PI-045 (Rev. 05/2008)

LICENSE FEE:
$20.00 Per Product

MICHIGAN DEPARTMENT OF AGRICULTURE
PESTICIDE AND PLANT PEST MANAGEMENT DIVISION
P.O. Box 30776
Lansing, MI 48909
(517) 373-0946

APPLICATION FOR ANIMAL REMEDIES LICENSE(S)
(In Accordance with Act No. 134, Public Acts 1929)

COMPLETE ENTIRE APPLICATION. PLEASE PRINT LEGIBLY.

(Note: This form must be completed. Unsigned/incomplete forms will be returned.)

LICENSEE NAME (AS IT APPEARS ON LABEL) _____
ADDRESS (AS IT APPEARS ON LABEL.) _____
CORRESPONDENCE SHOULD BE ADDRESSED TO:

FIRST & LAST NAME: _____ **TITLE:** _____
COMPLETE ADDRESS: _____
PHONE NO.: _____ **FAX NO.:** _____ **FEDERAL ID #:** _____
E-MAIL ADDRESS: _____**WEB ADDRESS:** _____
Is this application submitted in response to a violation notice? YES ___ NO ___
If yes: Violation # _____ **Date of Violation** _____
IS APPLICANT NAME AND ADDRESS DIFFERENT THAN LICENSEE? YES ___ NO ____
IF YES, COMPANY NAME AND ADDRESS IS: _____
_____

Application is hereby made for the licensing of the following Animal Remedies. Labels for each product listed below and /or on the enclosed license renewal printout are attached and are certified to be actual labels or true copies. I am enclosing $20.00 (check or money order) for each product. (Identical products having different brand names, trade names, or manufactured with varying potencies are licensed as separate products.)

REFUND POLICY: Refunds of under $5.00 will Not be considered unless requested in writing. Therefore, care must be exercised to assure Payments are for the exact amount required.

_____
Signature & Title of Person Preparing Application **Date**

Products listed on this application and/or the attached license renewal printout will be licensed for the period beginning July 1 (or the actual date of licensing if submitted later than July 1) and ending June 30, 20___, unless denied or cancelled in accordance with Section 5, Act No. 134, P.A. of 1929, as amended.

STOP! Before completing this application, read the accompanying information sheet. It lists additional information that must be submitted if your product is a veterinary biological. It also defines remedies, contains important criteria for determining whether a product is an animal remedy or a commercial feed, and explains what products are exempt from this license.

COMPLETE TRADE NAME OF PRODUCT(S) (INCLUDING BRAND NAME)	NADA Number	USDA LIC. Number

(LIST ADDITIONAL PRODUCTS ON NEXT PAGE.)

RETURN APPLICATION, LICENSE FEE, AND LABELS TO THE MICHIGAN DEPARTMENT OF AGRICULTURE, PESTICIDE AND PLANT PEST MANAGEMENT DIVISION, P.O. BOX 30776, LANSING, MICHIGAN 48909

COMPLETE TRADE NAME OF PRODUCT(S) (INCLUDING BRAND NAME)	NADA Number	USDA LIC. Number

IMPORTANT INFORMATION!

Animal Remedy License Applications

Before completing your Remedy License Application form, you will need to be familiar with the following information concerning **VETERINARY BIOLOGICALS**, remedies that are **EXEMPT** from licensing, **APPROVED NEW ANIMAL DRUG APPLICATION (NADA)s**, and products that may be determined to be **commercial feeds** rather than remedies. **YOUR FAMILIARITY WITH THIS MATERIAL MAY PREVENT UNNECESSARY AND LENGTHY DELAYS IN THE PROCESSING OF YOUR APPLICATION.**

What is a Remedy?

Act No. 134 provides the legal definition of a remedy. It states that the term "livestock remedy" includes all condimental *feeds*, *medicated or medicinal stock foods*, stock food *tonics*, stock or condition *powders*, *conditioners*, animal *regulators*, proprietary *medicines*, or any preparations of like nature in either solid or liquid form used for **any animal except man**, and administered internally, and claimed to stimulate, invigorate, cure ailments, or **other reasons**: Provided ...."

Many products that fit this definition may also appear to meet the definition of a commercial feed. The following guidelines should assist you in determining which products should be regulated as remedies.

Products Subject to Regulation as Remedies

1. Any product, including but not limited to, any animal drug or veterinary biological, which is not specifically exempt (see next section) and is not a commercial feed, and which is administered internally to **any animal except man**, is a remedy if it claims 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 that 21 CFR 500.52 regulates the use of terms such as "tonic", "tone", "toner", or "conditioner" in labeling.

Note: BE SURE TO INCLUDE THE NEW ANIMAL DRUG APPLICATION (NADA) APPROVAL NUMBER FOR ALL NEW ANIMAL DRUGS ON YOUR LICENSE APPLICATION. Products which have been reviewed by FDA and determined to be of no significant safety concern as labeled, may be submitted with supporting documentation.

2. Because of revised interpretations by EPA and FDA, pour-on insecticides, which were once regulated as pesticides, are now considered to be new animal drugs. Since the methods of administration have been determined to meet the definition of "internally", they are subject to regulation as remedies.

3. Biotechnologically-produced hormones, such as bovine somatotropin (BST).

Note: *Aquarium fish products* are to be considered remedies only if the label meets the preceding criteria and indicates direct injection, insertion into gullet, or dosage in feed. (Remember, feeds for fish maintained as pets are not considered commercial feeds under the Commercial Feed Law.)

