

flexible contracts, it is necessary to deduct incidental insurance and substandard risk charges from cash value because the need for charges to support them is constant while the timing and amount of payments are unpredictable.

The lack of relationship between premium payments and deductions of incidental insurance and substandard risk charges precludes application of a bifurcated sales load computation without use of a set of artificial assumptions. According to an industry commentator, there appears to be no practical means to attribute these charges to payments prospectively since it cannot be known in advance how the frequency or amount of payments will relate to these periodic deductions from cash value.

The inclusion of these charges within the definition of "payment" in one sense will result in a greater amount of permissible sales load because the base against which sales load is measured, i.e., "payments" during a contract period, will expand to the extent a portion of a payment is attributable to incidental insurance or substandard risk charges. However, the deduction of incidental insurance and substandard risk charges periodically from cash value, rather than from payments, results in insureds having larger amounts of their premium payments allocated to the separate account and added to their cash values. Larger cash value benefits the insured by reducing the basic insurance charge and giving the insured the opportunity for greater investment return. Based on these considerations, the Commission has determined to amend paragraph (c)(7).

Paragraph (c)(7), as amended, excludes from the definition of "payment" incidental insurance and substandard risk charges only when those charges are deducted from premium payments in the same manner as scheduled contracts subject to rule 6e-2.¹¹ To the extent those charges are deducted from cash values, however, they are to be included within the definition of "payment."

List of Subjects in 17 CFR Part 270

Investment companies, Reporting and recordkeeping requirements, Securities.

¹¹ If either of those charges is deducted from premium payments before allocation of the net premium to the separate account, it must be excluded from the definition of "payment" for purposes of measuring sales load and refund rights, i.e., each charge is treated independently.

Text of Amendments to Rule 6e-3(T)

In accordance with the foregoing Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 270—[AMENDED]

1. The authority citation of Part 270 continues to read in part as follows:

Authority: Sections 6(e) and 38(a) of the Investment Company Act of 1940, as amended, 15 U.S.C. 80a-6(e) and 37(a). * * *

2. By revising paragraphs (b)(13)(iii) (E) and (c)(7) of § 270.6e-3(T) to read as follows:

§ 270.6e-3(T) Temporary exemptions for flexible premium variable life insurance separate accounts.

(b) * * *

(13) * * *

(iii) * * *

(E) The deduction of premium taxes imposed by any state or other governmental entity, the cost of insurance, charges assessed for incidental insurance benefits or if the insured does not meet standard underwriting requirements, and, if the separate account is organized as a management investment company, an investment advisory fee;

(c) * * *

(7) "Payment," as used in paragraphs (b)(13)(i), (b)(13)(ii), and (b)(13)(v)(A) of this Rule and in sections 27(a)(2) and 27(h)(2) solely with respect to flexible contracts, means for a contract period the gross premiums paid less any portion of such gross premiums deducted for the item specified in paragraph (c)(4)(viii) and, if deducted prior to the allocation of net premiums to the separate account, for the items specified in paragraphs (c)(4)(vi) and (c)(4)(vii) of this Rule. "Payment," as used in any other section of this Rule, means the gross premiums paid or payable for the flexible contract, *Except*, that "Payment" shall not include any amount deducted by the life insurer to recover excess sales loading previously applied to keep the contract in force pursuant to paragraph (b)(13)(iv)(B)(2) of this Rule.

Regulatory Flexibility Act Certification

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Chairman of the Commission previously certified that rule 6e-3(T) will not have a significant economic impact on a substantial number of small entities. No comments were received on that certification. The amendments do not alter the basis for this determination.

Paperwork Reduction Act

These amendments to rule 6e-3(T) are not subject to the Act because they do not impose an information collection requirement.

Administrative Procedure Act

Because this rulemaking is exemptive in nature, the Commission finds, pursuant to section 553(d)(1) of the Administrative Procedure Act (5 U.S.C. 553(d)(1)), that the 30 day delay in effectiveness is not required, and, accordingly, the rule amendments will become effective immediately upon publication in the *Federal Register*. The Commission has determined, pursuant to section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)), that there is no need to republish rule 6e-3(T) to obtain additional comment on its decision to amend this rule since the issues were raised by both Investment Company Act Releases 1362 (Nov. 23, 1983) (48 FR 54043 (Nov. 30, 1983); 29 SEC Docket 365 (Dec. 8, 1983)) and 14234 and in fact were commented upon.

By the Commission.

John Wheeler,

Secretary.

July 10, 1985.

