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agencies to conduct a page-by-page review of all of their regulations and to ''eliminate or revise those that are outdated or otherwise in need of reform.''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.

[FR Doc. 96–30052 Filed 11–22–96; 8:45 am]

BILLING CODE 4160–01–F

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

guidance with respect to the application of Title I to the general account assets of insurers. The information provided to the Department in response to this document will assist the Department in developing the proposed regulations.

DATES: Comments must be received on or before January 24, 1997.

ADDRESSES: Comments (preferably, at least three copies) should be addressed to: Pension and Welfare Benefits Administration, Office of Exemption Determinations, Room N–5649, 200 Constitution Ave., N.W., Washington, D.C. 20210. Attention: ''General Account Contracts''.

FOR FURTHER INFORMATION CONTACT: Lyssa E. Hall, Office of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202) 219–8971 (not a toll-free number) or Timothy Hauser, Plan Benefits Security Division, Office of the Solicitor, (202) 219–8637 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

A. Background

Life insurance companies issue a variety of group contracts for use in connection with employee pension benefit plans, some of which provide benefits the amount of which is guaranteed, some of which provide benefits that may fluctuate with the investment performance of the insurance company, and some of which offer elements of both. Under section 401(b)(2) of ERISA, if an insurance company issues a ''guaranteed benefit policy'' to a plan, the assets of the plan are deemed to include the policy, but do not solely by reason of the issuance of the policy, include any of the assets of the insurance company. Section 401(b)(2)(B) defines the term ''guaranteed benefit policy'' to mean an insurance policy or contract to the extent that such policy or contract provides for benefits the amount of which is guaranteed by the insurer. In addition, in paragraph (b) of ERISA Interpretive Bulletin 75–2, 29 CFR 2509.75–2 (1975), the Department stated that if an insurance company issues a contract or policy of insurance to a plan and places the consideration for such contract or policy in its general asset account, the assets in such account shall not be considered to be plan assets.[1]

On December 13, 1993, the Supreme Court rendered its decision in *John Hancock Mutual Life Insurance Co.* v. *Harris Trust & Savings Bank*, 114 S. Ct. 517 (1993) (Harris Trust) which interpreted the meaning of ''guaranteed benefit policy''. In its decision, the Court held that a contract qualifies as a guaranteed benefit policy only to the extent it allocates investment risk to the insurer:

> [w]e hold that to determine whether a contract qualifies as a guaranteed benefit policy, each component of the contract bears examination. A component fits within the guaranteed benefit policy exclusion only if it allocates investment risk to the insurer. Such an allocation is present when the insurer provides a genuine guarantee of an aggregate amount of benefits payable to retirement plan participants and their beneficiaries.

Accordingly, under the Supreme Court's decision, an insurer's general account includes plan assets to the extent it contains funds which are attributable to any nonguaranteed components of contracts with employee benefit plans. Because John Hancock's contract provided for a return that varied with the insurer's investment performance, the Court concluded that John Hancock held plan assets, and was, therefore, a fiduciary with respect to the management and disposition of those assets. Under the reasoning of the Court's decision, a broad range of activities involving insurance company general accounts are subject to ERISA's fiduciary standards.

Because of the retroactive effect of the Supreme Court decision, numerous transaction engaged in by insurance company general accounts may have violated ERISA's prohibited transaction and general fiduciary responsibility provisions. The insurance industry believed that, absent legislative or administrative action, it would be subject to significant additional litigation and potential liability with respect to the operation of its general accounts.

If the underlying assets of a general account include plan assets, persons who have engaged in transactions with such general account may be viewed as parties in interest under section 3(14) of ERISA and disqualified persons under section 4975 of the Code, including fiduciaries with respect to plans which have interests as contractholders in the general account. For example, insurance companies are a source of loans for smaller and mid-sized companies. Many of these companies have party in interest relationships with plans that have purchased general account contracts. Application of the prohibited transaction rules to the general account of an insurance company as a result of the *Harris Trust* decision could call such loans into question under ERISA. Lastly, the underlying assets of an entity in which a general account acquired an equity interest may include plan assets as a result of the *Harris Trust* decision.

