The Current Regulatory Status of Veterinary

Homeopathic Drugs in the United States

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Regulatory background:

Homeopathic medicines have been classified as drugs in the United States since their inclusion in the Federal Food, Drug, and Cosmetic Act of 1938 (FFD&CA). . Under the FFD&CA , any article *intended* for use in the diagnosis, cure, mitigation, treatment or prevention of disease of man *or other animals*, or intended to affect the structure of function of man or other animals, is regarded as a "drug". Unless a drug is generally recognized by qualified scientific experts as safe and effective for its labeled uses, it is a new drug under the law. FDA requires scientific data, including clinical trials, to prove efficacy and safety. For homeopathic drugs, the Homeopathic Pharmacopoeia of the United States (HPUS) provides clear criteria for eligibility of drugs for inclusion in the HPUS as well as guidelines for safety, identification, homeopathic drug provings, clinical verification and good manufacturing practices. The HPUS limits its scope to homeopathic drugs for human use. FDA's position on the marketing of homeopathic drugs for man is spelled out in Compliance Policy Guide 7132.15, *Conditions Under Which Homeopathic Drugs May Be Marketed.*

No homeopathic drugs for veterinary use are approved under existing veterinary drug regulations. FDA has communicated to the industry that it believes

homeopathic drug products for veterinary use which lack approved new animal drug applications are misbranded drugs and subject to further action, including recall. It is FDA's position that over-the-counter veterinary "homeopathic" products making significant drug claims are to be regulated and held to the same scientific standards of safety and efficacy as any veterinary drug. In addition, FDA has communicated to the industry that the parenteral route of administration of any drug product without established therapeutic benefit would place an animal at unnecessary risk, regardless of whether or not the product is administered by or on the order of a veterinarian. Consequently, when promotional materials are established as labeling, the products may be considered unapproved new animal drugs which are adulterated under section 501(a)(5) of the act.
Equally important, a number of liability insurance carriers have considered that they will not provide products liability coverage to a manufacturer and/or distributor who promotes a product for an unapproved use.

The most recent FDA statement[1] on the use of homeopathic veterinary drugs appears in April 2006 guidance concerning the Grade "A" of the Pasteurized Milk Ordinance, which provides guidance to state officials on inspecting milk producing operations. Concerning homeopathic drugs, the PMO states as follows:

Homeopathy is an alternative therapeutic modality developed in the late 1700's by a German physician for use in humans. Homeopathic medicine is considered an unconventional form of veterinary practice. FDA can find no justification for regulating veterinary homeopathic drugs any differently from other drugs subject

to the FFD&CA. There are currently no FDA approved homeopathic drugs for veterinary use.

Homeopathic drugs found on dairy operations must comply with the drug labeling and storage requirements of Item 15r of the PMO. If these do not comply with the drug labeling requirements, they are addressed like other unapproved drugs, and should not be stored on dairy operations or used to treat dairy animals. If homeopathic drugs are properly labeled they are subject to the same storage requirements as any other drug.
NOTE: A thorough reading of the label for homeopathic drugs will often disclose Item 15r deficiencies.

Here again, FDA states that no homeopathic veterinary drugs are approved for use in animals, yet it talks of examining the labeling of such products.

Homeopathic veterinary practice in the United States.

Although no homeopathic drugs have been approved for veterinary use, FDA has thus far taken little action against homeopathic drug products for veterinary use. In fact, FDA has gone so far as to provide written guidance on labeling of a product which it nonetheless states is illegal and which it reserved the right to act against in the future.

Communication from FDA with Representatives of AAHP

In 1991, a meeting[2] was arranged with FDA's Center of Veterinary Medicine (FDA CVM) after the publication of an article in the "FDA Veterinarian" that called into question the validity of veterinary homeopathy. The meeting was attended by representatives of the AAHP and the American Holistic Veterinary Medical Association. At the meeting, CVM emphasized that it did not object to the practice of veterinary homeopathy by licensed practitioners. CVM's principal concern was that some products may not work as claimed and/or could endanger the animal. As a practical matter, CVM indicated that it would not take action against products used by licensed practitioners for companion animals. CVM reserved judgment as to whether it would take action against any product used for food producing animals.

The Situation in Europe:

Interestingly, the situation in Europe is quite different. European authorities widely acknowledge homeopathic drugs as a medicinal product for application on or in the animal body. In Germany, for example, homeopathic veterinary drugs which are medicinal drugs as defined in the relevant Act[3] (similar to the FFD&CA) may be placed on the market as homeopathic medicinal products within the purview of the present Act, if they have been entered into the Register for Homeopathic Medicinal Products kept by the Higher Federal Authority. In detail, guidance for the registration of Homeopathic Veterinary Drugs is provided. A marketing authorization (similar to the American NADA) is not necessary. Even though comprehensive documents (specified in the German Act) must be enclosed with

the application for registration, no particulars need to be submitted describing effects and fields of application nor to the documents and expert opinions on the clinical trials.

Summary

The regulatory situation regarding Homeopathic Veterinary Drugs in the United States is rather tentative. There is considerable risk of future action by FDA or other relevant agencies. FDA has never said that it would develop an alternative to the NADA for homeopathic drugs to reach the market. At first sight, the situation in Europe seems to be more regulated since industry has obtained more guidance. The result of this guidance is that the industry may market and distribute homeopathic medicines as veterinary drugs.

1 FDA Milk Safety Branch. Current information adressing item 15r-drug and chemical control of the grade “A” pasteurized milk Ordinance (PMO). Memorandum; 2006 April 19.

2 A. Lorman. AAHP meets FDA Center for Veterinary Medicine. Memorandum; 1991 December 4.

3 german law on the trade in drugs; 2000 July 30.