposes and may be important in understanding trends in resistance. In 2009, after a request of Congresswoman Slaughter, the only microbiologist in congress, this data was made public. This reporting should become the standard of annual summary reporting.
2. Medically important drug classes should be aggregated and reported in a separate fashion from those that are not important in human medicine. In prior reporting FDA has commingled medically important and non-medically important drugs into “Not Independently Reported” (NIR) and “Not Independently Reported Exports” (NIRE)
when sold by fewer than 3 drug sponsors, under the auspices of proprietary information. However, there would be no violation of confidential business information restrictions if FDA were to simply divide NIR and NIRE by relevance to human medicine. In so doing, the FDA would be allowing public health experts to correctly focus resources and attention on the use of those drugs that are critical to the human medicine.

3. Sales data that is collected by month should be reported by month. Seasonal fluctuations in buying habits could be identified, and may provide useful information as it pertains to antibiotic resistance patterns. Inclusion of this monthly data summary would again aid the Agency in transparency efforts.

CSPI notes that while ADUFA requires industry to report the previous year’s sales data by March 31st, ADUFA has no such deadline for when the FDA makes public summaries of sales data. As we are now in 2013, sales data summaries from 2011 have still yet to be released. CSPI encourages FDA to release data within 90 days of collection. Consumer stakeholders are entitled to timely information, especially in light of the Agency’s decision to seek voluntary measures to address the public health emergency of injudicious antibiotic usage in food animals.

We urge FDA to reconsider their public dissemination of antimicrobial sales data gathered under the provisions of ADUFA. Route of drug administration should be included in public reports. Medically important antibiotics, given to food animals, should be teased out of sales data and separately reported. And monthly information collected should be reported as such in the annual summary. These specific recommendations have not been included in the draft reauthorization request. The Center for Veterinary Medicine in following its mission statement to put consumer protection first, should consider ways to better protect public health and seek further authority from the 113th Congress to expand upon the mandates under Section 105 of the 2008 ADUFA Amendments.

FDA has chosen to pursue voluntary reform in antibiotic use in food-producing animals. CSPI remains skeptical of this approach and urges the agency to maintain a rigorous schedule of ensuring cooperation. Robust data collection and timely public dissemination of that data is one key avenue for ensuring that stakeholders are able to assess both industry compliance and FDA’s performance as a guiding agency behind reform. Without public access to this information, stakeholders will remain in the dark about any progress.

Sincerely,

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