



CENTER FOR FOOD SAFETY

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COMMENTS ON THE FOOD AND DRUG ADMINISTRATION'S DRAFT GUIDANCE ON NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD PRODUCING ANIMALS: RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT USE WITH GFI #209

July 12, 2012

Docket Numbers FDA-2011-D-0889 and FDA-2010-D-0094

The Center for Food Safety (CFS) submits the following comments on the Food and Drug Administration (FDA) Draft Guidance 213 entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209." CFS simultaneously submits comments on Final Guidance 209: "The Judicious Use of Medically Important Antimicrobial Drugs in Food Producing Animals."

CFS is a non-profit, membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture. CFS is actively involved in the campaign against the use of antimicrobials in food animal production. In 2009 the Center for Food Safety, along with the Institute for Agriculture and Trade Policy, petitioned FDA to ban the use of arsenic-based antimicrobials in food animals.¹ In August, 2010, CFS submitted comments to FDA on Draft Guidance 209 asking FDA to reconsider the use of all antimicrobials in animal agriculture where the use of such drugs impacts human health or the environment. In March, 2012, CFS submitted comments supporting FDA's recent ban on certain extra-label uses of cephalosporin and requesting FDA take similar actions on other important human antimicrobials.

¹ *Citizen Petition Seeking Withdrawal of Approval of Roxarsone and Certain Other Arsenical Additives in Animal Feed*, Center for Food Safety & Inst. For Agric. and Trade Policy (Dec. 2009), available at <http://truefoodnow.files.wordpress.com/2009/12/arsenic-petition-12-8-09-final.pdf>

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CFS represents over 200,000 members² throughout the country that support enhanced animal welfare and regularly purchase organic products, including organic meat and dairy, due to concerns about the use of antimicrobials in animal production. CFS and its members believe it is imperative that FDA promote a cautious approach to the use of antimicrobials in food animal production in order to address antimicrobial resistance.

BACKGROUND

Antibiotics and similar drugs that inhibit the growth of microorganisms—together antimicrobials—are used in human medicine to treat patients with infectious diseases. Since the 1940s, these drugs have greatly improved public health and reduced illness and death from infectious diseases.

Antimicrobials are also administered to animals raised for food. Antimicrobials are routinely administered to healthy animals in order to speed growth and to compensate for unsanitary conditions.³ The Johns Hopkins Center for a Livable Future estimates that nearly 80 percent of antibiotics sold in this country are administered to food animals. Of the 80 percent, 70 percent are administered for non-therapeutic reasons, such as to promote growth and prevent disease in overcrowded and unsanitary conditions.⁴ Ralph Loglisci of the Center for a Livable Future argues that industry is “lumping the use of antibiotics to make up for poor living conditions and animal husbandry in the same therapeutic category.”⁵

“There is clear evidence of adverse human health consequences due to resistant organisms resulting from non-human usage of [antimicrobials].”⁶ As early as the late 1960s, researchers reported a dramatic increase in strains of enteric bacteria of animal origin showing resistance to one or more antimicrobials. Researchers found that the “[m]isuse and overuse of antimicrobial drugs creates selective evolutionary pressure that enables antimicrobial resistant bacteria to increase in numbers more rapidly than antimicrobial susceptible bacteria and thus increase the opportunity for individuals to become infected by resistant bacteria.”⁷ Food animals

² CFS simultaneously submits 14,198 comments from its members to the docket.

³ *Avoiding Antibiotic Resistance: Denmark’s Ban on Growth Promoting Antibiotics in Food Animals*, Pew Charitable Trusts (Nov. 1 2010), <http://www.pewhealth.org/reports-analysis/issue-briefs/avoiding-antibiotic-resistance-85899391798> (last visited July 10, 2012).

⁴ *Antibiotic Resistance and Food Safety*, Union of Concerned Scientists (Nov. 12, 2009), http://www.ucsusa.org/food_and_agriculture/solutions/wise_antibiotics/food-safety-antibiotics.html (last visited July 10, 2012)..