On March 25, 1994, the American Council of Life Insurance (ACLI) submitted an application for a class exemption from certain of the restrictions of sections 406 and 407 of ERISA and from certain excise taxes imposed by section 4975 (a) and (b) of the Code. The ACLI requested broad exemptive relief for transactions which included the following: all internal operations of general accounts, all investment transactions involving general account assets, including transactions with parties in interest with respect to plans that have purchased general account contracts, and the purchase by the general account of securities issued by, and real property leased to, employers of employees covered by plans that have purchased general account contracts.

On August 22, 1994, the Department published a notice of proposed Class Exemption for Certain Transactions Involving Insurance Company General Accounts. (59 FR 43134). Although the ACLI requested exemptive relief for activities in connection with the internal operation of general accounts, the Department determined that it did not have sufficient information regarding the operation of such accounts to make the findings required by section 408(a) of ERISA. Accordingly, the proposed class exemption did not provide relief for transactions involving the internal operation of an insurance company general account. The final exemption (Prohibited Transaction Exemption [PTE] 95–60, 60 FR 35925) was published in the Federal Register on July 12, 1995.

B. Public Law 104–188

In response to the Supreme Court decision in *Harris Trust*, Congress amended section 401 of ERISA by adding a new subsection 401(c) which clarifies the application of ERISA to insurance company general accounts. Pub. L. 104–188, § 1460. This statutory provision requires that the Department, not later than June 30, 1997, issue proposed regulations providing guidance for the purpose of determining, in cases where an insurer issues one or more policies (supported by the assets of the insurer's general account) to or for the benefit of an employee benefit plan, which assets held by the insurer (other than plan assets held in its separate accounts) constitute plan assets for purposes of part 4 of Title I and section 4975 of the

[1] Paragraph (b) of 29 CFR 2509.75–2 was removed effective July 1, 1996. 61 FR 33847, 33849 (July 1, 1996).

Code and to provide guidance with respect to the application of Title I to an insurer's general account assets. The proposed regulations must be subject to public notice and comment until September 30, 1997, and final regulations shall be issued not later than December 31, 1997.

The regulations will only apply to those general account policies which are issued by an insurer on or before December 31, 1998. In the case of such policies, the regulations will take effect at the end of the 18 month period following the date the regulations become final. Pub. L. 104–188, however, authorizes the Secretary to issue additional regulations designed to prevent avoidance of the regulations described above. These additional regulations, if issued, may have an earlier effective date.

The Department must ensure that the regulations issued under Pub. L. 104–188 are administratively feasible, and protect the interests and rights of the plan and of its participants and beneficiaries. In addition, the regulations must require, in connection with any policy (other than a guaranteed benefit policy) issued by an insurer to or for the benefit of an employee benefit plan, that: (1) an independent plan fiduciary authorize the purchase of the policy (unless the purchase is exempt under ERISA section 408(b)(5)); (2) the insurer provide information on an annual basis to policyholders (as prescribed in such regulations) disclosing the methods by which any income and expenses of the insurer's general account are allocated to be policy and the actual return to the plan under the policy and such other financial information as the Department determines is appropriate; (3) the insurer disclose to the plan fiduciary the extent to which alternative arrangements supported by the assets of the insurer's separate accounts are available, whether there is a right under the policy to transfer funds to a separate account and the terms governing any such right, and the extent to which support by assets of the insurer's general account and support by assets of the insurer's separate accounts might pose differing risks to the plan; and (4) the insurer must manage general account assets prudently, taking into account all obligations supported by such general account.

Compliance with the regulations issued by the Department will be deemed compliance by such insurer with sections 404, 406 and 407 of ERISA. In addition, under this statutory provision, no person will be liable under part 4 of Title I or Code section 4975 for conduct which occurred before the date which is 18 months following the issuance of the final regulation on the basis of a claim that the assets of an insurer (other than plan assets held in a separate account) constitute plan assets. The limitation on liability is subject to three exceptions: (1) the Department may circumscribe this limitation on liability in regulations intended to prevent avoidance of the regulations which it is required to issue under the statutory amendment; (2) the Department may bring actions pursuant to paragraph (2) or (5) of section 502(a) for breaches of fiduciary responsibilities which also constitute violations of Federal or State criminal law; and (3) civil actions commenced before November 7, 1995 are exempt from the amendment's coverage.

