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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 564

[Docket No. 95N-0313]

**Standards for Animal Food and Food Additives in Standardized Animal Food**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations to remove its animal food standards regulations. The action is in response to the administration's "Reinventing Government" initiative, which seeks to streamline government to ease the burden on regulated industry and consumers, and it is intended to remove unnecessary regulations.

**DATES:** This final rule becomes effective on *(insert date 30 days after date of publication in the Federal Register)*.

**FOR FURTHER INFORMATION CONTACT:** George Graber, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6651, E-mail: ggraber@bangate.fda.gov.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of November 25, 1996 (61 FR 59845), FDA published a proposed rule that would remove part 564 (21 CFR part 564), Definitions and Standards for Animal Food, of subchapter E, Animal Drugs, Feeds, and Related Products. Subpart A of part 564 contains procedural regulations for establishing standards for animal food, and subpart B contains regulations applicable to food additives included in standardized animal foods.

FDA continues to believe, as stated in the preamble to the proposed rule, that because neither FDA nor the private sector has ever used the procedures in part 564 to develop a regulatory standard, part 564 is unnecessary. Further, should FDA ever receive a request to develop an animal food standard regulation, the agency could determine whether procedural regulations are necessary and issue such procedures through the notice and comment rulemaking process as the standard was being developed.

## **II. Response to Comments**

Forty-two comments were received on the proposed rule. Four comments were from organizations and the remainder from individuals. The majority of comments appear to have been prompted by an “Action Alert” (Alert) issued by one organization that states that there is no Federal regulation of animal food. The Alert states that enforcement is inconsistent and that standards for animal nutrition are inadequate.

1. Thirteen comments were identical form letters that repeat virtually the same language contained in the Alert, but concluding with the statement “Apparently, there is no interest by your department, the FDA, in developing a regulatory standard for animal and food additives, although there is a need for such standards. Therefore, the current regulation should be eliminated as a part of President Clinton’s ‘Reinventing Government’ initiative.”

2. Twelve comments digress from the issue at hand, to discuss topics such as bovine spongiform encephalopathy or other animal food safety matters that do not relate to part 564.

3. The remaining comments paraphrased the form letter mentioned previously. Many included the erroneous statement that “At the present there is NO federal regulation of animal food,” adding that regulation is only at the State level. The comments inaccurately concluded that part 564 provides our only authority to regulate animal foods, implying that in this regulation’s absence we have no authority to regulate.

FDA disagrees with comments that suggest removal of part 564 adversely affects the agency’s authority to regulate animal food. A misconception of FDA’s regulatory authority apparently exists,

because the agency has never relied on part 564 for regulation of animal food. FDA's authority under the Federal Food, Drug, and Cosmetic Act (the act), and the regulations under 21 CFR part 501 (labeling), 21 CFR part 502 (common or usual names), 21 CFR part 509 (contaminants), 21 CFR parts 570, 571, and 573 (food additives), 21 CFR part 579 (irradiation), 21 CFR part 582 (generally recognized as safe (GRAS) substances), and 21 CFR part 589 (prohibited substances), provide adequate authority for the needed regulation of animal food formulation and labeling.

The act prohibits the sale of adulterated and misbranded food in interstate commerce. The definition of food relates to food for man or animal, i.e., feed. The act also allows the agency to establish standards of identity or standards of fill as needed. However, there has been no interest or perceived need by the agency or other parties in developing standards under part 564.

In addition to the existing regulations and statute cited previously, FDA and State regulatory authorities recognize the common feed ingredient definitions established by the Association of American Feed Control Officials (AAFCO) with input from FDA. Feed ingredient definitions consist of specifications established to standardize feed ingredients to ensure that the production, sale and use of ingredients will result in safe and effective feeds. AAFCO has also developed standards, such as the AAFCO Dog and Cat Nutrient Profiles and Feeding Protocols, to help ensure that pet foods contain ingredients needed to meet the animals' nutritional requirements. FDA considers these protocols to be acceptable and appropriate for the evaluation of performance characteristics of commercial foods for dogs and cats.

The definitions and standards that AAFCO issues have served as models for State laws and regulations covering feed ingredients and their proper labeling. Because most pet food manufacturers market products in more than one State, those companies are obligated to manufacture and label pet food products to be in compliance with both FDA and State laws. Thus, the agency finds no basis to conclude that removal of part 564 would adversely affect the authority to regulate animal food.

### III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, and distributive impacts and equity). The Regulatory Flexibility Act requires agencies to examine the economic impact of a rule on small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any 1 year by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation). The agency has reviewed this final rule and has determined that the rule is consistent with the principles set forth in the Executive Order and in these two statutes. FDA finds that the rule will not be a major rule under the Executive Order.

