for all real estate-related financial transactions except those in which:

(1) The transaction value is $100,000 or less;

(2) Either:

(i) A lien on real property has been taken as collateral solely through an abundance of caution and where the terms of the transaction as a consequence have not been made more favorable than they would have been in the absence of a lien; or

(ii) The regulated institution has not taken as collateral a lien on real property and either the institution is fully protected by other collateral, or the borrower qualifies for unsecured credit;

* * * * *

(d) *Effective date.* Savings associations are required to use State certified or licensed appraisers as set forth in this part no later than December 31, 1992.

Dated: March 31, 1992.

By the Office of Thrift Supervision.

Timothy Ryan,

Director.

[FR Doc. 92-7963 Filed 4-10-92; 8:45 am]

BILLING CODE 6720-01-M

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12 CFR Part 567

[No. 92-135]

RIN 1550-AA40

Regulatory Capital: Residential Bridge Loans

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Thrift Supervision (OTS) is revising its risk-based capital regulation to include in the 50 percent risk-weight category certain construction loans to finance the building of pre-sold, 1–4 family residences. Only those loans made in accordance with sound lending principles to builders with substantial project equity would qualify for the 50 percent risk-weight. To qualify for the 50 percent risk-weight category, the loans must satisfy specific prudential criteria and conservative underwriting standards. Included in these criteria is the requirement that a builder must have substantial equity at risk in the construction project. In addition, the homes generally will be required to be sold under firm contracts to purchasers who have obtained firm commitments for permanent qualifying mortgages. The home buyer also must have made a substantial earnest money deposit. This regulatory amendment is intended to facilitate lending to creditworthy builders to finance the construction of pre-sold homes.

EFFECTIVE DATE: May 13, 1992.

FOR FURTHER INFORMATION CONTACT: John F. Connolly, Program Manager, Capital Policy, (202) 906-6465, Supervision Policy, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: On December 17, 1991,[1] OTS proposed to amend its capital rule, 12 CFR part 567, (the "Proposal") by placing certain conservatively underwritten residential construction loans ("residential bridge loans") in the 50 percent risk-weight category in computing risk-based capital requirements. Such loans are currently in the 100 percent risk-weight category.

Loans to individuals to fund construction of their own homes are already included in the 50 percent category under the risk-based capital rules of the Office of the Comptroller of the Currency ("OCC") and the OTS. The proposed amendment would give parallel treatment to qualifying residential bridge loans made directly to builders for the construction of pre-sold homes. The other federal banking agencies are considering adoption of similar capital treatment for these types of loans.

Supervisory Experience

In general, supervisory experience and available data suggest that single-family residential construction loans experience lower loss rates than either acquisition and development loans for residential property or construction loans for multifamily and commercial real estate properties. Furthermore, experience suggests that institutions can reduce losses significantly on residential construction through adherence to the prudential lending criteria set forth in this rule.

Data for residential construction lending from the Thrift Financial Reports for the six quarters ending June 30, 1991 show that savings associations experienced average charge-offs on 1–4 family residential construction loans of 0.60 percent of such loans over that period. This compares favorably with charge-off rates on multifamily construction lending and non-residential construction lending of 1.62 percent and 2.7 percent, respectively.

Furthermore, the 1–4 family residential construction lending category includes higher-risk loans such as loans for large tract construction, speculative construction, and some land development loans. This broader category, therefore, is a riskier category of lending than would be eligible for the 50 percent risk-weight category under this rule. Moreover, residential bridge loans that are supported by firm purchase contracts and substantial purchaser earnest money deposits contain elements of safety that are not present in speculative and tract development lending. Consequently, the OTS anticipates that loss rates on residential bridge loans meeting the strict underwriting criteria of this rule will be significantly less than those on a typical portfolio of residential construction loans. For these reasons, the OTS has concluded that placing residential bridge loans in the 50 percent risk-weight category should provide ample capital protection against the risk of these loans.

Relationship to Section 618 of the Resolution Trust Corporation Refinancing, Restructuring, and Improvement Act of 1991

Section 618 of the Resolution Trust Corporation Refinancing, Restructuring, and Improvement Act of 1991[2] directs the OTS and the other banking agencies to place certain pre-sold, single-family construction loans and multifamily housing loans in the 50 percent risk-weight category for the purpose of computing risk-based capital requirements. As stated in the preamble to the Proposal, this rulemaking preceded, and was independent of, that statutory provision. Nevertheless, this final rule satisfies the residential construction loan provisions of section 618(a).

