



April 1, 2014

Liz Wagstrom, DVM, MS, DACVPM  
Chief Veterinarian  
National Pork Producers Council  
122 C Street N.W., Suite 875  
Washington, D.C. 20001

Dear Dr. Wagstrom:

This letter is in response to your February 26, 2014 letter addressed to me. I also understand that you later spoke with Drs. Neal Bataller and Craig Lewis regarding the letter's subject. In your letter, you pose questions regarding the extra-label use of drugs in food-producing animals for situations that may cause temporary discomfort to animals undergoing minor surgical procedures, such as castration and tail docking in swine.

The regulations addressing extra-label drug use in animals, Title 21 Code of Federal Regulations Part 530, states that "such use is limited to treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat." We consider the use of analgesics and anesthetics for the purpose of alleviating pain, suffering and discomfort in animals as an acceptable justification for using approved drugs in an extra-label manner.

Extra-label drug use is restricted to the use of approved animal drugs and approved human drugs. "Approved drugs" include those that are the subject of: (1) an approved New Animal Drug Application (**NADA**) for animal drugs; (2) an approved New Drug Application (**NDA**) for human drugs; (3) an approved Abbreviated New Animal Drug Application (**ANADA**) for animal drugs; or (4) an approved Abbreviated New Drug Application (**ANDA**) for human drugs.

Extra-label drug use does not include the use of: (1) conditionally approved NADAs; (2) indexed animal drugs; (3) approved animal drugs that are administered by feed; (3) human drugs that are the subject of an OTC Drug Monograph; and (4) unapproved animal drugs. Please contact us if you are unsure what specific drug products fit into which category.

If you have any questions regarding this letter, please contact Dr. Neal Bataller at 240-276-9062 or [Neal.Bataller@fda.hhs.gov](mailto:Neal.Bataller@fda.hhs.gov).

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dan G. McChesney", is written over a faint, larger version of the same signature.

Daniel G. McChesney, Ph.D.  
Director, Office of Surveillance and Compliance  
Center for Veterinary Medicine