

January 9, 2008

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Mr. Cort Jensen  
Montana Department of Agriculture  
303 North Roberts  
P.O. Box 200201  
Helena, MT 59620-0201

Re: drafting rules to implement Montana's Certified Natural Beef Program (MCA 80-11-801)

Dear Mr. Jensen:

Keep Antibiotics Working (KAW) appreciates this opportunity to provide input on the development of the Montana Certified Natural Beef Program. Keep Antibiotics Working ([www.KeepAntibioticsWorking.com](http://www.KeepAntibioticsWorking.com)) is a coalition of health, consumer, agricultural, environmental, humane and other advocacy groups with more than nine million members dedicated to eliminating a major cause of antibiotic resistance: the inappropriate use of antibiotics in food animals. To ensure the continued effectiveness of antibiotics important for treating sick people and animals, KAW advocates for a responsible approach to antibiotic use in animal agriculture. More specifically, KAW seeks to end the non-therapeutic agricultural use of antibiotics important to human medicine, a position supported by over 350 organizations including the American Medical Association, the Infectious Diseases Society of America, and the American Academy of Pediatrics.

The Montana Certified Natural Beef Program has great potential to create economic benefits for Montana producers, as well as protect the public's health. It is essential that the Program adopt and implement strong standards to ensure the integrity of its brand, including standards regarding antibiotic use.

KAW recommends that the Montana Department of Agriculture include among its certification criteria for Montana Certified Natural Beef a requirement that cattle *not be given medically important antibiotics for non-therapeutic purposes*, defined as follows:

**Non-therapeutic use** is any use of an antibiotic as a feed or water additive for an animal in the absence of a clinical sign of disease. Non-therapeutic uses generally include growth promotion, feed efficiency, weight gain, improved pigmentation, routine disease prevention, or any other routine purpose. Antibiotic uses for disease prevention are considered non-therapeutic unless it can be shown that one or more animals within a barn, pasture, or feedlot carry a disease, or unless an infection likely to occur because of a specific, non-customary situation (e.g. injury to an animal).

**Medically important antibiotics** are those important to human medicine. Policy guidance from the FDA defines seven such classes of antibiotics: penicillins, tetracyclines, macrolides, lincosamides, streptogramins, aminoglycosides, and sulfonamides.

Alternatively the Montana Department of Agriculture may want to consider a stricter standard depending upon its marketing objectives. To fully participate in premium markets, adoption of a more restrictive standard may be necessary. Several groups have taken this approach. For example, the Food Alliance, one of the nation's leading certification organizations for environmentally friendly and socially responsible agriculture products, administers a standard for participation in its certification program that restricts *all* antibiotics used for non-therapeutic purposes, including drugs not used in human medicine. Beef cattle produced by the Association of Family Farms and Niman Ranch are also produced without non-therapeutic use of medically and non-medically important antibiotics.<sup>1</sup>

Other programs, along with the recently proposed 'Naturally Raised' process-verified label from USDA, are even more restrictive, through the prohibition of antibiotic use for both therapeutic and non-therapeutic purposes (while therapeutic antibiotics can be used, meat from animals treated with therapeutic antibiotics must be diverted to conventional markets). Brands such as Coleman Natural Beef adhere to a "no antibiotics—ever" policy<sup>2</sup>; organically certified meats are also raised without any antibiotics. In the past year, the South Dakota Department of Agriculture has expanded its South Dakota Certified Enrolled Cattle™ (SDCEC) program to include a more restrictive Natural program. For the SDCEC Natural program, "Natural" means that no hormones have been administered to the cattle, and the cattle have been raised without the use of antibiotics or ionophores.<sup>3</sup> The more restrictive standards may be more difficult for producers to comply with, but they may be easier for consumers and producers to understand, particularly given the absence of federal standards defining non-therapeutic use at the present time.

