Chronology of Antibiotics for Food Animals in the United States
April 13, 2015
Keep Antibiotics Working

Prior to 1962 – penicillin, streptomycin, chlortetracycline, chloramphenicol, and bacitracin were regulated for human and animal use by batch certification. Other animal drugs subject to same standard as human drugs.

1962 – Drug Amendments of 1962, PL 87-781, requires Food and Drug Administration ("FDA") to find that new human and animal drugs are both safe and effective.

1968 - Animal Drug Amendments of 1968, PL 90-399, consolidates regulations for animal drugs, including requiring a regulation for each new approved drug and continuing in effect any past approvals subject to further FDA review.

April 1970 – FDA Commissioner establishes Antibiotics in Animal Feed Task Force.

January 1972 – FDA Task Force recommends restrictions on antibacterial agents in animal feeds.

February 1972 – FDA proposes to revoke approvals for subtherapeutic uses of anti-bacterial agents unless new safety data are submitted. 37 Fed. Reg. 2444 (February 1, 1972).

August 1977 – FDA proposes to withdraw approval for all use of penicillin in animal feeds because new evidence shows subtherapeutic use is not safe for people and therapeutic use is not effective. 42 Fed. 43770 (August 30, 1977)

October 1977 – FDA proposes to withdraw its approval for subtherapeutic use of tetracycline in animal feeds because new evidence shows that such use is not safe for people. 42 Fed. Reg. 56264 (October 21, 1977).

1980 – National Academies of Science, in response to a request from House Appropriations committee, concludes that evidence is inconclusive as to whether subtherapeutic use of antibiotics in food animals is a human health risk.

May 1980 – Representatives Dingell and Waxman introduce a bill (HR 7285) to limit the subtherapeutic use of antibiotics in animal feed.

June 1980 – House report on FY 1981 FDA appropriation directs the FDA "to hold in abeyance" its proposal to restrict the use of penicillin and tetracycline in food animals until further research is done. H.R. Rept. 96-1095 (June 17, 1980) at 106.

1984 – Study commissioned by FDA shows link in tetracycline resistance in people and chickens

November 1988 – Generic Animal Drug and Patent Term Restoration Act, PL 100-670, extends to animal drug the benefits given to generic human drugs, including selling generic drug without duplicating previous evidence on safety and efficacy.

October 1994 – Animal Medicinal Drug Use Clarification Act of 1994, PL 103-396, allows in some circumstances off-label use of approved animal drugs.

September 1996 – Animal Drug Availability Act, PL 104-250, makes the approval process of animal drugs more flexible.

October 1996 – FDA approves, over the objection of the Centers for Disease Control, the use of fluoroquinolones for sick poultry.

March 1999 – Center for Science in the Public Interest, Environmental Defense Fund, Food Animal Concerns Trust, Public Citizen's Health Research Group, and Union of Concerned Scientists petition FDA to ban the nontherapeutic use of six medically important antibiotics in animal feed.

November 1999 – introduction in 106th Congress of Preservation of Essential Antibiotics for Human Diseases Act (HR 3266) to review safety of currently approved medically important antibiotics used to promote growth of food animals.

October 2000 – FDA announces it is asking the two manufacturers of fluoroquinolones for sick chickens to stop selling it. 65 Fed. Reg. 64,954 (October 31, 2000). While Abbott agrees, Bayer asks for an administrative hearing.

November 2000 – Congress directs Secretary of Health and Human Services to create an interagency task force to advise the Secretary on steps to address the public health threat of antimicrobial resistance. P.L. 106-505 section 319E.

December 2000 – FDA issues regulations governing veterinary feed directive drugs. 65 Fed. Reg. 76924.

November 2001 – conference report on FY 2002 FDA appropriation adds an additional $3 million for antibiotic research (following House vote on June 28, 2001 of 271-140 in favor of floor amendment). H.R. Rept. 107-275 at 82.

February 2002 – introduction in 107th Congress of Preservation of Antibiotics for Medical Treatment Act (HR 3804 and S 2508) to review safety of currently approved medically important antibiotics used to promote growth of food animals and in Senate version to ban the use of fluoroquinolones in poultry and to authorize transition payments to farmers to reduce use of antibiotics in agriculture.

November 2002 – Animal Drug User Fee Act, PL 108-130, authorizes collection of fees from animal drug companies and establishes goals for FDA's review of animal drugs.

July 2003 – introduction in 108th Congress of Preservation of Antibiotics for Medical Treatment Act (HR 2932 and S 1460) to review safety of currently approved medically important antibiotics used to promote growth of food animals, to collect data on use of medically important antibiotics in food animals, and in Senate version to authorize research and transition payments to farmers to reduce such use.

