DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Rockville MD 20857

JUL 18 2014

K. Fred Gingrich II, DVM
Vice President, American Association of Bovine Practitioners
Country Roads Veterinary Services, Inc.
776 Main Street, RD #5
Ashland, OH 44805

Dear Dr. Gingrich:

This letter is in response to your July 7, 2014 email addressed to Dr. William Flynn of the FDA, Center for Veterinary Medicine. You had inquired about the extralabel use of meloxicam in bovine animals for the intended use of analgesia in situations such as dehorning and castration. Dr. Flynn had provided a partial response to your inquiry but also indicated that we would send you a letter more fully describing our response.

The regulations addressing extralabel drug use in animals, Title 21 Code of Federal Regulations Part 530, state 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 extralabel manner.

Extralabel 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; and (4) an approved Abbreviated New Drug Application (A**NDA**) for human drugs. Extralabel 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; (4) unapproved animal drugs; or (5) unapproved human drugs. Presuming the extralabel use involves FDA-approved meloxicam, such use would likely be permitted under the regulations provided all other applicable conditions are met, including those addressing the avoidance of residues that may present a risk to the public health.

Section 530.13 of the extralabel drug use regulations addresses conditions under which the use of certain compounded drugs is permitted. The regulations only permit the use of compounded drugs that utilize approved animal drugs and approved human drugs as the starting ingredients. Further, the regulations restrict the use of compounded drugs to situations where there is no approved animal drug or approved human drug that, when used as labeled or in an extralabel

manner according to Part 530, will, in the available dosage form and concentration, appropriately treat the animal. Since the FDA-approved meloxicam may be compounded prior to administration to animals, these regulations as they pertain to compounding may be relevant.

If you have any questions regarding this letter, please contact me at 240-276-9062, Neal.Bataller@fda.hhs.gov.

Sincerely yours,

Neal Bataller, ME, DVM
Director, Division of Surveillance
Center for Veterinary Medicine