May 23, 2000

Dear Doctor,

This letter is to inform you of several new changes Fort Dodge Animal Health (FDAH) will be implementing this year regarding EtoGesic® Tablets (etodolac). Recent trends in veterinary medicine indicate that pet owners are seeking more comprehensive information on the medications prescribed for their pets. As part of our commitment to providing practicing veterinarians with the latest information, we are providing the most up-to-date safety information concerning possible side effects associated with the use of EtoGesic. With the permission and guidance from the FDA-Center for Veterinary Medicine (CVM), FDAH has initiated several measures to educate clients on both the benefits of EtoGesic and potential risks associated with using NSAIDs. Outlined below are the changes FDAH will implement regarding EtoGesic in the next few months.

The EtoGesic package insert has been updated to include a section showing post approval adverse event reporting. The most frequently reported side effects have been gastrointestinal signs. Other reported side effects include renal, hematologic, neurologic, dermatologic and hepatic signs. We encourage you to read this new section of the package insert to increase your awareness of the types of possible side effects being reported to Fort Dodge Animal Health. As with all NSAIDs, there is the potential for side effects with EtoGesic. Thus, this new section was included as part of FDAH's commitment to provide veterinarians with information that allows for the safe use of EtoGesic.

The following normally apply to the use of most prescription medications including the use of any NSAID in dogs:

- Conduct an appropriate physical examination of all dogs before administering or prescribing any prescription medication.
- Consider obtaining appropriate diagnostic support, such as laboratory tests, in addition to your examination of animals that may be at higher risk of adverse responses to a drug. These animals would include geriatric animals, animals with active or a history of liver disease, inflammatory bowel disease, renal disease, or other chronic condition.
- Evaluate potential drug interactions in animals being treated with concurrent medications, especially steroids or other NSAIDs.
- Consider establishing baselines and periodically monitoring hematology and serum biochemical data in patients that will be treated for prolonged periods.
- Advise owners to watch for signs of drug intolerance. Such signs might include inappetence, vomiting, diarrhea, melena, PU/PD, anemia, jaundice, lethargy, ataxia, seizure, or behavior changes. Owners should be informed that if they see unusual or unexpected changes in their dog they should not administer additional medication and contact you.

- Before refilling an initial prescription and at appropriate intervals thereafter, check with owners or examine the dog to determine if there is continuing need for the medication and that it is well tolerated.
- If you suspect a drug reaction or intolerance in a patient, discontinue the drug, examine the patient, obtain appropriate diagnostic support, provide appropriate supportive therapy and contact the manufacturer.

Fort Dodge Animal Health will also begin including the attached Client Information Sheet with each bottle of EtoGesic. Similar to Patient Prescribing Information (PPI), which is commonly distributed with human pharmacy prescriptions, the Client Information Sheet is written in "consumer-friendly" language and provides information in easily understood terms about the benefits and side effects associated with the use of NSAIDs and EtoGesic. This Client Information Sheet will supplement the information provided in the Package Insert. The Client Information Sheet will be printed on the reverse side of the Package Insert so that it is easy for pet owners to locate and read.

Both FDAH and the CVM encourage the dispensing of EtoGesic in child resistant packaging that includes the complete manufacturer's prescribing and client information. The ultimate packaging that achieves these objectives is the original packaging supplied by the manufacturer. To better enable veterinarians to meet these dispensing objectives, EtoGesic will be available in 30-count and 90-count bottles in the near future. The current 100-count and 250-count sizes will be phased out as inventories are depleted. The new, smaller-count bottles will make it easy to dispense either one- or three-month supplies of EtoGesic without counting tablets or re-packaging. Now, all you have to do is place your prescription label on the bottle.

In summary, this letter is part of FDAH's continued commitment to provide veterinarians and pet owners with the most up-to-date and complete information about the safe and effective use of EtoGesic. FDAH and the CVM encourage veterinarians to provide owners with information about both the risks and benefits associated with all potential therapeutic options for their arthritic dog. If you have any questions or comments about the contents of this letter, please feel free to contact FDAH at (800) 477-1365. Enclosed with this letter is a copy of the EtoGesic Package Insert and Client Information Sheet that will be included with the new 30-count and 90-count bottles of EtoGesic Tablets.

Sincerely,

David Hustead, DVM
Director, Professional Services