WAC 16-250-094 Drug and feed additives. (1) Prior to approval of a registration application and/or approval of a label for commercial feed which contain additives (including drugs, other special purpose additives, or nonnutritive additives), 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 21 C.F.R., or which are "prior sanctioned" or "informal review sanctioned" or "generally recognized as safe" for such use; or

(b) When the commercial feed is itself a drug and is generally recognized as safe and effective for the labeled use or is marketed subject to an application approved by the United States Food and Drug Administration under section 512 of the Federal Food, Drug, and Cosmetic Act; or

(c) When one of the purposes for feeding a commercial feed is to impart immunity (that is to act through some immunological process) the constituents imparting immunity have been approved for the purpose through the Federal Virus, Serum and Toxins Act of 1913, as amended; or

(d) When the commercial feed is a direct fed microbial product and:

(i) The product meets the particular fermentation product definition; and

(ii) 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

(iii) The source is stated with a corresponding guarantee expressed in accordance with WAC 16-250-036(7).

(e) When the commercial feed is an enzyme product, and:

(i) The product meets the particular enzyme definition defined by the Association of American Feed Control Officials; and

(ii) The enzyme is stated with a corresponding guarantee expressed in accordance with WAC 16-250-036(8).

(3) An artificial color may be used in commercial feed only if it has been shown to be harmless to animals. The department will accept the permanent or provisional listing of an artificial color in the United States Food and Drug Administration regulations as safe for use as satisfactory evidence that the color is harmless to animals provided that the manufacturer's use of the artificial color is consistent with the conditions, limitations, and tolerance prescribed by the federal regulation.

(4) Any feed ingredients or feed product must not contain materials that enhance the natural color of a feed if it conceals inferiorities.

[Statutory Authority: RCW 15.53.9012, 15.53.9013, 15.53.9016, and chapter 34.05 RCW. WSR 18-21-191, § 16-250-094, filed 10/24/18, effective 11/24/18.]