Issues Under Consideration

The Department is publishing this notice to provide interested persons with an opportunity to submit information and comments which will be considered by the Department in developing the regulations mandated by Pub. L. 104–188.[2]

In order to assist interested parties in responding, this notice contains a list of specific questions designed to elicit information that the Department believes would be especially helpful in developing a notice of proposed rulemaking. The questions developed by the Department may not address all issues relevant to the development of the regulation. Therefore, the Department further invites interested parties to submit comments on other matters that they believe are pertinent to the Department's consideration of the regulation.

Annual Disclosures

(1) What information relating to the financial soundness of an insurer do plan fiduciaries currently rely upon in selecting an insurer?

(2) Should additional information be required to be disclosed to plan fiduciaries prior to selecting an insurer? What would be the cost of supplying this information? To what extent would these costs be passed on to the contractholders?

(3) What annual information would plan fiduciaries find helpful in evaluating the appropriateness of an existing general account contract?

(4) Is there any information which should be disclosed more frequently than annually? Should this information be provided or available upon request?

(5) Do insurers currently disclose to potential contractholders the availability of alternative insurance arrangements supported by separate accounts, the right to transfer funds under a general account contract to a separate account, and the terms governing any such right?

(6) In general, what are the comparative risks and benefits of general account contracts vis-a-vis separate account contracts?

(7) To what extent, and in what format, should insurers be required to disclose information concerning the following:

(a) The expenses allocated to the contract and the basis for the allocation;

(b) The investment income allocated to the contract and the basis for the allocation;

(c) The mortality or morbidity experience attributed to the contract and the basis for the attribution;

(d) The allocation of any other aspect of the insurance company's financial performance which has an impact on the contract's return, and the basis for the allocation;

(e) The timing of the allocation of expenses, investment income, mortality or morbidity experience, and of any other factors affecting the contract's return;

(f) Any charges or provisions attributable to the contract for risks or profits, and the basis for the charges or provisions;

(g) Comparative data concerning the return, expenses, investment income, profit and risk charges attributable to other contracts, and an explanation of any disparities;

(h) The particular investment income allocation methodology or methodologies employed by the insurer, and any departures from the general methodologies in the actual allocation of investment income to the contract;

(i) Financial or familial relationships or transactions between (1) the insurer, its officers, or directors, and (2) the plan, the plan sponsor, or plan fiduciaries;

(j) Financial transactions between the insurer and any person or entity in which the insurer, its officers, or directors have a financial interest or familial relationship.

Do different formats have different cost implications? Which items are costly to produce, or involve confidential or proprietary information? What professional skills are required to prepare the required information?

[2] Section 1460 of Pub. L. 104–188 does not distinguish between welfare plans and pension plans that purchase general account contracts from insurers. Accordingly, the Department urges interested persons to submit information and comments which are relevant to welfare plans that have purchased general account contracts.

(8) Should the insurer be required to retain documentation supporting the required disclosures, and to make the supporting documentation available to the Secretary of Labor, plan sponsors, plan fiduciaries, or plan participants and beneficiaries? To what extent are these documents retained as part of current business practice? What are the estimated costs of retaining and producing these documents to the appropriate parties?

(9) How should the insurer calculate the actual return to the plan for purposes of any disclosure requirement? In particular,

(a) Should the insurer be required to take into account any market value adjustments, termination expense adjustments, withdrawal charges, or surrender charges in stating the contract's return?

(b) Should the regulations permit different approaches for calculating the rate of return for contracts requiring the issuance of annuities as opposed to those in which benefit payments are made without the issuance of an annuity?

(c) Should the regulations require that dividends that are anticipated or declared buy not yet paid, be included in determining the contract's return?

(d) To what extent should the regulations permit the return to be reported on a gross basis (i.e., before expenses or charges)?