In view of the similarity between the Proposal and the provisions of section 618(a), the OTS concluded that the Proposal provided reasonable notice and basis for comment on both the Proposal and the applicable provisions of section 618(a). Accordingly, the OTS has determined that it is not necessary to publish a revised proposal for comment.

Analysis of Comments

The OTS sought comment on all aspects of the Proposal, and specifically solicited comment on the builder equity and home purchaser earnest money deposit requirements of the Proposal. In response, the OTS received 19 comment letters from savings associations, trade associations, and other companies involved in various aspects of residential construction. Key points

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[1] 56 FR 67551 (December 31, 1991)

[2] Pub. L. 102-233, 105 Stat. 1761 (Dec. 12, 1991).

made in the comments are summarized below.

Builder's Equity

The OTS specifically requested comment on the minimum amount of project equity to require a builder to have in a home construction project. The proposed rule required the builder to have project equity equal to at least 25 percent of the projected value of the residence.

Commenters generally agreed with the concept of requiring substantial "builder equity" to ensure that the builder has a sufficient financial stake in a home's construction. Most commenters, however, said that requiring a 25 percent equity position was too high and would impair the usefulness of the proposal as a means to facilitate the availability of credit to sound borrowers. These commenters generally stated that a builder equity requirement of 10–15 percent would provide adequate protection to the lender while enhancing the benefits to be derived from increasing the credit available for conservative, pre-sold residential construction.

Other commenters discussed the difficulty of defining builder equity because of the wide variation of construction practices. Recommended approaches to computing a builder's equity included limiting the loan amount to a percentage of the sales contract and defining the builder's financial stake to be the payment of some percentage of actual construction costs.

In light of these comments, the OTS has decided to modify its approach for ensuring that a builder has substantial equity at risk. Under the modified approach, a builder's financial stake will result from the combination of the following requirements. First, the builder will be required to fund a significant percentage of direct construction costs before any drawdown on the loan. Generally, this will require the builder to pay the first 10 percent of direct costs. Second, the loan will be limted to 80 percent of the sales price. Finally, the lender and builder must adhere to an acceptable funds disbursement system. With regard to the latter, the thrift will be required to disburse funds under a system designed to ensure the retention of sufficient undisbursed loan funds throughout the construction process to fund project completion. Generally, this requires use of a construction budget or cost breakdown and a reasonable funds disbursement policy. This would identify cost overruns and cause the builder at that time to cover costs overruns and other nonapproved costs not in accordance with the initial construction budget.

For example, if the sales price of the house was $100,000 and direct costs (*i.e.*, land, labor and material) were $90,000, the residential bridge loan could be for up to $80,000. The builder would be required to fund the first $9,000 of direct costs for the home's construction.

Purchaser's Earnest Money Deposit

The OTS also requested comment on the amount of earnest money deposit that home purchasers should be required to make. The Proposal required an earnest money deposit equal to 5 percent of the loan amount.

The majority of commenters stated that a 5 percent deposit was higher than necessary in light of the other criteria being imposed. Several commenters said that a large deposit requirement would hinder the usefulness of the rule change because purchasers generally will be unwilling or unable to make such a deposit. One commenter also suggested that such large, nonrefundable, "liquidated damages" provision is not permissible under California law.

The majority of commenters recommended following the customary practice of keying the earnest money to the sales price, not the loan amount. Because the sales price is a larger amount, requiring a lower percentage can result in a comparable deposit.

After considering these comments, the terms of Section 618, and the protective effects of the other criteria being imposed, the OTS has decided to modify the deposit requirements. As modified, this final rule will require a substantial earnest money deposit. This is generally expected to be at least 3 percent of the sales price.

Other Comments

A number of commenters sought clarification of whether loans financing multi-home projects would qualify as residential bridge loans under the proposal. Some commenters discussed difficulties of applying the requirements of the proposal to multi-home projects.

The OTS has decided to address this issue in its final rule by requiring that sufficient documentation be retained for each loan, as well as the home construction and sale, to demonstrate adequately compliance with the criteria of this rule. This permits loans for homes in multi-home projects to qualify as residential bridge loans on the same terms as residential bridge loans for the construction of single-home projects.

Although the separate documentation requirements may add an element of complexity for lenders and builders choosing to have loans in multi-home projects qualify as residential bridge loans, this requirement is necessary to ensure compliance with the criteria of this rule.