⁵ Ralph Loglisci, *Antibiotic Resistance in Food Animals: FDA Takes Strong Stance, But Public Health May Remain at Risk Until Congress Acts*, Ctr. for a Livable Future (July 6, 2010), <http://www.livablefutureblog.com/2010/07/antibiotic-resistance-in-food-animals-fda-takes-strong-stance-but-public-health-may-remain-at-risk-until-congress-acts/> (last visited July 10, 2012)..

⁶ Ctr. for Veterinary Med., FDA, #209 *Guidance for Industry: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* at 11 (Apr. 11, 2012) [hereinafter FDA, *Guidance 209*] (citing FAO et al. Report, *Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Scientific Assessment* (2003)).

⁷ FDA, *Guidance 209*, *supra* note 5, at 11.

are “factories” for resistant organisms.⁸ The resistant bacteria are passed to humans through food or through direct contact with food animals or food animal waste. The use of antimicrobials in food animals is reducing the effectiveness of related antibiotics when used to treat humans. FDA warns this “is a mounting public health problem of global significance.”⁹

Yet, more than 40 years after the initial research on antimicrobial resistance was released, U.S. producers continue to use antimicrobial drugs in food animal production at unprecedented levels. Charged with addressing antimicrobial use in food animals, FDA is relying on two new guidance documents—Guidance 209 and 213—to address this imminent public health threat. While a much belated step in the right direction, these guidance documents fail to take the necessary step of instituting binding, mandatory measures to end the misuse of antimicrobials in animal agriculture. Based on 50 years of scientific research indicating a need for drastic change, CFS recommends that FDA take the following actions:

1. Comply with the March 22, 2012 and June 1, 2012 Southern District of New York Court orders¹⁰ directing FDA to withdraw the non-therapeutic uses of tetracyclines and penicillin and evaluate the safety risks of other medically important antibiotics;
2. Comply with its statutory duty and formally withdraw medically important antibiotics from use in food animal production;
3. Clarify that routinely administering low-doses of antimicrobials on a herd wide basis is not appropriate preventative use and refuse to approve new label uses of antimicrobials for disease prevention;
4. Increase transparency by instituting mandatory procedures to monitor, track, and report progress on antimicrobial use and antimicrobial resistance; and
5. Strengthen veterinary oversight of animal drugs.

FDA SHOULD COMPLY WITH RECENT COURT ORDERS

As an initial matter, CFS urges FDA to comply with two recent court orders directing FDA to take action on antimicrobial use. In the first, the court determined that FDA “unlawfully withheld agency action by failing to implement withdrawal proceedings pursuant to the Food, Drug, and Cosmetic Act ... for certain uses of penicillin, oxytetracycline, and chlortetracycline in food-producing animals,”¹¹ and ordered FDA to complete the appropriate withdrawal proceedings for the relevant New Animal Drug Applications (NADAs) and Abbreviated New Animal Drug Applications (ANADAs). “Specifically, the Commissioner of the FDA or the Director of the [Center for Veterinary Medicine (CVM)] must re-issue a notice of the proposed withdrawals (which may be updated) and provide an opportunity for a hearing to the relevant drug sponsors; if drug sponsors timely request hearings and raise a genuine and substantial issue of fact, the FDA must hold a public evidentiary hearing.”¹²

⁸ *Id.* at 5-17.

⁹ *Id.*

¹⁰ *Natural Res. Def. Council v. FDA*, No. C11-03562, 2012 WL 983544 (S.D.N.Y. Mar. 22, 2012); *Natural Res. Def. Council v. FDA*, No. C11-03562, 2012 WL 1994813 (S.D.N.Y. June 1, 2012).

¹¹ *Natural Res. Def. Council v. FDA*, No. C11-03562, 2012 WL 983544 (S.D.N.Y. Mar. 22, 2012).

¹² *Id.* at *20.

In the second, the court found that “FDA failed to offer a reasoned explanation, grounded in the statute, for its refusal to initiate withdrawal proceedings [on petitions to withdraw certain medically important antibiotics], and, therefore, its action was arbitrary and capricious and otherwise not in accordance with law.”¹³ The court has required the FDA to “evaluate the safety risks” of these medically important antibiotics, and “either make the finding that the drugs are not shown to be safe or provide a reasoned explanation as to why the Agency is refusing to make such a finding.” The court explained that while the administrative record was over 3,000 pages long and contained numerous scientific studies, FDA “did not address or even mention the scientific evidence in its responses.” FDA therefore woefully failed for to comply with its duty to review the citizen petitions for seven and twelve years respectively.

