

## Potassium bromide products marketed for use in dogs

I read with interest the article “A systematic review of the safety of potassium bromide in dogs,” which was published in the March 15, 2012, issue of *JAVMA*. The authors indicate that currently there are no commercially available potassium bromide products approved by the US FDA for use in dogs. However, for the past several years, I have been using a product (K-Bro Vet) from PRN Pharmica with the understanding that it is just such a product. The packaging contains the caution statement that “Federal law restricts this drug to use by or on the order of a licensed veterinarian,” and the package inserts feature National Drug Code numbers.  
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1. Baird-Heinz HE, Van Schoick AL, Pelsor FR, et al. A systematic review of the safety of potassium bromide in dogs. *J Am Vet Med Assoc* 2012;240:705–715.

### The authors respond:

Thank you for your comments, which draw attention to important concerns regarding marketed but unapproved animal drugs that may not be clear to other veterinarians.

The presence of a National Drug Code (NDC) number on a drug label does not mean the drug has been approved by the FDA. Under the Federal Food, Drug, and Cosmetic Act, all drug manufacturers are required to register with the FDA and to provide a list of their marketed drug products. Each reported animal drug product is assigned a unique NDC number. This requirement applies to all marketed drugs, regardless of whether they are approved or unapproved.

The presence of the cautionary statement on an animal drug label is also not an indication the drug has been approved by the FDA. Under the Federal Food, Drug, and Cosmetic Act, animal drug products that can only be safely used under the professional supervision of a licensed veterinarian must bear the label statement “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.” This requirement applies to all marketed drugs, both approved and unapproved. Therefore, inclusion of either an NDC number or a prescription statement on the drug label does not denote approval by the FDA of the firm or any of its marketed drug products.

There are other statements associated with marketed animal drugs that should also not be taken as an indication that the drugs have been approved by the FDA. These statements include “Registered and listed with the FDA,” “Made in an FDA-registered facility,” “Made in an FDA-inspected facility,” and “Made in an FDA-approved facility.”

Drugs that have been approved by the FDA have either a New Animal Drug Application number or, for generic animal drugs, an Abbreviated New Animal Drug Application number. The New Animal Drug Application number or Abbreviated New Animal Drug Application number and the statement “Approved by FDA” are usually on the label. Animal drugs conditionally approved by the FDA have a Conditional New Animal Drug Application number, which appears on the drug label as part of the following required statement: “Conditionally approved by FDA pending a full demonstration of effectiveness.”

There are several sources for determining whether an animal drug has been approved by the FDA. Most FDA-approved animal drugs are listed in the Animal Drugs @ FDA searchable online database and are also listed in a document called the Green Book. The Green Book is published in its entirety each January and updated monthly. Both information sources are available on the FDA website ([www.fda.gov/AnimalVeterinary](http://www.fda.gov/AnimalVeterinary)). Additional information regarding unapproved animal drugs can be found at the same site.

The FDA is aware that unapproved animal drugs are marketed in the United States, including the product referenced in your letter. The AVMA and FDA have both expressed serious concerns about the continuing presence of unapproved animal drugs in the marketplace. These drugs are not reviewed by the FDA and may not meet the FDA’s strict standards for safety, effectiveness, and manufacturing quality.

As part of its initiative to address this problem, the FDA has asked for public comments on strategies to address this issue.

As your letter highlights, access to reliable information about animal drugs is critical for veterinary prescribing decisions.

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