Products Exempt from Regulation as Remedies

The definition provides that certain remedies are specifically exempt from regulation under Act 134.

1. Remedies prescribed and used by a veterinarian, regularly licensed in Michigan, **for use in connection with his/her own practice**. Thus, the following are exempt from licensing:

   - Drugs which are mandated by the Federal Food, Drug, and Cosmetic Act to be sold by prescription only. Such drugs should always bear the statement, "Caution: Federal Law restricts this drug to use by or on the order of a licensed veterinarian".

   - Veterinary biological products which are restricted to prescription use by their USDA/APHIS product license. Federal regulations covering such products require the statement "Restricted to use by or under the direction of a veterinarian" or "Restricted to use by a veterinarian" to be used on all carton labels and enclosures.

   Note: Label statements such as "For Veterinary Use Only" or "Restricted Drug" are not to be accepted as indications that such products are "prescription" drugs. "For Veterinary Use" simply limits the products to use for animals, and not for humans. "Restricted Drug" is a term generally found on certain products registered in some states such as California, but does not mean it requires a prescription.

2. Any product which is not administered **internally**, as this term is defined in Regulation 203. This includes all topical drugs or other preparations, such as ointments, salves, liniments, balms or wound dressings/sprays.

3. Products determined to be commercial feeds by the Department will not be licensed as remedies at this time. The labeler of any product which is a commercial feed as defined in the Commercial Feed Law - Act No. 120 must have a Commercial Feed license. Following are a few examples of such products:

   - 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 diseases or stress conditions, the products are considered to be unapproved drugs, in addition to being commercial feeds**;

   - Approved medicated feeds, supplements, concentrates and premixes;

   - Milk replacers;

   - Direct-fed microbial products, such as fermentation products and enzymes, which make no drug claims (they may be marketed in carriers for mixing in feed, in oral pastes, and in boluses);

   - 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 makes no direct or implied drug claims.)

Special Definitions and Terms

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 - 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. Note: Such products intended only for diagnosis and which are not administered internally to the animal, do not meet the definition of a remedy.

Additional Requirements for Veterinary Biologicals

Under the provisions of Public Act No. 134 of 1929, as amended, "Livestock and Poultry Remedies", most veterinary biologicals 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 biologicals 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 of 1988, as amended, state:

All of the following information is required when requesting permission to distribute, in this state, veterinary biologicals which are conditionally or unconditionally licensed by the USDA or which have import permits for distribution and sale issued by the USDA;

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.

INCLUDE THIS INFORMATION WITH YOUR ANIMAL REMEDY LICENSE APPLICATION.

The license application approval process for your product(s) will include a review of this information by the State Veterinarian/ Animal Industry Division Director. Pesticide and Plant Pest Management Division will issue the license(s) upon notification that the required information is in order.

While this information and prior notification is required for all veterinary biologicals, those which are exclusively diagnostic in purpose and function are not remedies and will not require a state Remedy License. IN SUCH CASES, THE ABOVE INFORMATION SHOULD BE SENT DIRECTLY TO THE STATE VETERINARIAN'S OFFICE.

In addition, Section 43 of Act 466 states:

(1) A company, manufacturer, firm, mail or telephone order company, establishment, outlet, or mobile distributor in another state shall not export any veterinary biologicals for distribution or sale into this state unless prior notification prior to sale or distribution is given to the director and any stipulations set forth in or pursuant to title 9 of the code of federal regulations under "licenses for biological products" and all amendments thereafter adopted pursuant to rules promulgated by the director are met.

(2) A company or manufacturer manufacturing a veterinary biological within this state shall not distribute or sell any veterinary biological within this state unless notification prior to distribution or sale is given to the director and any stipulations set forth in or pursuant to title 9 of the code of federal regulations under "licenses for biological products" and all amendments thereafter adopted pursuant to rules promulgated by the director are met.

(3) The director shall pursue restrictions on the distribution and use of veterinary biologicals when the director determines that such restrictions are necessary for the protection of domestic animals or the public health, interest, or safety, or both, as set forth in title 9 of the code of federal regulations under "licenses for biological products" and all amendments thereafter adopted pursuant to rules promulgated by the director.

(4) Veterinary biologicals shall be administered only by a licensed veterinarian or under the supervision of a licensed veterinarian unless used in compliance with section 18814 of the public health code, Act No. 368 of the Public Acts of 1978, being section 333.18814 of the Michigan Compiled Laws.

(5) A veterinary biological that is required in title 9 of the code of federal regulations under "licenses for biological products" and all amendments thereafter adopted pursuant to rules promulgated by the director to be administered by, on the order of, or under the supervision of a veterinarian, shall be distributed only to veterinarians, distributors who distribute the veterinary biological only to veterinarians, or to pharmacies and other appropriate retail outlets to be sold only on the prescription or order of a veterinarian.

(6) When the director determines with advice and consultation from the livestock industry involved and the veterinary profession that the protection of domestic animals or the public health, interest, or safety, or both, or that a control or eradication program for a disease or condition necessitates the report of the sale, use, distribution, or administration of a veterinary biological or diagnostic test, the director may require that any person who sells, uses, distributes, or administers a veterinary biological or diagnostic test report that information to the department within 10 working days. If a form is required, the form shall be supplied by the department.

If you have additional questions, contact:

Pesticide & Plant Pest Management Division, at (517) 373-9749

Director and State Veterinarian, Animal Industry Division, at (517) 373-1077