In both orders, the court does not compel FDA to reach a certain conclusion, only finds that the agency comply with the relevant procedures. That said, CFS believes that once the agency complies with its statutory duties, the weight of the evidence will mandate immediate withdrawal of NADAs and ANADAs for medically important antibiotics.

VOLUNTARY ACTION IS NOT ENOUGH – FDA MUST INITIATE WITHDRAWAL PROCEEDINGS

CFS encourages FDA not to naively and unlawfully rely on a voluntary participation scheme to reduce antimicrobial resistance. FDA does not deny it has the authority to withdraw NADAs and ANADAs for antimicrobials, nor does it deny that there is an urgent public health crisis emerging from the overuse and abuse of antimicrobials in animal agriculture. Yet FDA’s present course of action is to promote voluntary measures for industry to implement, over time, as the solution to this immediate crisis. Voluntary oversight schemes spanning many fields have an abysmal record of failure, in part because the regulated industries have no incentive to change. It is highly unlikely the drug sponsors that make a profit from the use of antimicrobials in food animal production, or animal production facilities that use antimicrobials in food animal production to counteract overcrowded and unsanitary conditions, will voluntarily end the practice. Moreover, FDA has a statutory duty to withdraw New Animal Drug Applications for important human antimicrobials forthwith.

The Federal Food, Drug and Cosmetics Act (FFDCA) defines a “new animal drug” as “*any drug intended for use for animals other than man, including any drug intended for use in animal feed...*”¹⁴ Antimicrobials used in animal agriculture are “new animal drugs.” The FDA must withdraw approval of an NADA when a drug is found to be unsafe.¹⁵ Under the FFDCA §360(b), the Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of a new animal drug if the Secretary finds:

¹³ *Natural Res. Def. Council v. FDA*, No. C11-03562, 2012 WL 1994813, at *19 (S.D.N.Y. June 1, 2012) (citing *Mass. v. EPA*, 549 U.S. 497, 534 (2007)).

¹⁴ 21 C.F.R. § 510.3(g) (2009) (emphasis added).

¹⁵ See 21 U.S.C. § 360b(e)(1) (2009).

- A. “[E]xperience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved or the condition of use authorized under subsection (a)(4)(A);”¹⁶
- B. New evidence, tests, or methods developed since approval of the application show that the drug is not safe for use “under the conditions of use upon the basis of which the application was approved...; or”¹⁷
- C. New information, combined with the evidence available at the time the application was approved show a “lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.”¹⁸

The FFDCFA creates a mandatory duty to withdraw when new evidence shows an animal drug to be unsafe.¹⁹ When determining whether a new animal drug (or category of new animal drugs) must be withdrawn for safety purposes, two issues are considered: whether there is a reasonable basis from which serious questions about the safety of the new animal drug may be inferred; and, whether the use of the new animal drug under the approved conditions is shown to be safe.²⁰

When applied to antimicrobials used in food animals, the above provisions indicate a statutory duty to withdraw. Antimicrobial resistant infections threaten human health. For example, *methicillin-resistant Staphylococcus aureus* (MRSA) is established in concentrated animal feeding operations (CAFOs) in the U.S. and routinely infects workers and their families.²¹ Evidence now exists that livestock associated MRSA, sequence type 398 (“ST398”) has entered general population in the U.S. In March of this year, U.S. researchers reported that a childcare worker in Iowa, with no connection to livestock, had tested positive for ST398.²² The appearance of ST398 in the U.S. is part of a growing global phenomenon: livestock associated MRSA, with corresponding worker infections, has been documented in food animal facilities and slaughterhouses in Europe and in Canada.²³ In the last five years infections in humans from ST398 have ranged from relatively minor to fatal.²⁴ The first recorded fatality occurred in August 2010 when a previously healthy fourteen year old girl died from necrotizing pneumonia

¹⁶ *Id.* § 360b(e)(1)(A).

¹⁷ *Id.* § 360b(e)(1)(B).