In addition to the adoption of a strong antibiotic use standard, we also urge the Montana Department of Agriculture to implement a system to monitor and identify any livestock treated with allowable antibiotics. As part of this system, KAW recommends that the Montana Department of Agriculture establish a program to collect records of production practices employed by certified producers including, but not necessarily limited to, information on antibiotic use. If specific antibiotics and uses are permitted, a comprehensive system that requires farmers to keep records on use would be essential to protect the brand. Montana might also want to consider a system that would make relevant drug use information available to consumers. Consumers are increasingly interested in where their food comes from and how animals are raised. Setting up a system to provide information to consumers would put Montana ahead of competition that is already occurring among state-certified natural beef products.

In conclusion, KAW applauds the Montana Department of Agriculture for taking steps to become a national leader in providing healthful, high-quality beef and urges the agency to strongly consider a certification standard that, *at minimum*, prohibits the use of medically important antibiotics for non-therapeutic purposes. Such a requirement would not only address an important public health problem by reducing the threat of antibiotic resistance, but also increase the market value of Montana's premium beef brand.

Thank you for considering these comments and providing an opportunity for our participation in the development of a strong standard for Montana Certified Natural Beef.

Submitted on behalf of Keep Antibiotics Working by:

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<sup>1</sup> Niman Ranch Beef Cattle Protocol: <http://content.nimanranch.com/images/static/BeefProtocols.pdf> (accessed December 20, 2007).

<sup>2</sup> Coleman Natural Foods FAQ: [http://www.colemannatural.com/userfiles/File/CNF\\_FAQs\\_0506.pdf](http://www.colemannatural.com/userfiles/File/CNF_FAQs_0506.pdf) (accessed December 20, 2007).

<sup>3</sup> South Dakota Certified Enrolled Cattle™ Natural Program: <http://www.southdakotacertifiedbeef.com/ForProducers/docs/FinalNaturalHandout.pdf> (accessed December 20, 2007)

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## **Background**

### **Economic gains for producers; increased supply for consumers**

While demand for meats produced without antibiotic feed additives continues to grow, the supply of such meat produced in the U.S. is insufficient to meet this demand. In addition, there are potential trade benefits for producers who do not use antibiotics. Montana is well positioned to take advantage of this economic opportunity.

#### *Individual consumers*

Many recent surveys indicate that US consumers prefer meat raised without the routine use of antibiotics and are willing to pay premium prices for it. A national survey conducted in 2003 found that 74 percent of respondents were concerned about the use of antibiotics in meat production. Of people aware of agriculture's contribution to antibiotic resistance, 6 out of 10 said they would be likely to buy meat produced without antibiotics for non-therapeutic purposes.<sup>4</sup>

Another survey found that hormones and antibiotics were the most important factors influencing consumers' willingness to pay for 'natural' beef. According to this survey, 38 percent of consumers were willing to pay a 10 percent premium for 'natural' steak (produced without the routine use of antibiotics among other things) and 67 percent were willing to pay a 12 percent premium for 'natural' ground beef.<sup>5</sup>

#### *Corporate purchasers*

Large-volume meat purchasers have begun to seek meat produced with fewer antibiotics. For example, McDonalds – one of the largest meat purchasers in the world – has implemented an antibiotic policy that bans the use of medically important antibiotics for growth promotion in chicken.<sup>6</sup> Compass USA, the second-largest food-service company in the U.S., adopted a similar policy that also applies to pork.<sup>7</sup> Another leading food-service company, Bon Appétit Management Co., has a policy that bans the use of all medically important antibiotics for non-therapeutic purposes in chicken and turkey. All three policies contain purchasing preferences for suppliers of other meats – including beef – who reduce antibiotic use.<sup>8</sup>

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<sup>4</sup> Whole Foods Market survey 2003. see Whole Foods press release at: [http://www.wholefoodsmarket.com/pressroom/pr\\_05-28-03.html](http://www.wholefoodsmarket.com/pressroom/pr_05-28-03.html) (accessed December 20, 2007). See discussion in Pérez, L. et al., *The Natural Beef Market In the United States*, (2003), available at <http://www.agmrc.org/NR/rdonlyres/85FEA4E8-745D-4F6E-B0E0-9C1D86C89884/0/naturalbeefmarket.pdf> (accessed January 13, 2006).

