OTSC Quarterly Newsletter

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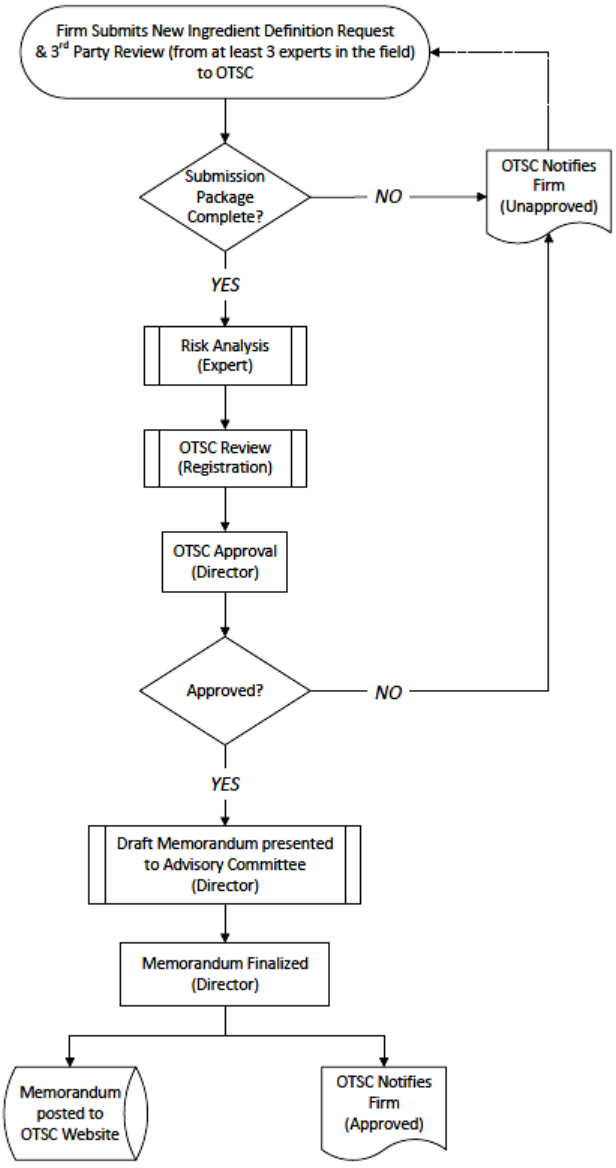
Approval Process for New Ingredient Definitions, Uses or Products

Texas Administrative Code Title 4. Agriculture, Chapter 61, Commercial Feed Rules require the guarantor of the commercial feed to name each ingredient or grouping of ingredients on the label. Those ingredients shall be either the official term(s) adopted by the Association of American Feed Control Officials (AAFCO), the common or usual name for the ingredient, or a name approved by the Office of the Texas State Chemist (OTSC). While AAFCO does have a formal ingredient approval process, it may not always be best suited for the submitter of a new ingredient or for a new use of an existing ingredient. As such, the OTSC has recently revised its criteria for approving new ingredient definitions, uses, or products for use in Texas in Feed Industry Memorandum No. 5-21: Criteria for Approving New Ingredient Definitions, Uses, or Products. In addition, OTSC responds to requests by feed manufacturers and consumers of feed to approve new products or ingredients in consultation with its advisory committee and experts to ensure the safety of feed and to protect the market place from fraudulent practices.

In November 2016, the Service issued Feed Industry Memorandum No. 5-30: Procedure for Reviewing and Approving Feed Ingredients or Drug Definitions, Uses or Products. The memorandum provides an explanation of the process flow for approval of an ingredient definition. Every request must be accompanied by a third party risk assessment. Once the application is reviewed and conditionally approved by the OTSC, a draft Feed Industry Memorandum is prepared with the new proposed definition. The draft definition, accompanied by the risk assessment and relevant studies by qualified researchers, are reviewed by the OTSC Advisory Committee for unintended consequences of the new ingredient definition. Based on input by the advisory committee, OTSC will grant final approval of the ingredient and post the new ingredient definition on the OTSC website. The steps for reviewing and approving feed ingredients or drug definitions, uses, or products are outlined in the process flow below.



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Protects consumers & enhances Agri-Business through its Feed & Fertilizer Regulatory Compliance Program, surveillance & monitoring of Animal-Human health & environmental hazards, & preparedness planning.

Mandatory Review of Agency Laws, Rules, and Policies Conducted

The Office of the Texas state Chemist (OTSC) conducted a mandatory review of agency laws, rules, and policies in the fall of 2016. After the review, proposed revisions were submitted in December 2016 to the Texas Register and posted in January 2017 to allow 30 days for public review and comment. After the required comment period, the proposed revisions were adopted to the Texas Administrative Code, Title 4. Agriculture, Chapter 61, Commercial Feed Rules §61.22 Labeling of Commercial Feed, (1) Purpose Statement. The revisions are administrative and should have a minimal impact on the regulated animal feed industry. As a result, the requirements for a purpose statement on a commercial feed label in Texas now align with Regulation 3 - Label Information (3) Purpose Statement in the Model Regulations under the Model Bill of the Association of American Feed Control Officials (AAFCO).

The rules were effective at the time of adoption, January 31, 2017. Enforcement discretion will be used until June 1, 2017. After June 1, 2017, non-compliant label inventories will be considered on a case by case basis. The new rule can be accessed on the OTSC website (http://otscweb.tamu.edu/Laws/PDF/FeedRules.pdf)

VFD Common Format for Forms for Use by Drug Sponsors and Veterinarians

The final rule revising the Veterinary Feed Directive (VFD) regulations in 21 CFR Part 558 became effective on October 1, 2015. The rule "outlines the process for authorizing use of VFD drugs (animal drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian) and provides veterinarians in all states with a framework for authorizing the use of medically important (used in animals and human medicine) antimicrobials in feed when needed for specific animal health purposes." (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm448446.htm)

According to the VFD rule, the use of all VFD drugs in feed requires a VFD form authorizing a client to obtain and use medicated feed containing the VFD drug. To assist veterinarians, their clients and distributors quickly identify relevant information on the VFD form, the FDA has issued Guidance for Industry Document #233 – Veterinary Feed Directive Common Format Questions and Answers. The guidance document addresses information to be submitted by the drug sponsor to the FDA to obtain approval for use in a medicated feed and information to be provided by the veterinarian to the producer. The VFD form provided by the sponsor during the approval process will be made available for use by veterinarians when authorizing their client to obtain and use medicated feed containing the VFD drug. Although the FDA recommends use of the VFD common format outlined in the guidance document, the veterinarian is not required to use the common format or the sponsor's form and may instead create his or her own VFD form, as long as it includes the required elements outlined in the Regulations. In addition, the veterinarian is required to keep the original VFD form for two years.

Currently, the FDA is in the process of implementing the VFD rule, including the use of VFD forms by drug sponsors, producers and veterinarians. During the interim implementation phase, FDA investigators will be examining VFD forms both upstream (to veterinarians) and downstream (to producers) for primarily educational purposes to facilitate compliance with the rule. More information on the VFD can be accessed on the FDA website (http://www.fda.gov/AnimalVeterinary/)DevelopmentApprovalProcess/ucm071807.htm)