October 2003 – FDA issues Guidance 152 on how it will evaluate the safety of new antimicrobial animal drugs and establishes a three-tier ranking of the importance of human antibiotics based on their importance in treating food-borne infections.

December 2003 – conference report on FY 2004 USDA appropriation bill "strongly encourages" USDA to not purchase chickens for school lunches that were given fluoroquinolones. H.R. Rept. 108-401 at 463.

March 2004 – Administrative Law Judge ("ALJ") orders that Bayer's fluoroquinolone be withdrawn. Bayer appeals to the FDA Commissioner.

May 2004 – Citing its 1977 proposal, FDA asks three producers of penicillin for animals to respond to FDA's concerns about the products' impact on antibiotic resistance.

August 2004 – Minor Use and Minor Species Animal Health Act. PL 108-282, makes it easier to get FDA approval of animal drugs for fish and other "minor species".

February 2005 – World Health Organization establishes a three-tier ranking of the importance of human antibiotics based on their importance in treating all human infections.

April 2005 – Environmental Defense, American Academy of Pediatrics, American Public Health Association, Food Animal Concerns Trust, and Union of Concerned Scientists petition FDA to ban herdwise/flockwise use of seven medically important antibiotics for growth promotion or certain disease prevention.

August 2005 – introduction in 109th Congress of Preservation of Antibiotics for Medical Treatment Act (HR 2562 and S 742) to review safety of currently approved medically important antibiotics used to promote growth of food animals, to collect data on use of medically important antibiotics in food animals, and in Senate version to authorize research and transition payments to farmers to reduce such use.

September 2005 – FDA Commissioner affirms ALJ's fluoroquinolone decision and orders Bayer to remove it from the market on September 12, 2005. Bayer does not appeal to the Court of Appeals.

September 2006 – FDA advisory committee votes 6 to 4 that the FDA should not approve the use of a fourth-generation cephalosporin to treat sick cattle and that, if approved, its off-label

uses should be restricted.

February 2007 – introduction in 110th Congress of Preservation of Antibiotics for Medical Treatment Act (HR 962 and S 549) to review safety of currently approved medically important antibiotics used to promote growth of food animals, to collect data on use of antibiotics in food animals, and in Senate version to authorize research and transition payments to farmers to reduce such use.

July 2007 – House report on FY 2008 FDA appropriation "directs" FDA to report by end of February 2008 on its revision of its criteria for assessing the safety of animal dugs and to finish its review of penicillin in animal feed by June 30, 2008. H.R. Rept. 110-258 at 98, 99.

July 2008 – section 7521 of Food, Conservation, and Energy Act, PL 110–234, authorizes research and education grants to farmers to reduce use of antibiotics in agriculture.

July 2008 – FDA proposes banning in the fall of 2008 the extra-label use of all cephalosporin antibiotics in food-producing animals. 73 Fed. Reg. 38110 (July 3, 2008).

August 2008 – section 105 of Animal Drug User Fee Amendments of 2008, PL 110-316, directs FDA to collect and publish data on annual use of antibiotic animal drugs in food-producing animals.

November 2008 – FDA announces it will not ban the extra-label use of all cephalosporin antibiotics in food-producing animals. 73 Fed. Reg. 71923 (November 26, 2008)

February 2009 -- Conference report on FY 2009 FDA appropriations "encourages" FDA to work with USDA and CDC "to address the issue of MRSA in domestic farm animals." Committee Print on Omnibus Appropriations Act, 2009 at 45-46.

March 2009 – introduction in 111th Congress of Preservation of Antibiotics for Medical Treatment Act (HR 1549 and S 619) to review safety of currently approved medically important antibiotics used to promote growth of food animals.

June 28, 2010 – FDA asks for public comment on its proposed Guidance 209 that in order to protect the public health there be a voluntary reduction in using medically important antibiotics to accelerate the growth of food animals.

July 14, 2010 – At hearing of House Energy and Commerce Committee, the FDA, the Centers for Disease Control, and the United States Department of Agriculture each testify that there is substantial scientific evidence that the use of antibiotics in food animals leads to resistant infections in people.

July 2010 – Senate report on FY 2011 FDA appropriation says FDA should evaluate the safety of antibacterial drugs currently approved for use in food-producing animals to ensure that such

uses are consistent with the standards currently used in premarket safety reviews and should report the results to the Committee within one year. S. Rept. 111-221 at 94.

December 2010 – Pursuant to the Animal Drug User Fee Amendments of 2008, FDA reports that in 2009 drug companies sold in the United States 28.7 million pounds of antibiotics for use in food animals.

March 2011 and June 2011 – introduction in 112th Congress of Preservation of Antibiotics for Medical Treatment Act (HR 965 and S 1211) to review safety of currently approved medically important antibiotics used to promote growth of food animals.