<sup>5</sup> Grannis, J., N. Hooker, and D. Thilmany. *Consumer Preference for Specific Attributes in Natural Beef Products*. WAEA Annual Meetings, June 29-July 1, 2000. See discussion in Pérez, L. et al. (cited above).

<sup>6</sup> See [http://www.mcdonalds.com/corp/values/purchasing/antibiotics/global\\_policy.html](http://www.mcdonalds.com/corp/values/purchasing/antibiotics/global_policy.html) (accessed December 20, 2007).

<sup>7</sup> See <http://static.digitallook.com/digitalcorporate/cms/29/assets/050802InnovativePartnership.pdf> (accessed December 20, 2007).

<sup>8</sup> See [http://www.bamco.com/website/commit\\_ar.html](http://www.bamco.com/website/commit_ar.html) (accessed December 20, 2007).

Similarly, Health Care Without Harm, an international coalition that includes numerous health-care facilities, adopted model purchasing guidelines that call for purchasing meats produced with reduced antibiotic use.<sup>9</sup> To date, 105 facilities have signed the Healthy Food in Healthcare Pledge. All signatories have committed to buying meats that are, among other attributes, produced without the routine use of antibiotics as feed additives. Other large buyers have expressed interest in adopting such policies as supplies of meats produced with fewer antibiotics become more widely available.

#### *Trade implications*

In May 2004, the U.S. Government Accountability Office (GAO) released a report highlighting the looming trade implications for countries that do not improve their agricultural antibiotic-use practices to meet those of industry leaders.<sup>10</sup> GAO noted that U.S. meat exports were about \$7 billion in 2002 (p. 16) and observed that two of our major competitors in world meat markets (New Zealand and Denmark) have banned the use of medically important antibiotics for growth promotion in food animals, as has the European Union (p. 43). GAO further noted that Japan, a major market for US meat exports, is now reviewing such uses (p. 43) and considering a ban. The report also flags the need for collection of better data on antibiotic use in agriculture.

In addition, a 1999 report from Iowa State University on pork production concluded that if just one of the U.S.'s major trading partners decided to restrict imports from the U.S. because of concerns about antimicrobial resistance, losses to the industry would "dwarf" any conceivable benefits of these feed additives.<sup>11</sup>

Thus, to keep up with international trends and maintain, if not expand, their market share, U.S. meat producers need to reduce antibiotic use. By including antibiotic use as a criterion for program participation, this is an excellent opportunity for the Montana Certified Natural Beef Program to achieve a price premium and expanded market.

#### **Public health benefits**

The rise of antibiotic-resistant bacteria is a major public health crisis. Resistant infections are increasingly difficult and expensive to treat.

Already, an estimated 14,000 Americans die every year from drug-resistant infections, and the National Academy of Sciences calculates that the increased health care costs associated with antibiotic-resistant bacteria exceed at least \$4 billion annually<sup>12</sup> – a figure that reflects the cost of additional antibiotics and longer hospital stays, but not lost workdays or human suffering.<sup>13</sup>

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<sup>9</sup> See <http://www.noharm.org/details.cfm?type=document&id=893> (accessed January 13, 2006).

<sup>10</sup> U.S. Government Accountability Office, ANTIBIOTIC RESISTANCE: Federal Agencies Need to Better Focus Efforts to Address Risk to Humans from Antibiotic Use in Animals, GAO-04-490, April 2004. [www.gao.gov/cgi-bin/getrpt?GAO-04-490](http://www.gao.gov/cgi-bin/getrpt?GAO-04-490) (accessed January 13, 2006).

<sup>11</sup> Dermot J Hayes, Helen Jensen, Lennart Backstrom, and Jay Fabiosa. Economic Impacts of a Ban on the Use of Over-the-Counter Antibiotics in U.S. Swine Rations. 1999. CARD Staff Report December 1999. <http://www.card.iastate.edu/publications/DBS/PDFFiles/99sr90.pdf> (accessed January 13, 2006).

