

How to Determine if Your Product Requires a Michigan Animal Remedy License

Be sure to review the following information before completing an Animal Remedy License application. By taking a few minutes to review this information, you may prevent unnecessary and lengthy delays in the processing of your application.

Step 1 – Determine if your product is regulated as an animal remedy.

Unless your product is a commercial feed (including supplements), your product may be regulated in Michigan as an animal remedy if:

1. It is an animal drug, a veterinary biological product, a type A medicated feed article, a biotechnologically-produced hormone (such as bovine or porcine somatotropin), an animal regulator, a proprietary medicine, or any preparation of like nature in either solid or liquid form used **for any animal except man** and
2. It is administered **internally**, and
3. It is **promoted to** –
 - a. Treat, cure or prevent diseases or other undesirable conditions, such as internal or external parasites or other pests;
 - b. Have an effect on the body or the function of any animal, such as increase milk production, increase stamina, prevent dry flaky skin, reduce shedding, reduce stress, relieve itching, etc.
 - c. Condition, regulate, or act as a tonic. (Note: 21 CFR 500.52 also regulates the use of terms such as "tonic", "tone", "toner", or "conditioner" in labeling.
4. It is a pesticide/drug* product for any of the uses listed below. (*NOTE: You should not find EPA registration numbers on these products.*)
 - Treatments for control of horse **bots** (e.g. Negabot Paste);
 - Treatments that are administered orally or **parenterally** for control of cattle grubs;
 - Treatments for control of demodectic mange mites;
 - Treatments that are administered orally or **parenterally** for control of fleas (or other external parasites);
 - Treatments for control of ear mites;
 - Treatments for control of ticks if the product labeling includes claims for control of ear mites; animal drinking water treatments with direct or implied claims for control of animal parasites or diseases;
 - [Aquatic treatments for the control of parasites and/or fish in ponds or aquariums. **NOTE:** Because of the requirement that a product must be administered internally to be a remedy, these aquatic treatments usually will not meet the criteria established for remedies under Regulation 203.]

* **NOTE:** Certain products are both pesticides *and* drugs depending on how they are used. In defining "pesticide," the Federal Insecticide, Fungicide and Rodenticide Act, Sec. 2 [136] specifically excludes "any article that is a 'new animal drug' within the meaning of section 201(w) of the Federal

Food, Drug, and Cosmetic Act..." The Environmental Protection Agency (EPA) and the FDA have agreed to coordinate regulatory activities concerning these products. Through an August 1996 Federal cooperative agreement, the application of a pesticide for any of the uses in the preceding list cause the product to be considered an animal drug and to be under the primary jurisdiction of the FDA. As such, we will handle them as remedies provided they meet the other criteria outlined herein.

5. It is an ***Aquarium fish product*** and the label indicates direct injection, insertion into gullet, or dosage in feed (remember, feeds for fish maintained as pets are not considered commercial feeds due to a specific exemption in Act 120's definition of commercial feed).

Step 2 – Determine if your product is exempt from regulation as an animal remedy.

Your product is exempt from regulation in Michigan as an animal remedy if:

1. It is **not administered "internally,"** as defined in Michigan Regulation No. 203. This includes all drugs or other preparations administered topically, such as ointments, salves, liniments, balms or wound dressings/sprays.
2. It is a drug that Title 21 of the Code of Federal Regulations mandates be sold by prescription only. Such drugs must always bear the statement, "**Caution: Federal Law restricts this drug to use by or on the order of a licensed veterinarian**".
3. It is a veterinary biological product that, according to its USDA/APHIS product license, has been restricted to prescription use only. Federal regulations covering such products require one of the following statements to be used on all carton labels and enclosures:
"**Restricted to use by or under the direction of a veterinarian**" or "**Restricted to use by a veterinarian**".

NOTE: Other label statements such as "For Veterinary Use Only" or "Restricted Drug" do not make a product exempt from licensing. The statement "For Veterinary Use Only" simply means the product is intended for animal, rather than human, use. "Restricted Drug" is a term generally found on certain products registered in certain states such as California, but does not mean it requires a prescription elsewhere.