May 25, 2011 – Natural Resources Defense Council, Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, and Union of Concerned Scientists file suit in New York City asking a federal judge to order the FDA to withdraw its approvals for the subtherapeutic use of penicillins and tetracyclines in animal feed and to act on the March 1999 and April 2005 petitions.

June 15, 2011 – On a point of order, section 740 – prohibiting the FDA from restricting the use of any substance unless it is based on "hard science" -- is struck from the FY 2012 FDA appropriations bill, HR 2112.

September 2011 – Senate report on FY 2012 FDA appropriation: (1) directs the FDA to set a timeline for when it will issue final version of Guidance 209, any changes in the Veterinary Feed Directive, and order regarding extra label uses of cephalosporins and (2) recommends that the FDA take steps to assure that currently approved antibiotics for use in food animals meet current safety standards. S. Rept. 112-73 at 80.

October 2011 -- Pursuant to the Animal Drug User Fee Amendments of 2008, FDA reports that in 2010 drug companies sold in the United States 29.1 million pounds of antibiotics for use in food animals (after initially reporting 2010 sales of 31 million pounds).

November 2011 – FDA denies March 1999 and April 2005 petitions.

December 2011 – FDA announces it is closing its 1977 investigations of the safety of using penicillin and tetracycline in animal feeds. 76 Fed. Reg. 79697 (December 22, 2011).

January 2012 – FDA announces that beginning in April 2012 it will restrict some extra-label uses of cephalosporin antibiotics in food animals. 77 Fed. Reg. 735 (January 6, 2012).

March 22, 2012 -- Federal judge orders the FDA to institute its 1977 bans on the use of penicillins and tetracyclines in animal feed unless the companies present evidence that such use is safe; in May the FDA appeals.

April 2012 – FDA issues final version of Guidance 209 urging voluntarily limiting medically important antibiotics to uses in food animals that are necessary for assuring animal health and selling such drugs only pursuant to a veterinarian's prescription. FDA asks for public comments on draft Guidance 213 to inform drug companies how to voluntarily modify their product labels in order to conform to Guidance 209. FDA also asks for public comment on the draft text of a proposed regulation to facilitate the transition of certain animal drugs from an over-the-counter status to a status that requires veterinary oversight. 77 Fed. Reg. 22217 (April 13, 2012).

April 2012 – Senate report on FY 2013 FDA appropriation directs FDA to report within 120 days of the issuance of the final Guidance 213 on compliance with Guidance 213 and how FDA will meet its public health responsibility. S. Rept. 112-163 at 78.

June 1, 2012 – Federal judge orders the FDA to determine whether the scientific evidence supports the claims of the March 1999 and April 2005 petitions that the nontherapeutic use of seven classes of medically important antibiotics is unsafe and to initiate withdrawal proceedings for those that it determines are unsafe; in September FDA appeals.

June 2012 – House report on FY 2013 FDA appropriation directs USDA and FDA to seek public comment on collecting more detailed data on antibiotic use in food-producing animals and then to work collaboratively to develop a strategy for implanting the best approach; FDA is also directed to ensure that USDA continues to analyze and report on NARMS data. H.R. Rept. 112-542 at 47.

July 2012 – FDA seeks comments on possible changes to its regulations relating to records and reports on antibiotic use in food-producing animals. 77 Fed. Reg. 44177 (July 27, 2012).

August 8, 2012 – Federal judge orders the FDA within 17 months to notify penicillin and tetracycline producers of their opportunity to request a hearing to show that the nontherapeutic use of such drugs in food animals is safe and, if the companies request a hearing, an additional 41 months to complete the process.

February 2013 -- Pursuant to the Animal Drug User Fee Amendments of 2008, FDA reports that in 2011 drug companies sold in the United States 29.8 million pounds of antibiotics for use in food animals.

February 2013 – introduction in 113th Congress of Delivering Antimicrobial Transparency in Animals Act of 2013 (HR 820): (1) to require manufacturers of food animal antibiotic drugs by March 31 to submit additional previous year's sales data to the FDA; (2) to require large live poultry dealers, swine contractors, and feed lot operators by March 31 to submit to the FDA information on the previous year's use of such drugs in animal feed; (3) to require the FDA to disclose more of the food animal antibiotic drug sales and use data; (4) to require the FDA to make public summaries of these data by November 30; (5) to have the FDA increase its collaboration with the USDA on collecting data on the use of antibiotics in food animals; (6) to

have the FDA publish the final version of Guidance 213 within 180 days; and (7) to have the GAO within three years of the issuance of Guidance 213 commence a study evaluating its effectiveness and the effectiveness of the FDA's data collection regarding antibiotic resistance and to report to Congress within one year the results of this study.

