

## REGULATORY PROCESSES FOR APPROVAL OF NEW INGREDIENTS

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### Abstract

Every time a new ingredient is introduced into the market place to be used as a feed or feed additive, most of the world takes little notice of the amount of effort that has gone into the entrance of this item into the food supply. For as long as the U.S. Food and Drug Administration (FDA) has regulated food for people, it has been regulating feed for animals. Although the FDA does not require approval for all animal feed or human food before they are marketed to the public, it does require that all feeds follow the tenets laid down by the Federal Food, Drug, and Cosmetic Act of 1958 (FFDCA). This act requires all foods to 1) be pure and wholesome, 2) be produced under sanitary conditions, 3) contain no harmful substances, and 4) be truthfully labeled. Companies can elect to petition for pre-market approval for any feed additives or they can petition for the use of a feed additive to be Generally Recognized As Safe (GRAS). Both methods require that the tenets of the FFDCA are met; however, the GRAS classification is reserved for a specific intended use of an additive in a specific intended species. In either case, the burden of proving these tenets lies with the companies submitting the petitions. For the companies that manufacture feeds for zoo animals, this can be a difficult situation when no research exists to prove that a feed additive is safe for some of the more exotic species. The question then becomes “What do the feed companies do then?” The use of both methods can be best illustrated in the recent surge in interest of organic trace minerals as a replacement for traditional inorganic trace minerals in feeds due to the increased bioavailability of many organic trace minerals.

### Useful References:

U.S. FDA Animal & Veterinary Section

<https://public.govdelivery.com/accounts/USFDA/subscriber/new?preferences=true#tab1>

U.S. FDA Animal & Food & Feeds Product Regulation:

<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/ucm050223.htm>

U.S. FDA Free e-mail subscription with updates on regulation changes and product recalls

<https://public.govdelivery.com/accounts/USFDA/subscriber/new?preferences=true#tab1>

U.S. Government Code of Regulations: Items Generally Recognized As Safe

[http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=3db61ec216c75c94a6eefc6be40125d&tpl=/ecfrbrowse/Title21/21cfr582\\_main\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=3db61ec216c75c94a6eefc6be40125d&tpl=/ecfrbrowse/Title21/21cfr582_main_02.tpl)