

CHAPTER 7-16-10 DRUGS AND ADDITIVES IN FEED

Section
7-16-10-01 Drugs and Additives in Feed

7-16-10-01. Drugs and additives in feed.

1. Prior to approval of either a registration application or approval of a label for commercial feed which contains additives, or both, the distributor may be required to submit evidence to prove the safety and efficacy of the commercial feed when used according to the directions furnished on the label.
2. Satisfactory evidence of safety and efficacy of a commercial feed may be:
 - a. When the commercial feed contains such additives, the use of which conforms to the requirements of the applicable regulation in title 21, Code of Federal Regulations, or which are "prior sanctioned" or "informal review sanctioned" or "generally recognized as safe" for such use.
 - b. When the commercial feed is itself a drug as defined in subsection 7 of North Dakota Century Code section 4.1-41-01 and is generally recognized as safe and effective for the labeled use or is marketed subject to an application approved by the food and drug administration under section 512 of the Federal Food, Drug, and Cosmetic Act.
 - c. When one of the purposes for feeding a commercial feed is to impart immunity, the constituents imparting immunity have been approved for the purpose through the federal Virus, Serum, and Toxins Act of 1913 as amended.
 - d. When the commercial feed is a direct fed microbial product and:
 - (1) The product meets the particular fermentation product definition;
 - (2) The microbial content statement as expressed in the labeling is limited to the following: "Contains a source of live (viable) naturally occurring microorganisms." This statement shall appear on the label; and
 - (3) The source is stated with a corresponding guarantee expressed in accordance with these rules.
 - e. When the commercial feed is an enzyme product and:
 - (1) The product meets the particular enzyme definition defined by the association of American feed control officials; and
 - (2) The enzyme is stated with a corresponding guaranteed expressed in accordance with these rules.

History: Effective July 1, 2020.

General Authority: NDCC 4.1-41-20

Law Implemented: NDCC 4.1-41-06