¹⁸ *Id.* § 360b(e)(1)(C).

¹⁹ *Rhone-Poulenc, Inc. v. FDA*, 636 F.2d 750, 752-53 (D.C. Cir. 1980) (upholding FDA’s order withdrawing the new animal drug approval for the use of diethylstilbestrol (DES)).

²⁰ Ctr. for Veterinary Med., FDA, *Proposal to Withdraw Approval of the New Animal Drug Application for Enrofloxacin for Poultry*, Docket No. 00N-1571 at 2 (Mar. 16, 2004) (initial decision).

²¹ Tara Smith & Nicole Pearson, *The Emergence of Staphylococcus Aureus ST398*, 11 *Vector-Borne and Zoonotic Diseases* 327, 331, (2011).

²² Erin Moritz & Tara Smith, *Livestock-Associated Staphylococcus Aureus in Childcare Worker*, 17.4 *Emerging Infectious Diseases*, (Apr. 2011), available at <http://www.cdc.gov/eid/content/17/4/742.htm>.

²³ Smith & Pearson, *supra* note 20, at 328.

²⁴ Smith & Pearson, *supra* note 20, at 332.

caused by MRSA ST398.²⁵ A 2010 study warned that it would be a mistake to assume that ST398 will continue to be responsible for relatively little disease compared to other MRSA strains.²⁶ Researchers analyzing the ST398 genome report that the organism has an unusual capacity to incorporate more dangerous elements, predicting that “it will only be a matter of time before [ST398] will increase virulence in the human host.”²⁷

MRSA is but one example of antimicrobial resistant infections threatening human health. Final Guidance 209 provides an overview of national and international reports and peer-reviewed scientific literature discussing adverse human health consequences from antimicrobial resistance and recommending for more than a decade that the U.S. take drastic measures to address the ongoing and future consequences. For example:

- In 1997, the WHO found that “the selection of resistant bacteria has adverse consequences for preventing and treating disease in humans, animals, and plants” recommending that “the use of antimicrobials for growth promotion in animal production be terminated if the drugs are also proscribed for use in humans.”²⁸
- In 2003, the Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (OIE), and the WHO convened a workshop to scientifically assess the risks of antimicrobial use in food animal production. The expert panel found “clear evidence of adverse human health consequences due to resistant organisms resulting from non-human usage of antimicrobials.”²⁹
- In 2003, the Institute of Medicine recommended that “FDA ban the use of antimicrobials for growth promotion in animals if those classes of antimicrobials are also used in humans.”³⁰
- In 2004, the United States Government Accountability Office (GAO) concluded that animals are the source of human infection. The GAO stated, “[w]e believe that there is a preponderance of evidence that the use of antimicrobials in food producing animals has adverse human consequences.”³¹
- In 2009, the American Academy of Microbiology recommended the elimination of unnecessary use such as for viral infections and prolonged treatment as “mandatory steps to an appropriate public health strategy to limit infections by resistant organisms.”³²

²⁵ Jean-Philippe Rasigade et al., *Lethal Necrotizing Pneumonia Caused By An ST398 Staphylococcus Aureus Strain*, 16.8 Emerging Infectious Diseases, 1330 (Aug. 2010), available at <http://wwwnc.cdc.gov/eid/article/16/8/pdfs/10-0317.pdf>.

²⁶ M. Schijffelen et al., *Whole Genome Analysis of a Livestock-Associated Methicillin-Resistant Staphylococcus aureus ST398 Isolate From a Case of Human Endocarditis*, 11 BMC Genomics, (2010) available at <http://www.biomedcentral.com/1471-2164/11/376> (last visited July 10, 2012)..

²⁷ *Id.* at 8.

²⁸ FDA, *Guidance 209*, *supra* note 5, at 8 (citing WHO Report, *The Medical Impact of Antimicrobial Use in Food Animals* (1997)).

²⁹ *Id.* at 11 (citing FAO et al. Report, *Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Scientific Assessment* (2003)).

³⁰ *Id.* (citing Inst. of Med. Report, *Microbial Threats to Health: Emergence, Detection and Response* (2003)).

³¹ *Id.* at 12 (citing 2004 GAO Report).