(10) Under what circumstances would regulations requiring disclosure of the contractholder's return apply to general account contracts before the end of the 18 month period following the issuance of the final regulations?

Market Value Adjustments Upon Termination of General Account Contracts

(1) In what ways is discretion exercised by insurers under general account contracts in imposing market value adjustments or in determining the amount of such adjustments?

(2) What standards should the Department adopt to assure that market value adjustments reflect market conditions at the time of contract termination?

(3) Should the Department require general account contracts to set forth in ''plain English'' the method for calculating market value adjustments that can be objectively verified by the contractholder pursuant to standards set forth in the contract? In this regard, should the Department require that the method used for calculating market value adjustments only use parameters that can be independently verified by the contractholder?

(4) Should the Department limit or forbid the imposition of termination expense adjustments, withdrawal charges, or surrender charges pursuant to general account contracts?

(5) Under what circumstances should regulations regarding market value adjustments and other termination charges be applicable to general account contracts prior to the end of the 18 month period following the issuance of the final regulations?

State Regulatory Requirements

(1) To what extent do State regulatory requirements parallel or conflict with some or all of the requirements imposed by section 1460 of Pub. L. 104–188?

(2) Should the Department of Labor regulation take into account any State regulatory requirements that serve as a protection to contractholders? If so, please describe the nature of such requirements and the state's enforcement mechanism to assure compliance with such requirements.

Impact on Small Entities

(1) In responding to the questions above, please address the anticipated annual impact of any regulatory proposals on small insurers, (insurers with annual receipts of less than $5 million, see Small Business Administration Size Standards, 61 FR 3280, Jan. 31, 1996) and small plans, (plans with fewer than 100 participants).

(2) Statistically, what are the sizes of the plans using insurance company general accounts? What is the volume of assets held in these accounts, and what percent is held by small plans? Is there an estimate of how many small plans may be affected by the regulations?

(3) How many small insurance companies offer products that may be subject to the regulations? Is there an anticipated effect on those small companies' competitiveness due to such a regulation?

(4) What would be the most economical and efficient method of compliance with the requirements imposed by the amendment for small insurance companies?

(5) In responding to the questions above, please state whether the insurance companies' costs of complying with any regulatory proposals are likely to be passed on to the contractholders. If so, what are the projected costs? Are large insurance companies more likely to absorb the costs, leaving their contractholders in better positions? If costs are passed on, will small plans be able to absorb the increase?

(6) How can the disclosed materials be provided in formats useful to small plans? How can these materials be structured in ''plain English,'' or must they require the assistance of professional service providers to be valuable?

Miscellaneous

(1) The regulations will apply only to ''policies which are issued by an insurer on or before December 31, 1998.'' To what extent should the regulations treat pre-existing policies which are amended after December 31, 1998 as policies issued on or before December 31, 1998?

(2) To what extent should the Department regulate transactions between the insurer and its subsidiaries; between the insurer and entities in which the insurer's officers or directors have a financial interest?

(3) To what extent can insurers exercise discretion to the detriment of plan contractholders in the allocation of income, expenses, dividends, and other financial costs and benefits? How should a limitation on that discretion be formulated? For example, should the Department require that income, expenses and surplus be allocated in a manner directly proportionate to the plan's actual contribution to each of these categories?

(4) What constraints, if any, should be placed on insurers' ability to unilaterally amend contract terms which affect the value of the plan's policy (e.g., terms concerning minimum interest rate guarantees, expense charges, and annuity purchase rates)?

(5) Do insurance companies and persons engaging in transactions with such companies believe that guidance is necessary regarding which general account contracts constitute ''guaranteed benefit policies'' within the meaning of section 401(b)(2) of ERISA in light of the *Harris Trust* decision? In this regard, what types of policies raise significant issues post *Harris*?

All submitted responses and comments will be made a part of the record of the proceeding referred to herein and will be available for public inspection.

Signed at Washington, DC this 20th day of November, 1996.

Olena Berg,

Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 96–30030 Filed 11–22–96; 8:45 am]

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