[FR Doc. 85-16948 Filed 7-16-85; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed for Feed Service Co., Inc., providing for the manufacture of 5- and 20-gram-per-pound tylosin premixes used to make complete feeds for swine, beef cattle, and chickens.

EFFECTIVE DATE: July 17, 1985.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION: Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001, is the sponsor of a supplement to NADA 111-637 submitted on its behalf by Elanco Products Co. The supplement provides

for the manufacture of 5- and 20-gram-per-pound tylosin premixes used to make complete feeds for swine, beef cattle, and chickens for use as in 21 CFR 558.625(f)(1)(i) through (vi). The supplement is approved and the regulations are amended to reflect the approval.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, RM. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) (April 26, 1985; 50 FR 16636) 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.

List of Subjects in 21 CFR Part 558

Animal drugs; Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

2. Section 558.625 is amended by revising paragraph (b)(54) to read as follows:

§ 558.625 Tylosin

(b) * * *

(54) To 030841: 5, 10, 20, and 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

Dated: July 11, 1985

Marvin A. Norcross,

Acting Associate Director for Scientific Evaluation.

[FR Doc. 85-16896 Filed 7-16-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed for Ag-Mark, Inc., providing for the manufacture of 5-, 10-, and 20-gram-per-pound tylosin premixes used to make complete feeds for swine, beef cattle, and chickens.

EFFECTIVE DATE: July 17, 1985.

FOR FURTHER INFORMATION CONTACT:

Benjamin A. Puyot, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION:

Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464, is the sponsor of a supplement to NADA 121-147 submitted on its behalf by Elanco Products Co. The supplement provides for the manufacture of 5-, 10-, and 20-gram-per-pound tylosin premixes used to make complete feeds for swine, beef cattle, and chickens for use as in 21 CFR 558.625(f)(1)(i) through (vi). The supplement is approved and the regulations are amended to reflect the approval.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, RM. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) (April 26, 1985; 50 FR 16636) 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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to

the Center for Veterinary Medicine, Part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

2. Section 558.625 is amended by revising paragraph (b)(66) to read as follows:

§ 558.625 Tylosin.

(b) * * *

(66) To 024174: 5, 10, 20, and 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

Dated: July 11, 1985.

Marvin A. Norcross,

Acting Associate Director for Scientific Evaluation.

[FR Doc. 85-16894 Filed 7-16-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 812

[Docket No. 76N-0324]

Investigational Device Exemptions; Conforming Amendments

Correction

In FR Doc. 85-15069, beginning on page 25908 in the issue of Monday, June 24, 1985, make the following corrections:

1. On page 25908, third column, seventh line from the bottom of the page, add "of" after "consideration".
2. In § 812.35(b), on page 25910, first column, sixth line, "will-being" should read "well-being".

BILLING CODE 1505-01-M

AFRICAN DEVELOPMENT FOUNDATION

22 CFR Part 1502

Availability of Records

AGENCY: African Development Foundation.

ACTION: Final rule.

SUMMARY: This action establishes the policies and procedures the African Development Foundation is adopting to permit the inspection and copying of documents of the Foundation in accordance with the requirements of the Freedom of Information Act. The regulations include procedures for

requesting documents and for processing such requests, and establishes the fees which shall be charged by the Foundation for costs associated with responding to requests.

EFFECTIVE DATE: August 17, 1985.

FOR FURTHER INFORMATION CONTACT: Paul Magid, General Counsel, Ann Richardson, Director, Administration and Finance, (202) 634-9853.

SUPPLEMENTARY INFORMATION: Proposed rulemaking was published on pages 18678-18680 of the Federal Register of May 2, 1985, and invited comments for 60 days ending July 1, 1985. No comments were received.

Executive Order 12291

The African Development Foundation has determined that this rule is not a major rule for the purpose of E.O. 12291 because it is not likely to result in an annual effect on the economy of \$100 million or more.

Paperwork Reduction Act

This rule imposes no obligatory information requirements on the public.

Regulatory Flexibility Act of 1980

The President of the Foundation certifies that this rule will not have a significant impact on a substantial number of small entities.

List of Subjects in 22 CFR Part 1502

Administrative practice and procedures, Freedom of Information, Records.

Accordingly, Part 1502 is added to 22 CFR Chapter XV to read as follows:

PART 1502—AVAILABILITY OF RECORDS

Sec.

- 1502.1 Introduction.
- 1502.2 Definitions.
- 1502.3 Access to Foundation records.
- 1502.4 Written requests.
- 1502.5 Records available at the Foundation.
- 1502.6 Records of other Departments and Agencies.
- 1502.7 Fees.
- 1502.8 Exemptions.
- 1502.9 Processing of requests.
- 1502.10 Judicial review.