<sup>12</sup> Institute of Medicine of the National Academies, The Resistance Phenomenon in Microbes and Infectious Disease Vectors: Implications for Human Health and Strategies for Containment -- Workshop Summary (2003), The National Academies Press, Washington, D.C., p.108, available at <http://books.nap.edu/books/0309088542/html/108.html#pagetop> (accessed January 13, 2006).

<sup>13</sup> "For the United States as a whole, the American Society for Microbiology estimated in 1995 that health care costs associated with treatment of resistant infections amounted to more than \$4 billion annually. And this figure significantly underestimates the actual cost of resistance, since it includes only direct health care costs and excludes an array of other costs, such as lost lives and lost workdays." Institute of Medicine of the National Academies, The Resistance Phenomenon in Microbes and Infectious Disease Vectors: Implications for Human Health and Strategies for

Patients in need of prescription drugs also shoulder the financial burden caused by antibiotic resistance. The newer-generation antibiotics that must be used when resistance develops to older ones are typically far more expensive. For example, a *single pill* of Zyvox – the first truly novel antibiotic to reach the market in more than 20 years – costs more than \$70. By contrast, a vial of tetracycline costs about \$4.<sup>14</sup>

The evolution of antibiotic resistant bacteria results from use and misuse in *both* human medicine and animal agriculture. No one doubts that misusing antibiotics in human medicine contributes to the crisis. But the public health and medical communities agree that agricultural use is also important. As the National Academy of Sciences' Institute of Medicine recently noted, "Clearly, a decrease in the inappropriate use of antimicrobials [antibiotics and related drugs] in human medicine alone is not enough. Substantial efforts must be made to decrease inappropriate overuse of antimicrobials in animals and agriculture as well."<sup>15</sup>

Though everyone is at risk if antibiotics lose their effectiveness, the threat is greatest for those with weaker immune systems, such as cancer patients undergoing chemotherapy (which suppresses the immune system), and transplant patients (whose immune system is intentionally suppressed to reduce the likelihood that the transplanted tissue will be rejected). Young children and seniors are also at special risk because the immune system functions less efficiently in the very young and the old than it does at other ages.<sup>16</sup>

The Montana Certified Natural Beef Program has the opportunity to mitigate this crisis by requiring that its certified producers do not use antibiotics inappropriately with their beef cattle. Doing so would slow the development of antibiotic resistant bacteria and preserve the effectiveness of antibiotics important for treating both humans and animals.

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Containment -- Workshop Summary (2003), National Academies Press, Washington, D.C., p.108, available at <http://books.nap.edu/books/0309088542/html/108.html#pagetop> (accessed January 13, 2006).

<sup>14</sup> From an American Nurses Association presentation; an approximation is:

[http://www.drugstore.com/qxn00009513502\\_333181\\_sespider/zyvox/zyvox.htm](http://www.drugstore.com/qxn00009513502_333181_sespider/zyvox/zyvox.htm) (accessed December 20, 2007) which says that 20 Zyvox tablets=\$1,475.64, over \$73/pill.

<sup>15</sup> Institute of Medicine, Board on Global Health (2003). *Microbial Threats to Health: Emergence, Detection, and Response*. National Academy of Sciences Press, Washington, DC p. 207. Retrieved January 30, 2004 from <http://books.nap.edu/books/030908864X/html/R1.html#pagetop> (accessed January 13, 2006).

<sup>16</sup> See Katherine Shea, Karen Florini and Tamar Barlam, "When Wonder Drugs Don't Work: How Antibiotic Resistance Threatens Children, Seniors, and the Medically Vulnerable" (Environmental Defense, 2001), available online at [http://www.environmentaldefense.org/documents/162\\_abrreport.pdf](http://www.environmentaldefense.org/documents/162_abrreport.pdf) (Accessed December 20, 2007).