National Pork Producers Council

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November 27, 2002

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

Re: Docket 98D-1146
"Draft Guidance #152 for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern"

Dear Dockets Management Branch:

These comments are submitted by the National Pork Producers Council on behalf of America's Pork Producers. The National Pork Producers Council (NPPC) conducts public policy outreach on behalf of its 44 affiliated state association members, representing over 80,000 pork producers. NPPC is committed to enhancing opportunities for the success of U.S. pork producers and other industry stakeholders by establishing the U.S. pork industry as a consistent and responsible supplier of high quality pork to the domestic and world market.

Food safety and animal health have long been a priority for America's pork producers because we understand that healthy hogs are important to maintaining a safe and wholesome food supply. We believe that the safe and judicious use of antibiotics are essential for the treatment, control, and prevention of diseases in our herds.

America's pork producers, in cooperation with the American Veterinary Medical Association and the American Association of Swine Veterinarians developed "Basic Guidelines of Judicious Therapeutic Use of Antimicrobials In Pork Production." These guidelines emphasize a number of important factors to be considered when decisions are made to use antimicrobials such as herd health; other non-microbial therapeutic options; and use of veterinarian prescription drugs and "extra-label" use only with veterinary consultation. 98D-1146 C76

We committed to the observation of these principles, the use of scientifically based risk assessment, surveillance, and local intervention to enable producers to safely use these products while minimizing the threat of antibiotic resistance from food borne pathogens.

We would like to share several issues of concern about Guidance #152.

- No data is presented to support the proposed categorization of drugs. The Guidance bases categorization on importance to human health, but provides no data to support this approach. We would like to see the FDA/CVM analysis publicly available.

- We do not see a clearly transparent process to add or shift drugs into new categories. This is of concern especially for drugs that are no longer used for human purposes.

- The Guidance penalizes an antimicrobial use in herd medication without providing information on "acceptable" size guidance on herd treatment. This approach is not compatible with modern agricultural practices. There are also a number of animal welfare and product safety (meat quality and needle safety) challenges presented by this approach. If producers are no longer able to group or herd medicate, this will almost ensure that individual pigs will be treated with more drug over longer periods of time. Experience has shown that while two symptomatic pigs may be treated by injection there may be many more asymptomatic pigs in the barn. Thus, the producer would be forced into treating an entire barn with several injection treatment courses over a longer time period rather than controlling administration of a drug, to the animals in a barn, through water or feed medication for a shorter duration of time.

- No data is presented to support a scientific-based qualification of actual risk of antibiotic resistance transference. We would like to see the FDA/CVM analysis publicly available.

- We have concerns about a new process for re-evaluating older antibiotics. The products have already been through the extensive FDA examination and approval process. FDA currently has the authority and a process to re-evaluate the safety of products already on the market. We believe that this approach will prove to be problematic as the threat of emerging diseases continue, the long lead time to get new drugs into the pipeline and the reexamination of older antibiotics will endanger the health of the U.S. swine herd. By reduce the use of currently approved antibiotics without clearly illustrating a path forward for the development of newer drugs, prices to the producer will increase and the number of new drugs in the pipeline will be reduced.

- The draft Guidance provides for FDA/CVM to prohibit "extra-label" use of antibiotics. We believe that this will severely limit the years of professional experience and judgment that veterinarians use when treating animals on the farm. We need to maintain some professional decision-making flexibility in using these antibiotics. Many times there are no preventive vaccines for diseases nor are there antibiotics labeled for emerging diseases, producers rely on their local veterinarian to use their educated judgment, diagnostic tools and intimate knowledge each producers' operation to make decisions that will save many animals.

- We believe that the consumption data are overstated. Over 65% of today's pork production is no consumed as fresh pork (chops, roasts); it is further processed (hams,

sausage, bacon). Further processing reduces the opportunity for passing food borne resistant bacteria into the human population

We appreciate the opportunity to present comments on behalf of America's pork producers. If you have any additional questions, please contact Ms. Audrey Adamson, Director, Federal Relations at (202) 347-3600.

Sincerely,

Dave Roper

Dave Roper
President
National Pork Producers Council