Authority: 5 U.S.C. 552, and 22 U.S.C. 290h-4.

§ 1502.1 Introduction.

(a) It is the policy of the African Development Foundation that information about its operations, procedures, and records be freely available to the public in accordance with the provisions of the Freedom of Information Act.

(b) The Foundation will make the fullest possible disclosure of its

information and identifiable records consistent with the provisions of the Act and the regulations in this Part.

(c) The Director of Administration and Finance (A&F) shall be responsible for the Foundation's compliance with the processing requirements of the Freedom of Information Act.

§ 1502.2 Definitions.

As used in this Part, the following words have the meanings set forth below:

(a) "Act" means the act of June 5, 1967, sometimes referred to as the "Freedom of Information Act" or the Public Information Section of the Administrative Procedure Act, as amended, Pub. L. 90-23, 81 Stat. 54, codified at 5 U.S.C. 552.

(b) "Foundation" means the African Development Foundation.

(c) "President" means the President of the Foundation.

(d) "Record(s)" includes all books, papers, or other documentary materials made or received by the Foundation in connection with the transaction of its business which have been preserved or are appropriate for preservation by the Foundation as evidence of its organization, functions, policies, decisions, procedures, operations, or other activities, or because of the informational value of the data contained therein. Library or other material acquired and preserved solely for reference or exhibition purposes, and stocks of publications and other documents provided by the Foundation to the public in the normal course of doing business are not included within the definition of the word "records." The latter will continue to be made available to the public without charge.

§ 1502.3 Access to Foundation records.

Any person desiring to have access to Foundation records may call or apply in person between the hours of 10 a.m. and 4 p.m. on weekdays (holidays excluded) at the Foundation offices at 1724 Massachusetts Avenue, NW., Suite 200, Washington, D.C. 20036. Requests for access should be made to the Director of A&F, at the Foundation offices. If request is made for copies of any record, the Office of A&F will assist the person making such request in seeing that such copies are provided according to the rules in this Part.

§ 1502.4 Written requests.

In order to facilitate the processing of written requests, every petitioner should:

(a) Address his or her request to: Director, Administration and Finance Division, African Development

Foundation, 1724 Massachusetts Avenue, NW., Suite 200, Washington, D.C. 20036.

Both the envelope and the request itself should be clearly marked: "Freedom of Information Act Request."

(b) Identify the desired record by name, title, author, a brief description, or number, and date, as applicable. The identification should be specific enough so that a record can be identified and found without unreasonably burdening or disrupting the operations of the Foundation. Blanket requests or requests for "the entire file of" or "all matters relating to" a specified subject will not be accepted. If the Foundation determines that a request does not reasonably describe the records sought, the requestor shall be advised what additional information is needed or informed why the request is insufficient.

(c) Include a check or money order to the order of the "African Development Foundation" covering the appropriate search and copying fees, or a request for determination of the fee and a promise to pay any amount over \$3.00 in connection with the FOIA request.

§ 1502.5 Records available at the Foundation.

The Administration and Finance Division will make available for public inspection and copying, to the extent not authorized to be withheld, the following works or classes of information:

(a) A copy of Foundation regulations, including those published in Title 22 of the Code of Federal Regulations or of any other title of the Code.

(b) Statements of policy and interpretations which have been adopted by the Foundation and which are not published in the Federal Register.

(c) Administrative staff manuals and instructions to staff that affect a member of the public;

(d) Any indexes providing identifying information regarding any record described in paragraphs (b) and (c) of this section.

(e) Brochures and other printed materials describing the Foundation's activities.

§ 1502.6 Records of other Departments and Agencies.

Requests for records which have been originated by, or are primarily the concerns of, another U.S. Department or Agency will be forwarded to the particular Department or Agency involved, and the petitioner so notified. In response to requests for records or publications published by the Government Printing Office or other

Government printing activity, the Foundation will refer the petitioner to the appropriate sales office and refund any fee payments which accompanied the request.

§ 1502.7 Fees.

(a) *When charged.* Fees shall be charged in accordance with the schedules contained in paragraph (b) of this section for services rendered in responding to requests for Foundation records under this sub-part unless the Director of A&F determines that such charges, or a portion thereof, are not in the public interest because furnishing the information primarily benefits the general public. Fees shall also not be charged where they would amount, in the aggregate, for a request or series of related requests, to less than \$3. Ordinarily, fees shall not be charged if the records requested are not found, or if located, are withheld as exempt.

