Form Approved: OMB No. 0910-0337, Expiration Date: September 30, 2022. See PRA 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 ISSUED: _____

MANUFACTURING SITE LEGAL BUSINESS NAME:

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

PHONE NUMBER: EXT.:

FAX NUMBER:

FDA DRUG ESTABLISHMENT No. (enter DUNS No.):

FACILITY ESTABLISHMENT IDENTIFIER (FEI) No.:

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

PHONE NUMBER: EXT.:

FAX NUMBER:

EMAIL ADDRESS:

TYPE OF APPLICATION:

☐ Original

☐ Supplemental: License No. ____ - ____

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 drug establishment registration each year with the FDA as required by 21 CFR 207.
- 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.
- For further information see https://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/default.htm

MAIL TO: Division of Animal Feeds, HFV-220, CVM, FDA, 12225 Wilkins Avenue, Rockville, Maryland 20852. License application should have an original handwritten (in ink) signature.

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:

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 15 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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