Furthermore, the separate documentation requirement does not resolve the difficulty of prorating joint costs of a large multi-home construction projects to individual home contracts. However, this problem, as a general matter, must also be dealt with in pricing and establishing the value of individual homes in a multi-home development. The OTS will look to the reasonableness of the proration of costs to the number of homes in a project and the contract prices for the individual homes. The OTS retains the discretion to determine that costs and builder's equity are not being pro-rated reasonably and to refuse to permit the reduced risk-weighting of related loans.

Another commenter urged the OTS to retain the flexibility to treat residential construction loans as residential bridge loans if the loans are supported by insurance contracts that guarantee completion and sale of the home at a contracted sale price. Another commenter suggested giving the reduced risk-weight to loans under certain affordable housing programs. The OTS is retaining the discretion to give the reduced risk-weight treatment to these and other conservatively underwritten residential construction loans that are demonstrated to be as safe as those meeting the specific criteria of this rule.

Several commenters noted that construction delays could be caused by requiring purchasers to have firm commitments for qualifying mortgages, particularly in multi-home projects. One commenter recommended substituting, as an alternative to a firm loan commitment, the issuance of a commitment for private mortgage insurance issued for the benefit of the permanent lender, whether or not identified as of the commitment date. This commenter noted that the determination of a mortgage insurance company to issue a mortgage insurance commitment would provide substantial assurance of the creditworthiness of the home purchaser and the value and marketability of the home under construction. The commenter asserted that reliance on such a commitment could reduce delays caused by waiting for a firm loan commitment from a permanent lender.

The OTS has determined that such a commitment may be substituted, with OTS approval, for a firm loan commitment. The existence of such an insurance commitment also will be considered as a factor to the extent

relevant when OTS weighs requests for other variances from the specified criteria of this rule.

The OTS concurs with a comment that "standard conditions precedent and subsequent" should not keep a contract from being considered firm. Such a standard condition of the purchase contract is satisfactory completion of the home by the builder in accordance with the contract. Such standard conditions, however, generally do not include conditions requiring a separate credit decision or conditions relying on the occurrence of events outside of the construction of the home (*e.g.*, sale of the purchaser's current residence).

The OTS also agrees with another commenter that the OTS should clarify that the rule will apply to 1–4 family residences, not just single family homes. This determination is consistent with the proposed actions of the other Federal banking agencies and with the OTS definition of a "qualifying mortgage loan" under the capital rules.

Several other commenters stated that there are alternatives to the percentage-of-completion schedule, such as a voucher system, that are equally safe. Under a voucher system, a lender makes disbursements to subcontractors and suppliers upon proof of satisfactory performance. The OTS will permit the use of any acceptable system requiring work to be satisfacorily completed at a preapproved cost before loan disbursements are made. The system must work together with the requirement that the lending thrift at all times retain sufficient undisbursed loan funds to finish the construction project. This means that cost overruns must be covered by the builder at the time they are identified.

Finally, one commenter urged the OTS to issue a final rule only in conjunction with the other Federal banking agencies. In order to maintain competitive equity between banks and savings associations, the OTS has worked with the other Federal banking agencies to develop parallel treatment of residential bridge loans.

Furthermore, the other Federal banking agencies are in the process of considering actions to provide parallel capital treatment to residential bridge loans. The OTS is ussuing this final rule prior to those agencies making their final determinations on the issues addressed by this rule. The OTS is working with them in considering these issues. The OTS will exercise the discretion granted to it by this rule to achieve as much harmony as possible with the final positions of the other Federal banking agencies.

The OTS has considered these and all other comments received in adopting this final rule.

Residential Bridge Loan Rule

The OTS is amending its capital regulation to place residential bridge loans in the 50 percent risk-weight category. To qualify for the 50 percent risk-weight the loans must meet the criteria specified below.

(1) The loan to the builder may not exceed 80 percent of the sales price of the pre-sold home.

(2) The loan must be secured by a first lien on the lot, house under construction, and other improvements.

(3) The lending association must disburse the loan funds under an acceptable funds disbursement system ensuring that the association retains sufficient undisbursed loan funds throughout the construction process to fund the project's completion in accordance with a reasonable initial construction budget. Under this system the builder will be required to cover any cost overruns (*i.e.*, any costs that exceed the initial construction budget) and any other costs not included in the construction budget.