(b) *Services charged for and amount charged.* For the services listed below expended in locating or making available records or copies thereof, the following charges shall be assessed:

(1) *Copies.* For copies \$.10 per copy of each page.

(2) *Clerical searches.* For each one quarter hour spent by clerical personnel in excess of the first quarter hour in searching for and producing requested records, \$2.30.

(3) *Non-routine, non-clerical searches.* Where the task of determining which records fall within a request and collecting them requires the time of professional or managerial personnel, and where the time required is substantial, for each one quarter hour spent in excess of the first quarter hour, \$5.40. No charge shall be made for the time spent in resolving legal or policy issues affecting access to records of known contents.

(4) *Other charges.* When a response to a request requires services or materials other than those described in paragraphs (b)(1) through (b)(3) of this section, the direct cost of such services to the Foundation may be charged, providing the requestor has been given an estimate of such cost before it is incurred.

(c) *Revision of Schedule.* The fee schedule will be revised from time to time, without notice, to assure recovery of actual costs of rendering information services to any person. The revised schedule will be available without charge.

§ 1502.8 Exemptions

The following categories are examples of records which, if maintained by the

Foundation, may be exempted from disclosure under 5 U.S.C. 552(b):

(a) Records specifically required by Executive Order to be exempt from disclosure in the interest of the national defense or foreign policy which properly classified pursuant to such Executive Order;

(b) Records related solely to the internal personnel rules and practices of the Foundation;

(c) Records specifically exempted from disclosure by statute (other than 5 U.S.C. 552b), providing that such statute (1) requires that the matter be withheld from the public in such a manner as to leave no discretion, or (2) establishes criteria for withholding or refers to particular types of matters to be withheld;

(d) Trade secrets and commercial or financial information obtained from any person which is privileged or confidential;

(e) Interagency or intra-agency memoranda or letters which would not be available by law to a private party in litigation with the Foundation;

(f) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(g) Investigatory files (including security investigation files and files concerning the conduct of employees) compiled for law enforcement purposes, except to the extent available by law to a private party.

The Foundation will not honor requests for exempt records or information.

§ 1502.9 Processing of requests.

(a) *Processing.* A person who has made a written request for records which meets the requirements of § 1502.4 shall be informed by the Director of A&F within ten working days of receipt of the Foundation's decision whether to deny or grant access to the records.

(b) *Denials.* If the Director of A&F, with the concurrence of the General Counsel, denies a request for records, the requestor will be informed of the name and title of the official responsible for the denial, the reasons for it, and the right to appeal the decision to the President of the Foundation within 15 working days of receipt of the denial. The President shall determine any appeal within 20 days of receipt and notify the requestor within the time period of the decision. If the decision is to uphold the denial, the requestor will be informed of the reasons for the decision and of the right to a judicial review of the decision in the federal courts.

(c) *Extension of time.* Where it is reasonably necessary to the proper processing of requests, the time required to respond to an FOIA request or an appeal may be extended for an additional 10 working days upon written notification to the requestor providing the reasons for the extension.

§ 1502.10 Judicial review.

On complaint, the district court of the United States in the district in which the complainant resides, or has his/her principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the Foundation from withholding Foundation records, and to order the production of any agency records improperly withheld from the complainant (5 U.S.C. 552(a)(4)(B)).

Dated: July 8, 1985.

Leonard H. Robinson, Jr.,

President, African Development Foundation.

[FR Doc. 85-16921 Filed 7-16-85; 8:45 am]

BILLING CODE 6117-01-M

22 CFR Part 1504

Employee Responsibilities and Conduct

AGENCY: African Development Foundation.

ACTION: Final rule.

SUMMARY: This rule is intended to implement and interpret E.O. 1222 (3 CFR 1964-1965 Comp.; 5 CFR 735.104); Title 18, U.S.C. 203, 205, 207, 208, 209; and Title II of the Ethics in Government Act of 1978, as amended (5 U.S.C.). The African Development Foundation finds and determines that publication of these regulations in the Code of Federal Regulations is necessary for the effective discharge of its functions and activities.

EFFECTIVE DATE: August 17, 1985.

FOR FURTHER INFORMATION CONTACT: Paul Magid, General Counsel, (202) 634-9853.

SUPPLEMENTARY INFORMATION: Proposed rulemaking was published on pages 18878-18884 of the Federal Register of May 3, 1985, and invited comments for 60 days ending July 2, 1985. No comments were received.

Regulatory Flexibility Act of 1980

Generally, these regulations do not contain substantive new material. It is, therefore, certified that they will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act.