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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDICATED FEED MILL LICENSE APPLICATION

Form Approved: OMB No. 0910-0337
Expiration Date: December 31, 2006
See OMB Statement on Reverse

FOR FDA USE ONLY

Approval Date:

Signed by:
(*For the Commissioner of Food and Drugs*)

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:

FAX number:

TYPE OF APPLICATION:

- ☐ Original Application
- ☐ Resubmission of Application
- ☐ Supplemental Application

FDA REGISTRATION NUMBER:

LICENSE NUMBER:

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).
- 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(9a)(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)(4)(B)(i) 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 Type B and C Medicated Feed labeling for each animal drug in animal feed 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 Association of American Feed Control Officials (AAFCO) Official Publication or sanctioned by FDA under 21 CFR 573, 582 and 584 as suitable for use in animal feeds.
- Supplementing your license application when changes in ownership or address occur. Supplements are to be sent promptly to the Division of Animal Feeds, CVM, FDA, 7500 Standish Place, Rockville, Maryland 20855.
- Complying with all other applicable provisions of the Act.

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 THE MOST RESPONSIBLE INDIVIDUAL FOR THIS MANUFACTURING SITE:

TITLE OF MOST RESPONSIBLE INDIVIDUAL:

SIGNATURE OF THE MOST RESPONSIBLE INDIVIDUAL: *(Application must be signed and dated)*

DATE:

Save Data | Next Page

Previous Page

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Paperwork Reduction Project 0910-0337
Hubert H. Humphrey Building, Room 531-H
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Washington, DC 20201

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FDA-3448 (12/03)

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