(4) To ensure that the builder has significant equity at risk in the project, the builder generally must incur at least the first 10 percent of direct costs (*i.e.*, the actual costs of land, labor, and materials). If the builder owns the lot, his cost basis in the lot (not the lot's appraised value) will be used to determine his payment of direct costs related to the project.

(5) Before making the loan, the savings association must obtain documentation showing that the prospective home purchaser intends to purchase the residence and has the ability to obtain a qualifying mortgage loan sufficient to purchase the residence. Generally, the OTS will require this documentation requirement to be satisfied by the home buyer signing a firm purchase contract for the residence and obtaining a firm commitment for a qualifying mortgage loan, as defined in 12 CFR 567.1(u), from the permanent lender. The association making the construction loan could commit to make the permanent loan itself or could obtain a loan commitment from a third-party lender.

The OTS retains the discretion, however, on a case-by-case basis to allow an association to rely on a commitment for private mortgage insurance for the benefit of a permanent lender. The mortgage insurance commitment could permit classification of a loan as a residential bridge loan prior to the home purchaser obtaining a firm loan commitment. The mortgage insurer must be approved by the Federal Home Loan Mortgage Corporation or the Federal National Mortgage Association.

(6) The prospective home buyer must make a substantial "earnest money" deposit that would be subject to forfeiture if the buyer defaults on the contract. In general, the earnest money deposit is expected to be at least 3 percent of the sales price, and shall be held by the savings association in escrow. The terms of the escrow must provide that in the event of default, the escrow funds are first to be used to compensate the association for its losses on the residential bridge loan with any remainder being turned over to the builder for use in accordance with the terms of the contract with the home purchaser.

(7) For multi-home projects, the documentation for each loan and home sale must be sufficient to demonstrate compliance with the criteria of this rule.

(8) The loan must be made for the construction of a home on a developed building lot that is platted and bonded, or satisfies comparable requirements of the appropriate municipal authority.

(9) If at any time during the life of the construction loan any of the criteria of this rule are no longer satisfied, the association must immediately recategorize the loan at a 100 percent risk-weight and must accurately report the loan in the association's next quarterly Thrift Financial Report;

(10) The home purchaser must intend that the home will be owner-occupied;

(11) The home purchaser(s) must be an individual(s), not a partnership, joint venture, trust corporation, or any other entity (including an entity acting as a sole proprietorship) that is purchasing the home(s) for speculative purposes; and

(12) The loan must be performing and not more than 90 days past due, as the OTS requires for permanent qualifying mortgages.

(13) The loan must be made in accordance with sound lending principles. The OTS retains the discretion to determine that any loans not meeting sound lending principles must be placed in a higher risk-weight category.

The general standards of the regulation are expected to be satisfied in the manner described above. The OTS, however, retains the discretion to modify the standards on a case-by-case basis upon OTS determination that the modification would not be inconsistent with the safety and soundness objectives of this rule.

Associations must make available to OTS examiners documentation demonstrating compliance with these criteria. The OTS may, upon review of the association's residential bridge loans and related documentation, determine that such loans do not meet the criteria of this rule. Such loans would then be placed in a higher risk-weight category.

The OTS plans to revisit these standards approximately one year after the effective date of this rule to evaluate the rule's operation and whether changes are needed.

Regulatory Flexibility Act

Pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b), it is hereby certified that this proposal will not have a significant or disproportionate economic impact on a substantial number of small entities. Furthermore, this proposed rule would not impose any new recordkeeping or other requirements on any associations and would lower the current risk-weighting of residential bridge loans from 100 percent to 50 percent. Accordingly, a Regulatory Flexibility Act Analysis is not required.

Executive Order 12291

The Director of the OTS has determined that this proposed regulation does not meet any of the conditions set forth in Executive Order 12291 for designation as a "major rule." Consequently, a Regulatory Impact Analysis is not required.

List of Subjects in 12 CFR Part 567

Capital, Reporting and recordkeeping requirements, Savings associations.

Accordingly, the Office of Thrift Supervision hereby amends part 567, chapter V, title 12, Code of Federal Regulations, as set forth below.

SUBCHAPTER D—REGULATIONS APPLICABLE TO ALL SAVINGS ASSOCIATIONS

1. The authority for part 567 continues to read as follows:

Authority: Sec. 2, 48 Stat. 128, as amended (12 U.S.C. 1462); sec. 3, as added by sec. 301, 103 Stat. 278 (12 U.S.C. 1462a); sec. 4, as added by sec. 301, 103 Stat. 280 (12 U.S.C. 1463); sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464); sec. 10, as added by sec. 301, 103 Stat. 318 (12 U.S.C. 1467a).

