

## Resources about Botanical Medicine for AABP Members

As compiled by Hubert Karreman, VMD, FACVBM

In addition to already posted links provided by AABP, these following resources may be of use in understanding botanical medicine itself and regulatory issues surrounding botanical medicine.

### American College of Veterinary Botanical Medicine

[www.acvbm.org](http://www.acvbm.org)

### Veterinary Botanical Medicine Association

[www.vbma.org](http://www.vbma.org)

### New Animal Drug Application and unapproved drugs

While a New Animal Drug Approval confers special recognition of it by the FDA and thus the cascade of other regulatory mechanisms that follow, it should also be remembered that the primary outcome of a successful New Animal Drug Application for a product is for the *marketing* of the product.

There are many, many drugs practitioners use that are in the market that are not approved. FDA CVM is well aware of thousands of drugs being marketed in the US that are not approved (haven't gone through the approval process) and therefore unapproved.

Here is a list of all drugs (with NADA and without NADA/unapproved) known to the FDA.

<https://www.fda.gov/industry/structured-product-labeling-resources/electronic-animal-drug-product-listing-directory>

Once the page opens, click the first link to see the actual file. There are 11,024 products shown, most of which do not have an approval. Some would surprise practitioners.

[https://download.open.fda.gov/Electronic Animal Drug Product Listing Directory.zip](https://download.open.fda.gov/Electronic_Animal_Drug_Product_Listing_Directory.zip)

### **GRAS: Substances Generally Recognized As Safe**

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-182>

### **GRASE or GRAS/GRAE: Products Generally Recognized As Safe and Effective**

"A drug is not considered a new animal drug **only** when it is generally recognized as safe and effective (GRASE). This is a very important concept to grasp, as much hinges on the GRASE determination. In order to conclude a GRASE determination, a drug must satisfy three criteria:

- **First**, the particular drug product must have been subjected to adequate and well-controlled clinical investigations that establish the product as safe and effective.
- **Second**, those investigations must have been published in the scientific literature available to qualified experts.
- **Third**, experts must generally agree, based on those published studies, that the product is safe and effective for its intended uses. At a minimum, the general acceptance of a product as GRASE must be supported by the same quality and quantity of scientific and/or clinical data necessary to support the approval of a New Drug Application"

From:US FDA Center for Drug Evaluation and Research: Bringing an Over-The-Counter (OTC) Drug to Market

"A product would not be considered a new drug if it is generally recognized as safe and effective (GRAS/GRAE) and has been used to a material extent and for a material time... As mentioned above, the Agency believes it is not likely that any currently marketed prescription drug product is grandfathered or is otherwise not a new drug. However, the Agency recognizes that it is at least theoretically possible." - FDA Guidance on Marketed Unapproved drugs (2006)

**21CFR545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.** This is a very long list of ingredients, with many botanicals specifically identified, that are in OTC products. It is interesting that while this listing specifically states that the included products and active ingredients do not have enough data to be considered GRASE, dates of approval for groups of products are clearly shown. Approval can occur via authority granted to the Commissioner, which may be the case in this specific area of 21CFR.

<https://www.govinfo.gov/content/pkg/CFR-2013-title21-vol5/pdf/CFR-2013-title21-vol5-sec310-545.pdf>

**Quality Standards for Botanicals: The Legacy of USP's 200 Years of Contributions**(published by the USP)

<https://acrobat.adobe.com/link/review?uri=urn%3Aaaid%3Ascds%3AUS%3A9d4e7bfb-e06a-3c79-9393-32217779525b>

**USP/NF Herbal Medicines Compendium (HMC) a listing of USP/NF recognized botanicals**

<https://hmc.usp.org/about/about-the-herbal-medicines-compedium>

**USP/NF list of active ingredients derived from botanicals for sale**

<https://store.usp.org/botanicals-herbal-medicines/category/USP-1902>

**VCPR.org** Protocols submitted by veterinarians to share among colleagues. A project started by Dr. Jim Ehrlich and funded by a USDA grant. Non-antibiotic and non-hormonal treatments utilizing botanical materials can be seen there.

<https://vcpr.org/signin?returnPath=%2Fspa%2Feditor%2Fspa%2Feditor%2Feditor>

My website for commercially available products [www.drkarremans.com](http://www.drkarremans.com)