AVMA American Veterinary Medical Association

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Deputy Administrator
Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
2401 Jefferson-Davis Highway
Alexandria, VA 22301

Re: Docket No. DEA-269P, Notice of Proposed Rulemaking, Schedules of Controlled Substances: Placement of Embutramide into Schedule III

Dear Sir or Madam:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, AVMA is the recognized national voice for the veterinary profession. The association's more than 72,000 members represent approximately 86% of U.S. veterinarians, all of whom are involved in myriad areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

The American Veterinary Medical Association has carefully considered the DEA's proposed rule to schedule the substance embutramide and products containing embutramide as Schedule III controlled substances.

The AVMA supports placement of the substance embutramide into Schedule III of the Controlled Substances Act to reduce the potential for drug diversion. **However, the AVMA does not support scheduling of the FDA approved, prescription drug Tributame™ Euthanasia Solution** because the characteristics of the final formulation vitiate the potential for abuse[1] and the benefits of an unscheduled humane euthanasia solution are exceedingly valuable.

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[1] 21U.S.C.811(f)(3) A

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a nonnarcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

The AVMA bases its recommendation to make a distinction between the active ingredient embutramide and the Tributame Euthanasia Solution on contrasting potentials for abuse. The AVMA believes embutramide (the raw ingredient normally handled by the manufacturer) has the potential for abuse and should be a Schedule III controlled substance. But, Tributame™ Euthanasia Solution does not have potential for abuse because other ingredients in the drug contaminate and invalidate the embutramide.

The abuse potential for the finished euthanasia product (Tributame™) is essentially non-existent because the untoward affects of the formulation would outweigh any nefarious desirable affects it could give the abuser and the formulation could not act as a source of clandestine GHB:

-The finished product will be far more expensive than other sources of embutramide,
-The finished product contains a cardiotoxin and dye that are leached onto the embutramide,
-The cardiotoxin would make a person sick if he/she attempted to abuse the veterinary drug for recreational use,
-Consequently, cheaper and less toxic sources of embutramide exist.

Furthermore, the potential public exposure to pentobarbital-based euthanasia solutions may decrease with the increased commercial availability of a non-controlled embutramide-based euthanasia solution.

The AVMA believes the drug's indication (euthanasia agent) is not an adequate reason to seek the controls associated with controlled substances. The product is restricted to prescription use and the danger associated with misuse is comparable to that of many other drugs. Likewise, household items such as drain cleaners, pesticides, herbicides, etc. are highly toxic, yet are not subject to the closed system of distribution associated with controlled substances.

In addition, given the diversity of circumstances in which animals must be humanely euthanized, the AVMA believes the benefits of an unscheduled humane euthanasia solution are exceedingly valuable.

In summary, the AVMA supports placement of the substance embutramide into Schedule III of the Controlled Substances Act to reduce the potential for drug diversion. However, the AVMA does not support scheduling of the FDA approved, prescription drug Tributame™ Euthanasia Solution because the characteristics of the final formulation vitiate the potential for abuse and the benefits of an unscheduled humane euthanasia solution are exceedingly valuable.

Thank you for the opportunity to comment on an issue that impacts veterinarians nationwide.

Sincerely,

Bruce W. Little, DVM
Executive Vice President

BWL/ECG