Form Approved: OMB No. 0910-0337, Expiration Date: January 31, 2010. See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDICATED FEED MILL LICENSE APPLICATION

FOR FDA USE ONLY

APPROVAL DATE:

SIGNED BY:

(For the Commissioner of Food and Drugs)

LICENSE NUMBER:

FDA REGISTRATION NUMBER:

MANUFACTURING SITE LEGAL BUSINESS NAME:

ADDRESS: *(Street, City, State and Zip code)*

PHONE NUMBER: EXT.:

FAX NUMBER:

MAILING ADDRESS/PHONE NUMBERS *(If different from above)*

PHONE NUMBER: EXT.:

FAX NUMBER:

TYPE OF APPLICATION:

- ☐ Original
- ☐ Resubmission
- ☐ Supplemental

As a Medicated Feed Mill Licensee, you have certified that:

- Animal feeds bearing or containing new animal drugs are manufactured and labeled in accordance with the applicable regulations published pursuant to section 512(i) of the Federal Food, Drug, and Cosmetic Act (the Act), or in accordance with the index listing published under section 572(e)(2) of the Act.
- The methods used in, and the facilities and controls used for, manufacturing, processing, packaging, and holding such animal feeds are in conformity with current good manufacturing practice as described in section 501(a)(2)(B) of the Act and 21 CFR 225.
- Your manufacturing facility will establish and maintain all records required by regulation or order issued under sections 512(m)(5)(A) and 504(a)(3)(A) of the Act, and will permit access to, or copying or verification of such records by FDA.

As a Medicated Feed Mill Licensee, you have committed to:

- Possessing current approved or index listed Type B and/or Type C Medicated Feed labeling for each Type B and/or Type C medicated feed to be manufactured prior to receiving the Type A Medicated Article containing such drug.
- Renewing registration each year with the FDA as required by 21 CFR 207.20 and 21 CFR 207.21.
- Using only non-drug feed components recognized in the Official Publication of the Association of American Feed Control Officials (AAFCO) or sanctioned by FDA under 21 CFR 573, 582 and 584 as suitable for use in animal feeds.
- Supplementing your license application promptly when changes in ownership or address occur.
- Complying with all other applicable provisions of the Act.

All license applications are to be sent to the Division of Animal Feeds, CVM, FDA, 7519 Standish Place, Rockville, Maryland 20855.

I CERTIFY that all of the statements made in this application are true and complete to the best of my knowledge and ability.
WARNING: A willfully false certification is a criminal offense. U.S. Code, Title 18, Sec. 1001.

NAME OF RESPONSIBLE INDIVIDUAL FOR THIS MANUFACTURING SITE:

TITLE OF MOST RESPONSIBLE INDIVIDUAL:

SIGNATURE OF RESPONSIBLE INDIVIDUAL: *(application must be signed and dated)*

DATE:

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Please DO NOT RETURN this application to this address.