



American College of Veterinary Botanical Medicine

Frequently Asked Questions Regarding Veterinary Botanical Medicine

www.acvbm.org

Question: What is the Quality of products upon which ACVBM will be based?

As a result of DSHEA (1994), human herbal products are minimally regulated (GRAS criteria). Animal “dietary supplements” do not fall under DSHEA but are minimally regulated. How will confidence in these products be addressed in the implementation of patient care provided by ACVBM diplomates? What role does ACVBM envision it will have in addressing the lack of regulation and thus quality of products used and/or promoted by its diplomates?

One of the advantages of having a program to educate veterinarians in herbal medicine is to provide them with the knowledge of the regulatory frameworks for the companies they want to work with and a set of questions to ask to qualify the quality of their products. A well-constructed education program can help veterinarians develop their own Vendor Qualification Questionnaire which should contain questions such as:

- Under which regulatory category is your product labeled for distribution?
- Is your company compliant with all applicable regulations?
- Is your company registered with the FDA? If not, why not?
- Do you/does your manufacturer have a Quality Control System?
- How do you handle: Testing Raw Material Identity; Heavy Metals; Micro Activity; Pesticides Policy
- Has your company been inspected by the FDA? When?
- Are you a member of any Trade Associations?
- How long have you been in business?
- Is your company recording Adverse Events that occur with Animals?

With respect to Dietary Supplements, which under the US regulatory system is a term that applies only to Dietary Supplements for humans, it is important to note that they are not just regulated by Dietary Supplement Health and Education Act of 1994. There are also regulatory requirements for Facility Registration under the Bioterrorism Act of 2002. And the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding requirements for adverse event reporting and record keeping for dietary supplements and non-prescription drugs marketed without an approved application. It is the combination of these three Acts and their attendant regulations that give the FDA the ability to identify companies who they regulate, through inspection to correct any regulatory issues and identify any problem products in the industry. This is relevant for veterinarians sourcing high quality herbs from human herb suppliers.

The regulations developed for compliance with the Dietary Supplement Health and Education Act of 1994 are not minimal. There are certain requirements for products in the market prior to 1994. These regulations are quite strict and center on the confirmation of raw material identity, elimination of any adulterants or contaminants and consistency in manufacturing. A documented Quality Control System

with specifications and master manufacturing procedures, personnel training, equipment and facility cleanliness, recording of customer complaints and adverse events are required. Regulations for label claims that must be filed with the FDA within 30 days of making such claims, limit the scope of what can be said about the product to how it affects the structure and function of a body. Such claims require research backup to be kept on file. Any product introduced for sale in the market after 1994 must submit a New Dietary Ingredient Application for approval by the FDA which must include the documented history of use or other evidence of safety. In addition, there are several trade associations that add Trade Recommendations, which must be complied with to maintain a membership.

Products labeled for animal use are under a completely different regulatory framework. They are either regulated as drugs by the FDA or as Foods which must comply with federal and state laws, guidance for such compliance can be found in documents provided by AAFCO (the Association of American Feed Control Officials). The National Animal Supplements Council (NASC) trade organization provides its members with an audited, self-regulatory framework that includes a Documented Quality Control System, definition of claims to mirror those allowed with human dietary supplements, adverse event reporting and recommends animal drug registration with the FDA.

Currently all imported products or ingredients being sold in quantity to veterinarians are subject to intense FDA scrutiny – much more than is applied to products manufactured in the USA from USA ingredients. Products are screened for contaminants, and labels reviewed for misleading claims and disallowed ingredients, on an ongoing basis. Companies manufacturing within the US have the option to join the NASC. Membership entails an audit process and requires demonstration of compliance with Good Manufacturing Processes (GMP) practices (similar to the pharmaceutical industry). An example is the use of mass spectrophotometry and thin layer chromatography to demonstrate appropriate levels of active ingredients as one part of the process. Reputable companies often fully disclose details of their own quality assurance programs on their websites and are thus easily identified as useful resources by college members.

It should be noted that many pet food companies that veterinarians rely upon receive no more regulation from the FDA than what is detailed above. Additionally, efficacy of therapy is not determined by the FDA, but is determined post-market based on treatment outcomes. When a product or approach is consistently rewarding for similar cases, this is directly suggestive of product consistency across batches, and by extension suggests a high level of quality control for that manufacturer. Naturally it is these more reliable products and methods that will form the core of any education imparted to college members, however as a College we do not advocate any specific brands or products in order to remain impartial.

The ACVBM and its Diplomates will play a role in encouraging veterinarians using herbs to ask the important questions, to report adverse events and to work with companies to improve quality where it matters to safety in particular, and also work with industry such as NASC to improve regulation. Having a College and Diplomates will raise the profile of botanical medicine, and improve safety by giving the public and veterinarians a source for referral and advice other than Dr Google and the thousands of websites selling uncontrolled herbs.