2. Section 567.1 is amended by adding paragraph (jj) to read as follows:

§ 567.1 Definitions.

* * * * *

(jj) *Qualifying residential construction loan.* (1) The term qualifying residential construction loan, also referred to as a residential bridge loan, means a loan made in accordance with sound lending principles satisfying the following criteria:

(i) The builder must have substantial project equity in the home construction project;

(ii) The residence being constructed must be a 1–4 family residence pre-sold to a home purchaser;

(iii) The lending thrift, prior to the making of the qualifying residential construction loan, must obtain sufficient documentation from a permanent lender (which may be the construction lender) demonstrating that:

(A) The home buyer intends to purchase the residence; and

(B) Has the ability to obtain a permanent qualifying mortgage loan sufficient to purchase the residence;

(iv) The home purchaser must have made a substantial earnest money deposit;

(v) The construction loan must not exceed 80 percent of the sales price of the residence;

(vi) The construction loan must be secured by a first lien on the lot, residence under construction, and other improvements;

(vii) The lending thrift must retain sufficient undisbursed loan funds throughout the construction period to ensure project completion;

(viii) The builder must incur a significant percentage of direct costs (*i.e.*, the actual costs of land, labor, and material) before any drawdown on the loan;

(ix) If at any time during the life of the construction loan any of the criteria of this rule are no longer satisfied, the association must immediately recategorize the loan at a 100 percent risk-weight and must accurately report the loan in the association's next quarterly Thrift Financial Report;

(x) The home purchaser must intend that the home will be owner-occupied;

(xi) The home purchaser(s) must be an individual(s), not a partnership, joint venture, trust corporation, or any other entity (including an entity acting as a sole proprietorship) that is purchasing the home(s) for speculative purposes; and

(xii) The loan must be performing and not more than 90 days past due.

(2) The documentation for each loan and home sale must be sufficient to demonstrate compliance with the criteria in paragraph (jj)(1) of this section. The OTS retains the discretion to determine that any loans not meeting sound lending principles must be placed in a higher risk-weight category. The OTS also reserves the discretion to modify these criteria on a case-by-case basis provided that any such modifications are not inconsistent with the safety and soundness objectives of this paragraph (jj).

3. Section 567.6 is amended by adding a new paragraph (a)(1)(iii)(D) to read as follows:

§ 567.6 Risk-based capital credit risk weight categories.

(a) *Risk-weighted Assets.* * * *

(1) *On-Balance Sheet Assets.* * * *

* * * * *

(iii) *50 percent Risk Weight (Category 3).* * * *

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(D) Qualifying residential construction loans as defined in § 567.1(jj) of this part.

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Dated: March 30, 1992.

By the Office of Thrift Supervision.

Timothy Ryan,

Director.

[FR Doc. 92–7961 Filed 4–10–92; 8:45 am]

BILLING CODE 6720–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket Nos. 86G–0104 and 86G–0105]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Ethyl Esters of Fatty Acids and Sulfated Butyl Oleate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethyl esters of fatty acids and sulfated butyl oleate in aqueous emulsions for dehydrating grapes to produce raisins. This action is in response to petitions filed by Victorian Chemical Co., Pty. Ltd.

DATES: Effective April 13, 1992; written objections and requests for a hearing by May 13, 1992.

ADDRESSES: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9519.

SUPPLEMENTARY INFORMATION: In notices published in the Federal Register of April 9, 1986 (51 FR 12212 and 12213), FDA announced that GRAS petitions 6G0312 and 6G0311, respectively, had been filed by Victorian Chemical Co., Pty. Ltd., P.O. Box 71, Richmond, Victoria 3121, Australia, proposing to affirm that ethyl esters of fatty acids and sulfated butyl oleate are generally recognized as safe (GRAS) for use in aqueous emulsions for dehydrating grapes to produce raisins. No comments were received in response to these notices.

The petitioner requested GRAS affirmation of ethyl esters of fatty acids and sulfated butyl oleate based upon a history of common use in food in Australia before 1958 (21 CFR 170.30(c)(2)). Section 170.30(c)(2) requires, among other things, that common use in food be documented by published or other information and be corroborated by information from a second, independent source that confirms the history and circumstances of use. In addition, 21 CFR 170.3(f) defines "common use in food" to mean a substantial history of consumption of a substance for food use by a significant number of consumers.