³² *Id.* at 14 (citing Am. Acad. of Microbiology, *Antibiotic Resistance: An Ecological Perspective on an Old Problem* (2009)).

- In 2012, Proceedings at the National Academy of Sciences concluded that “[e]ven a low, short-term (14-day) dose of in-feed antibiotics increased the prevalence and diversity of antibiotic resistance genes, including resistance to antibiotics not administered in the study, and increased the prevalence in *E. coli*.”³³

It is clear that immediate cessation of antibiotic use in food animal production systems can ameliorate the problems of antibiotic resistance and address the public health crisis. When antimicrobials are removed from food animal production, the incidents of resistance are drastically reduced. A recent study found a lower prevalence of antibiotic-resistant *Enterococci* on U.S. conventional poultry farms that recently transitioned to organic practices.³⁴ Another found that the prevalence of ampicillin-resistant and tetracycline-resistant *E. coli* was three- and four-fold greater in feces from antibiotic-treated animals respectively.³⁵

The scientific data in the agencies own guidance documents presents serious questions about the safety of using medically-important antimicrobials in food animal production. FDA’s proposed three-year voluntary phase out flies in the face of FDA’s statutory duty and is clearly not a strong enough measure to protect human health from the effects of antimicrobial use. Instead, “[a]n immediate ban on classes of antibiotics used therapeutically in humans, when used for growth promotion and prophylaxis in livestock”³⁶ is required. CFS urges FDA to take immediate and legally binding action to limit the use of antimicrobials in food animal production.

If FDA should refuse to withdraw NADAs and ANADAs for antimicrobials in violation of its duty under the FFDCA, it should make the following fundamental changes to Guidance 213.

FDA MUST ELIMINATE DISEASE PREVENTION USES AS WELL AS GROWTH PROMOTION USES

FDA’s guidance documents do not attempt to reduce or eliminate the use of antimicrobials for other injudicious uses, such as “disease prevention.” Final Guidance 209 and Draft Guidance 213 are non-binding recommendations which seek to address the use of medically important antimicrobial drugs in food animals for “production uses” only. FDA explains that “production uses” are those uses typically administered through feed or water on a herd-wide or flock-wide basis and are approved for increasing weight gain or improving feed efficiency.³⁷ While CFS agrees that antimicrobials may be used in certain circumstances to treat disease, disease prevention uses are often surprisingly similar to production uses—applied at sub-clinical doses, on a flock wide basis, to healthy animals—and also contribute to growing

³³ *Id.* at 17 (citing Nat’l Acad. Of Sci. Report, *In-feed Antibiotic Effects on the Swine Intestinal Microbiome* (2012)).

³⁴ *Id.* at 16 (citing 2011 Environmental Health Perspectives Study).

³⁵ *Id.* at 16 (citing Int’l J. of Food Microbiology Study, *Farm-to-fork Characterization of Escherichia coli Associated with Feedlot Cattle with a Known History of Antimicrobial Use* (2010)).

³⁶ Susan Holtz, Can. Inst. for Env’tl. Law and Policy, *Reducing and Phasing Out the Use of Antibiotics and Hormone Growth Promoters in Canadian Agriculture* (Apr. 2009), available at www.cielap.org/pdf/AHGPs.pdf.

³⁷ FDA, *Guidance 209*, *supra* note 5, at 4.

prevalence of antimicrobial resistance. FDA should therefore promote withdrawal of label uses for production uses and routine disease prevention.

Instead, Guidance 213 encourages drug sponsors to change label uses from production uses such as growth promotion to disease prevention where such classes of antimicrobials have disease prevention qualities. It is unlikely that this action will reduce the prevalence of antimicrobial resistance since all medically important classes of antimicrobials with growth promoter claims have continuous disease prevention claims in at least one species. Moreover, disease prevention uses currently have no limit on duration for administration, and are given simultaneously to all animals in a herd or flock. For this reason, CFS encourages FDA to alter Draft Guidance 213 and not approve supplemental new animal drug applications for disease prevention but instead eliminate the use of antimicrobials for disease prevention as well as growth promotion.

