The Center for Science in the Public Interest (CSPI)\(^1\) appreciates this opportunity to comment on the Food and Drug Administration’s (FDA) potential changes to its regulations relating to records and reports for approved new animal drugs. CSPI, individually and as part of the Keep Antibiotics Working (KAW) coalition, has worked extensively on this issue, particularly on the public health implications of the rise of antibiotic-resistant pathogens in the food supply. It is clear that the time for half-measures on antibiotic use and misuse in animal agriculture has passed. Any steps taken by FDA in an attempt to address this critical public health issue must be firm and authoritative.

Section 105 of the Animal Drug User Fee Amendments (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 in animals and the resulting public health threat to humans. The collection and dissemination of additional data will aid FDA and other stakeholders in the process of minimizing antibiotic use on-farm, and will provide clear data for sound policy decisions moving forward should FDA proceed with formal rulemaking on antibiotic use.

I. FDA should amend ADUFA to require species-specific tracking

FDA should amend ADUFA rules to require that drug sponsors disclose an estimate of the total amount of each approved active ingredient sold or distributed for each food producing species. Currently, if a drug is approved and labeled for use in more than one species, manufacturers only need to report total sales and do not need to report sales by species. This means that it is impossible to determine changes within and among food animal sectors. Use may vary dramatically between species—as do pathogens and pathogen controls—and thus it is critical that FDA and stakeholders know which drugs are used most often in which animal species.

II. FDA should Strengthen its Annual Summary Report

Currently, FDA is compiling additional antibiotic use data that ADUFA does not require the agency to

\(^1\) CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its Nutrition Action Healthletter and by foundation grants.
share publicly. CSPI strongly believes that transparency is an essential part of an antibiotic use reduction strategy, so that all stakeholders—including consumers and industry—can be made aware of the scope of the issue. CSPI believes that by strengthening its Annual Summary Report in the following ways, FDA can provide stakeholders with additional important data for decision-making. Notably, industry is already responsible for reporting these elements under ADUFA, so the inclusion of them in the Annual Summary presents no additional burden on industry.

1. Report the dosage form (i.e., route of administration, such as by injection, in feed or water, etc.) of antibiotics both in total and by drug class. Route of administration is not necessarily a surrogate marker for the indication or end use of the drug, but it tends to separate individual from group drug purposes and may be important in resistance models. This information was made public from the 2009 data at the request of Congresswoman Louise Slaughter. This should become a standard element of the annual summary, and would allow trend analysis over time.

2. Medically important drug classes not individually reported should be aggregated and reported separately from those that are not medically important. Medically important drugs are those that are used in human medicine as well as in food animals. In past annual summary reports 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 three drug sponsors. There would not be a violation of any confidential business information restrictions if FDA were to divide NIR and NIRE drug classes by their relevance to human medicine. Doing so would allow public health experts and regulators to better focus resources and attention on examining and decreasing the inappropriate and overuse of those drugs that are critical to the human health canon.

3. Report antibiotic sales by month. The results may only indicate seasonal fluctuations of buying habits, but they also may provide useful information on use and ultimately on antibiotic resistance. Adding this data to the summary report would also indicate FDA’s willingness to be more transparent to the public.

Finally, CSPI notes that while ADUFA requires industry to report their previous year’s sales data by March 31, ADUFA gives no deadline for when the FDA must make its summaries public. CSPI recommends that FDA impose a deadline on itself for the publication of such summaries, and urges the agency to consider 90 days as an appropriate timeframe. Stakeholders are entitled to timely information, particularly in light of FDA’s decision to seek voluntary reductions in antibiotic use on-farm. Stakeholders and the agency alike must have information quarterly in order to monitor whether the voluntary approach is working or whether additional steps must be taken. Over time, such reporting could help identify seasonal variation in drug usage, as well.

III. FDA Should Create a Public Database of VFD Data

CSPI commends FDA for considering additional avenues within its authority to gather data on antibiotic use. As discussed above, all sources and types of data are valuable in tackling an issue as critical and widespread as antibiotic resistance. To that end, FDA should create a database of data provided by veterinarians and feed mills by requiring annual reporting of Veterinary Feed Directive (VFD) data and sharing that information through a public database. Current regulations require that feed mills and veterinarians retain copies of VFDs (veterinary orders for antibiotics mixed in animal feed) that include the name of the drug, the targeted species and production class of animals, the approximate number of
animals to be fed, and the indication for which the VFD was issued. The regulations do not require electronic reporting of these records to FDA, for publication or otherwise.

Although VFD data would not capture antibiotics mixed into water or given to individual animals (such as by injection), a registry with data on drugs mixed into feeds would encompass the majority of antibiotic use in food animals, thereby enabling much more meaningful analysis of factors related to the development and spread of antimicrobial resistance in connection with the use of medically important antibiotics in animal agriculture.

IV. Conclusion

FDA should be commended for having taken long overdue action. However, the 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 the 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 access to this information, stakeholders remain in the dark about progress until well after the time for switching to a different approach has passed.

Sincerely,

Sarah A. Klein, J.D., M.A.
Senior Staff Attorney