

Pets and Vets: Therapeutic Vet Diet Compliance Policy Guide Finalized



Article By

[Food and Drug Law at Keller and Heckman](#)
[Keller and Heckman LLP](#)
[The Daily Intake](#)

- [Biotech, Food, Drug](#)
- [All Federal](#)

Tuesday, May 3, 2016

[FDA finalizes enforcement policy with respect to therapeutic veterinary diets.](#)

- As a general matter, companies may not make therapeutic or “drug” claims in connection with the marketing of food or feed, including pet food. However, in reality, therapeutic pet food products have been marketed for years without official drug approvals in accordance with FDA’s longstanding enforcement discretion policy in this space. In [2012](#), FDA issued a draft **Compliance Policy Guide (CPG)** explaining the criteria that the Agency would consider when determining whether to take enforcement action regarding dog and cat food diets intended to treat specific diseases. FDA generally has exercised enforcement discretion with respect to “drug requirements” for therapeutic pet food products where: (1) the product provided all or most nutrients in support of an animal’s total required daily nutrient needs; (2) labels and marketing materials made available to the general public did not contain claims to treat or prevent disease; and (3) the products were distributed only through licensed veterinarians.
- In April 2016, FDA issued a [final version](#) of its CPG on therapeutic veterinary diets. Consistent with the draft CPG, the final version confirms FDA’s view that although therapeutic veterinary diets technically are “drugs” under the law, the Agency is “less likely” to initiate enforcement action when 11 specific criteria are met (e.g., marketing solely through licensed veterinary channels, the manufacturer’s compliance with food regulatory requirements, and avoidance of “drug claims” directly on the product label, among others).

- Although the CPG provides a list of regulatory and marketing conditions that may diminish the risk of FDA enforcement action within this highly specialized market, the policy provides no exceptions to the requirement that ingredients in therapeutic veterinary diets be approved food additives, generally recognized as safe (GRAS), or listed in the Official Publication of the Association of American Feed Control Officials (AAFCO Manual). In this manner, although the CPG may provide manufacturers in this space with some flexibility related to the “drug” requirements, companies still must comply with the “food” requirements to market therapeutic veterinary diets.

© 2019 Keller and Heckman LLP

Source URL: <https://www.natlawreview.com/article/pets-and-vets-therapeutic-vet-diet-compliance-policy-guide-finalized>