The rule would remove the regulations establishing standards for animal foods, since neither FDA nor the private sector have ever used the procedures for developing a regulatory standard. FDA is taking this action in response to the administration’s “Reinventing Government” initiative which seeks to remove unnecessary regulations.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this rule will have on small entities, including small businesses, and certifies that the rule will not have a significant economic impact on a substantial number of small entities. FDA has also analyzed this rule in accordance with the Unfunded Mandates Reform Act and determined that the rule will not result in the expenditure by State, local, and tribal Governments, in the aggregate, or by the private sector of \$100 million. Therefore, no further analysis is required.

**IV. Environmental Impact**

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

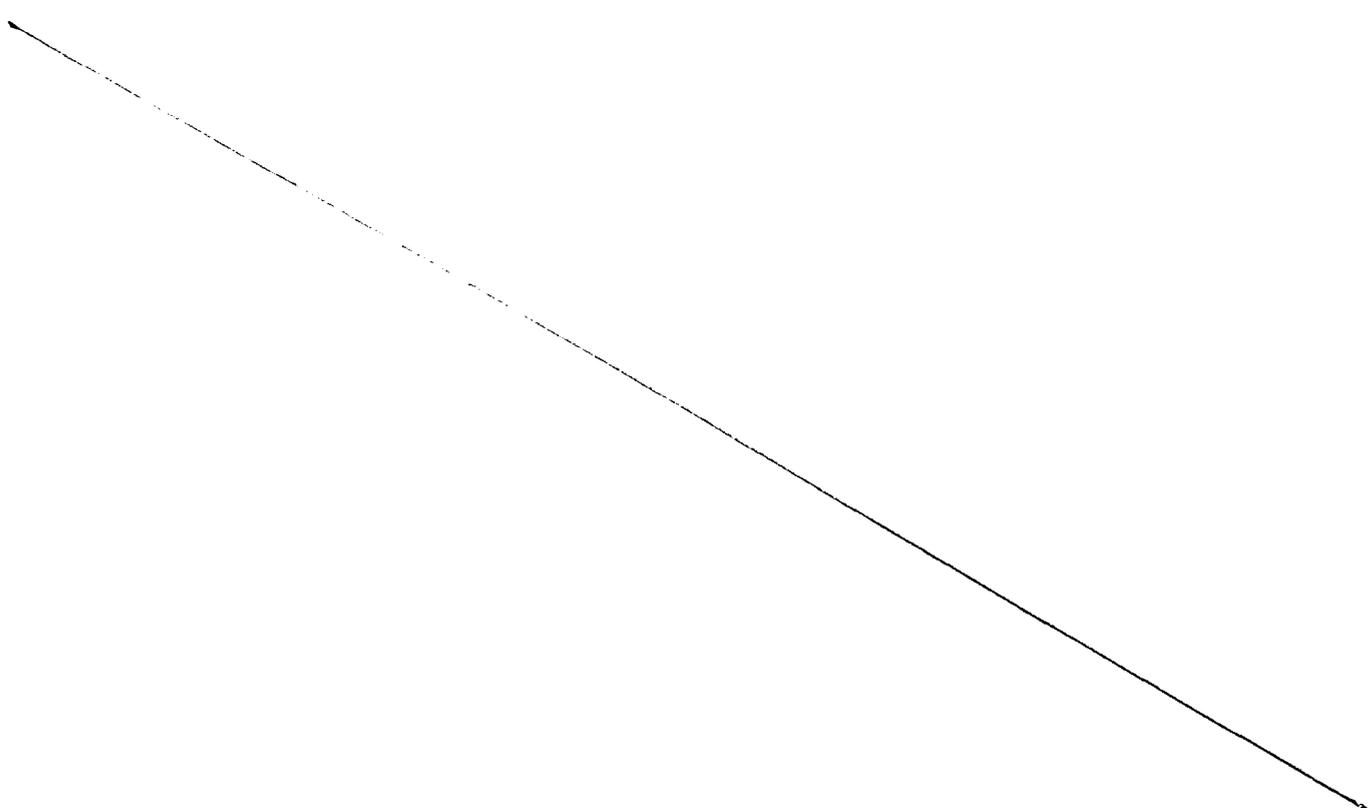
**V. The Paperwork Reduction Act of 1995**

FDA tentatively concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**List of Subjects in 21 CFR Part 564**

Animal foods, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 564 is removed and reserved.



**PART 564—DEFINITIONS AND STANDARDS FOR ANIMAL FOOD**

~~Part 564 [Removed and Reserved]~~

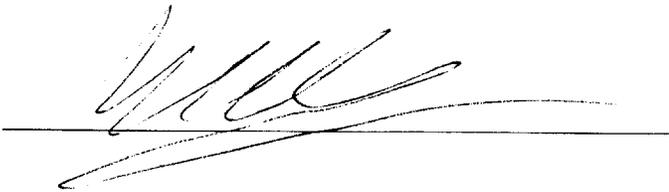
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1. Part 564 is removed and reserved.

Dated: January 23, 1999  
January 22, 1999

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

*Jen Windsor*



William K. Hubbard  
Acting Deputy Commissioner for Policy

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