

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to remove its animal food standards regulations. This 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 an unnecessary regulation.

DATES: Comments by February 24, 1997. The agency is proposing that any final rule that may be issued based upon this proposal become effective 30 days after date of publication of the final rule.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: George Graber, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1724.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 1995, President Clinton announced plans for the reform of the Federal regulatory system as part of the administration's "Reinventing Government" initiative. As part of this initiative, the President ordered all Federal agencies to conduct a page-by-page review of all of their regulations and to "eliminate or revise those that are outdated or otherwise in need of reform." The first results of FDA's efforts in implementing the President's plan were published in the Federal Register of October 13, 1995 (60 FR 53480).

In this document, FDA is proposing to remove the regulations in part 564 (21 CFR part 564) Definitions and Standards for Animal Food, of subchapter E, Animal Drugs, Feeds, and Related Products. Part 564 contains procedural regulations for establishing standards for animal food in subpart A, and regulations applicable to food additives in standardized animal food in subpart B. Because the procedures set out in

part 564 have never been used and because the agency does not believe that there is any interest in developing a regulatory standard, part 564 is unnecessary. If in the future there were ever to be a request from the industry or elsewhere 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. Analysis of Impacts

FDA has examined the impact of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). 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; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule would remove a regulation that is not being applied, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(9) 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.

IV. Request for Comments

Interested persons may, on or before February 24, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the

docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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, it is proposed that Title 21 chapter I be amended as follows:

PART 564—DEFINITIONS AND STANDARDS FOR ANIMAL FOOD

Part 564 [Removed]

Part 564 is removed.

Dated: October 23, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

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DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2510

Clarification of Application of ERISA to Insurance Company General Accounts

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Request for information.

SUMMARY: This document requests information from the public concerning issues which the Department has under consideration in developing regulations to clarify the application of the Employee Retirement Income Security Act of 1974 as amended (ERISA), to insurance company general accounts. Pursuant to section 1460 of the Small Business Job Protection Act of 1996 (Pub. L. 104-188), section 401 of ERISA has been amended. Section 401 now provides that no later than June 30, 1997, the Department must issue proposed regulations to: Provide guidance for the purpose of determining, where an insurer issues one or more policies to or for the benefit of an employee benefit plan (and such policies are supported by assets of the insurer's general account), which assets held by the insurer (other than plan assets held in its separate accounts) constitute assets of the plan for purposes of part 4 of Title I of ERISA and section 4975 of the Internal Revenue Code of 1986; and provide