March 2013 – introduction in 113th Congress of Preservation of Antibiotics for Medical Treatment Act of 2013 (HR 1150) to review safety of currently approved medically important antibiotics used to promote growth of food animals.

May 2013 -- introduction in 113th Congress of Antimicrobial Data Collection Act (S 895): (1) to have the FDA, in consultation with USDA, develop within 180 days a pilot data collection research program and within two years report to Congress the results of this program, (2) to require the FDA to disclose more of the food animal antibiotic drug sales and use data; (3) to require the FDA annually to make public summaries of these data by a date established by FDA; (4) to have the FDA publish the final version of Guidance 213 within 180 days; and (5) to have the GAO within three years of the completion of the pilot research program commence a study evaluating the effectiveness of Guidance 213 and the effectiveness of the FDA's data collection regarding antibiotic resistance and to report to Congress within one year the results of this study.

June 2013 -- House report on FY 2014 FDA appropriation directs FDA to issue final version of Guidance 213 by January 1, 2014 and to issue annual reports on its implementation. FDA and USDA are directed to collect data on antibiotic use in food animals, and FDA is directed to ensure that USDA continues to analyze and report on NARMS data. H.R. Rept. 113-116 at 53, 56.

June 2013 – Senate report on FY 2014 FDA appropriation directs FDA to publish more detailed data on antibiotic use in food animals. S. Rept. 113-46 at 79.

June 19, 2013 – House passes by voice vote Slaughter amendment to Federal Agriculture Reform and Risk Management Act (HR 1947) that authorizes USDA to study through 2018 antibiotic resistant bacteria.

June 2013 -- introduction in 113th Congress of Preventing Antibiotic Resistance Act of 2013 (S 1256) to review safety of currently approved medically important antibiotics used to promote growth of food animals and to enact a sense of the Senate regarding veterinary oversight of the use of medically important antibiotics.

June 2013 – Animal Drug and Animal Generic Drug User Fee Authorization Act of 2013, PL 113-14, authorizes through September 30, 2018 the collection of fees from animal drug companies and establishes goals for FDA's review of animal drugs.

December 2013 – FDA asks for public comment on proposed amendment to make more efficient the 2000 regulations governing veterinary feed directive (VFD) drugs, including (1) replacing the current federal definition of the veterinary-client-patient relationship with one defined by

each state, (2) allowing some VFD drugs to be distributed by unlicensed feed mills rather than only by licensed feed mills, and (3) reducing the time veterinarians, distributors, and clients must keep VFD records from the current two years to one year. 78 Fed. Reg. 75515 (December 12, 2013). FDA also issues final Guidance 213 informing drug companies how to voluntarily modify their product labels in order to conform to Guidance 209 and asking that they complete this process by the later of (a) December 2016 or (b) the issuance of the final VFD regulations.

May 2014 – Senate report on FY 2015 FDA appropriations bill urges FDA to develop a strategy for ensuring that the use of medically important antibiotics for disease prevention in food animals is judicious and appropriate, directs the FDA to issue the final VFD regulation by April 1, 2015, and encourages FDA to include a provision that veterinarians be familiar with the food animals and their premises when prescribing medically important antibiotics. S. Rept. 113-164 at 81.

June 2014 – House report on FY 2015 FDA appropriations bill encourages FDA to continue to use NARMS data and directs FDA to issue the final VFD regulation by December 2014. H.R. Rept. 113-468 at 62.

July 24, 2014 – In a 2-1 decision, a panel of the Court of Appeals for the Second Circuit reverses the district court decisions of March 2012 and June 2012; in September the plaintiffs petition the 13 active judges to rehear the case.

October 2014 – Pursuant to the Animal Drug User Fee Amendments of 2008, FDA reports that in 2012 drug companies sold in the United States 32.2 million pounds of antibiotics for use in food animals, including 19.6 million pounds of antibiotics that the FDA considers to be medically important for human use.

March 2015 – introduction in 114th Congress of Preventing Antibiotic Resistance Act of 2015 (S. 621) (1) to ban the use of those medically important antibiotics to prevent or control disease in food animals for which the FDA has not established a specific duration of treatment or specific dosage and for which the drug company fails to show that such use is safe for people and (2) to enact a sense of the Senate regarding veterinary oversight of the use of medically important antibiotics.

March 2015 – introduction in 114th Congress of Preservation of Antibiotics for Medical Treatment Act of 2015 (HR 1552) to review the safety of currently approved medically important antibiotics used to promote growth of food animals.

April 2015 -- Pursuant to the Animal Drug User Fee Amendments of 2008, FDA reports that in 2013 drug companies sold in the United States 32.6 million pounds of antibiotics for use in food animals, including 20.2 million pounds of antibiotics that the FDA considers to be medically important for human use.