If FDA remains nonetheless willing to approve supplemental NADAs to add disease prevention label uses to already approved antimicrobial new animal drugs, CFS encourages FDA to use Guidance 152 to evaluate any supplemental NADAs submitted pursuant to Guidance 213 and not create an exemption to the current requirement of a complete, qualitative, microbial food safety risk assessment.

FDA MUST INCREASE TRANSPARENCY

Another major weakness of Guidance 209 and Draft Guidance 213 is a severe lack of transparency and meaningful, timely public participation. For instance, it is unclear how the public will be able to verify that this process is actually limiting the use of antimicrobials in food animal production. By failing to provide transparency in record-keeping, FDA essentially suggests that the American public serve as guinea pigs for industry's "voluntary" reduction in antibiotic usage. CFS urges FDA to implement a transparent process whereby the public can assess whether the guidance documents are resulting in changes to the use of antimicrobials in food animal production and whether there is a public health benefit associated with those changes. The public should not be the government's laboratory for this compromised approach.

In order to increase transparency, CFS encourages FDA to publish data on (1) the number of companies notifying FDA of the intent to participate in FDA's program within three months of the finalization of Draft Guidance 213; (2) the number of companies that have products that are applied for production uses or routine disease prevention (as opposed to disease treatment); (3) the number of supplemental NADAs submitted pursuant to Guidance 213; and (4) a list of animal drugs that are still in use but not in compliance with Guidance 213. FDA should provide the public with quarterly updates on these and other relevant figures.

Moreover, FDA must develop a monitoring framework that includes certain targets for reductions in antimicrobial use and associated antimicrobial resistance so that the effectiveness of Guidance documents 209 and 213 can be evaluated. This monitoring program should describe specific anticipated results and address potential actions should these results not be met. Finally, FDA should include a monitoring program for on farm antibiotic use. Again, monitoring data must be based on samples taken early in the food chain process.

FDA MUST INCREASE VETERINARY OVERSIGHT

“FDA believes that the judicious use of medically important antimicrobial drugs intended for use in food-producing animals should involve the scientific and clinical training of a veterinarian.”³⁸ Yet, the voluntary nature of the Guidance makes this action implausible in light of producers’ belief that “animal pharmacology already is regulated and monitored by veterinarians much the same way human pharmaceuticals are monitored by physicians.”³⁹ This is not the case. Human antibiotics are administered only via prescription while “[m]ost of the [animal] feed-use antimicrobial drugs are currently approved for over-the-counter use.”⁴⁰

FDA itself argues that ensuring that veterinarians oversee the administration of antibiotics in food animals “is an important mechanism for helping to ensure appropriate use” of antibiotics in food animal production.⁴¹ CFS encourages FDA to use its regulatory authority to strengthen veterinary oversight of animal drugs. FDA can do this, in part, by developing a strong final Veterinary Feed Directive (VFD) Rule.⁴²

CONCLUSION

For the foregoing reasons, CFS urges FDA to use its regulatory authority to require producers to discontinue the non-therapeutic use of antimicrobial drugs in food animals.

Respectfully Submitted,

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³⁸ Ctr. For Veterinary Med., FDA, #213 Draft Guidance: *New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209* at 6 (Apr. 11, 2012).

³⁹ *Antibiotics In Agriculture - The Real Story*, Pork Magazine, (Aug. 19, 2010), available at http://www.porkmag.com/news_editorial.asp?pgID=675&ed_id=9783.

⁴⁰ Ctr. For Veterinary Medicine, FDA, #209 Draft Guidance for Industry: *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* at 11 (June 28, 2010) available at http://www.avma.org/advocacy/federal/regulatory/public_health/FDA_Draft_Guidance_209.pdf.

⁴¹ *Id.* at 17.

⁴² Center for Food Safety supports the Keep Antibiotics Working coalition’s recommendations on the Docket No. FDA–2010–N–0155: Veterinary Feed Directive; Draft Text of Proposed Regulation. Specifically, CFS opposes (1) removing requirements that veterinary feed directive (VFD) drugs only be issued in the context of a valid veterinarian-client-patient relationship, and (2) removing requirements that distributors keep records of the receipt and distribution of feeds containing VFD drugs. Additionally, CFS supports inclusion of a new requirement that distributors submit records to FDA regarding distribution of all animal feed containing a VFD drug.