4. It is an EPA-registered pesticide.
5. It is an ***Aquarium fish product*** that is incorporated directly into the aquarium so that it is not administered to the fish by means of direct injection, insertion into gullet, or dosage in feed (remember, feeds for fish maintained as pets are not considered commercial feeds due to a specific exemption in Act 120's definition of commercial feed).
6. It is a veterinary biological product intended only for diagnostic purposes.

Step 3 – Determine if your product is regulated in Michigan as a commercial feed. *The Michigan Department of Agriculture is not currently licensing commercial feeds as animal remedies. The labeler of any product that is a commercial feed as defined in the Commercial Feed Law, Act No. 120 of 1975, must possess a current Commercial Feed License.*

Following are a few examples of products regulated as commercial feeds in Michigan:

- Nutritional supplements, such as vitamin and mineral supplements, whether fed as tablets, boluses, powders, pastes, liquids or to be mixed in water. **When the labels of such products contain claims for use in the presence of disease, stress conditions, etc., these commercial feed products are also considered to be unapproved drugs under federal law**
- Approved Type B and Type C medicated feeds, supplements, concentrates and premixes
- Milk replacers
- Direct-fed microbial products, such as fermentation products and enzymes, which make no drug claims (they are often marketed as oral pastes, as boluses, and for mixing in feed)
- Oral electrolytes, when part of a milk replacer or other feed supplement. (Oral electrolytes are considered by FDA to be new animal drugs. As such, they are subject to pre-market approval in the form of an approved NADA. At the present time, however, FDA is not objecting to the distribution of oral electrolytes labeled only as "a supplemental source of nutrients", and make no direct or implied drug claims.)

Special Definitions and Terms Used in this Guide

Drug - any article recognized in the official United States Pharmacopoeia or other official source; any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases or parasites in animals; any article intended to affect the structure or function of the body of any animal.

New Animal Drug - any drug intended for use for animals, the composition of which is not generally recognized, among qualified scientific experts, as safe and effective for use under the conditions prescribed by its label. Until a new animal drug receives full approval by the U.S. Food and Drug Administration (FDA), it is considered to be unsafe and adulterated.

New Animal Drug Application (NADA) - a form submitted to FDA when seeking approval of a new animal drug.

Approved New Animal Drug Application (Approved NADA) - approval granted by FDA in the form of a federal regulation, indicating that a new animal drug has been evaluated and found to be safe and effective for its intended purposes, and establishing the conditions for labeling and use of the drug. It is not official until a notice of the regulation is published in the Federal Register.

Veterinary Biological Product - a product of biological origin used in the diagnosis, prevention, or treatment of animal disease, including, but not limited to, serums, vaccines, antitoxins, bacterins, and antigens.

If you have additional questions relating to the Animal Remedy Program, contact:

Feed & Seed Manager
Feed and Animal Remedies Programs
Pesticide & Plant Pest Management Division
517 373-1087

Additional Requirements for Veterinary Biological Products

Under the provisions of "Livestock and Poultry Remedies", Public Act No. 134 of 1929, as amended, most veterinary biological products are remedies, and must be licensed prior to distribution. In addition, Public Act No. 466 of 1988, as amended, "Animal Industry Act", has additional requirements for these products as outlined below.

Section 6 of Act 466 defines veterinary biological products as all viruses, serums, toxins, and analogous products of natural or synthetic origin, or products prepared from any type of genetic engineering, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in diagnosis, treatment, or prevention of diseases in animals.

The rules for P.A. 466 requires permission from the State Veterinarian distribute, in Michigan, veterinary biological products which are conditionally or unconditionally licensed by the USDA or which have import permits for distribution and sale issued by the USDA. Submit the following information to the State Veterinarian when requesting permission to distribute:

- a. A copy of the current USDA license for the product
- b. Any restrictions set forth by the USDA
- c. A complete product name--generic and trade
- d. Product information, including directions for use
- e. Slaughter withdrawal times, if applicable

This information and prior notification is required for all veterinary biological products, including those that are exclusively diagnostic in purpose and function. THIS INFORMATION SHOULD BE SENT DIRECTLY TO THE STATE VETERINARIAN'S OFFICE.

If you have additional questions about the requirements pertaining to veterinary biological products, contact:

State Veterinarian and Division Director
Animal Industry Division
Michigan Department of Agriculture
P.O. Box 30017
Lansing, MI 48909
517-373-1077