FDA has evaluated the data in the petitions and has concluded that the data in the petitions establish that prior to 1958, ethyl esters of fatty acids and sulfated butyl oleate were used only on an experimental basis for the dehydration of grapes. This past use of these substances does not constitute a substantial history of consumption by a significant number of consumers. Consequently, these substances do not qualify for GRAS affirmation based upon a history of common use in food before 1958 as required by §§ 170.3(f) and 170.30(c)(2).

Moreover, FDA has concluded that because the methyl esters of edible fatty acids are already approved as food additives (21 CFR 172.225) for dehydrating grapes, the petitioned use of ethyl esters of fatty acids and sulfated butyl oleate in dehydrating grapes should be evaluated as food additives, in accordance with 21 CFR 170.38(a), and, if their use is safe, listed in 21 CFR part 172. This action will ensure that similar substances and uses will be listed in the same part of the Code of Federal Regulations. FDA informed the petitioner of its decision to evaluate the substances as food additives, and the petitioner did not object.

Accordingly, FDA has evaluated the data in the petitions and other relevant material in light of the standard for food additives in section 409(c) of the act (21 U.S.C. 348(c)). In conducting this evaluation, the agency reviewed the data in the petitions and concludes that the consumption of sulfated butyl oleate resulting from its use on raisins will not exceed 1.1 milligrams (mg) per person per day (Ref. 1), which, after being metabolized, yields 0.18 mg of butanol per person per day, or 0.06 parts per million (ppm) in the diet. The L_{50} for butanol is 790 mg per kilogram (kg) of body weight per day in rats (or 47,400 mg per day for a 60-kg person). This L_{50} value is several orders of magnitude larger than the estimated exposure to butanol (0.18 mg per day) due to the use of sulfated butyl oleate in dehydrating grapes to raisins. In addition, the metabolism of butanol is well characterized and is of no toxicological concern (Ref. 2) under the petitioned conditions of use.

In addition, there is information in the petition that establishes that the consumption of ethyl esters of fatty acids due to their use in dehydrating grapes to raisins will not exceed 2.2 mg per person per day (Ref. 3). Upon metabolism, these esters will yield 0.35 mg of ethanol per person per day. On an equal exposure basis, methyl esters of fatty acids (which are listed in 21 CFR 172.225) have more toxic potential than the ethyl esters because of the potential for release of methyl alcohol. As stated above, the petitioned use is expected to contribute 2.2 mg of the less toxic ethyl esters of fatty acids to the daily diet, an amount that is well below the level of methyl esters of fatty acids that is considered safe (91 mg per person per day). Thus, the small exposure to ethyl esters of fatty acids is of no toxicological concern (Ref. 2).

Based on its review of the foregoing, FDA concludes that the proposed use of ethyl esters of fatty acids and the proposed use of sulfated butyl oleate are safe and that the food additive regulations in 21 CFR part 172 should be amended by revising § 172.225, and by adding § 172.270 as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of these actions. FDA has concluded that the actions will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting these findings, contained in environmental assessments, may be seen in the Dockets Management branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before May 13, 1992, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memoranda dated March 31, 1986, and April 4, 1986, from P. M. Kuznesof to J. Gordon, "Sulfated Butyl Oleate for Use in the Dehydration of Grapes to Raisins," Victorian Chemical Company.

2. Memoranda dated March 13, 1986, and April 11, 1986, from C.B. Johnson to J. Gordon, "Sulfated Butyl Oleate and Ethyl Esters of Fatty Acids for Use in the Dehydration of Grapes to Raisins."

3. Memoranda dated March 31, 1986, from P.M. Kuznesof to J. Gordon, "Ethyl Esters of Fatty Acids for Dehydration of Grapes to Raisins," Victorian Chemical Company.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 376).

2. Section 172.225 is revised to read as follows:

§ 172.225 Methyl and ethyl esters of fatty acids produced from edible fats and oils.

Methyl esters and ethyl esters of fatty acids produced from edible fats and oils may be safely used in food, subject to the following prescribed conditions:

(a) The additive consists of a mixture of either methyl or ethyl esters of fatty acids produced from edible fats and oils and meets the following specifications:

(1) Not less than 90 percent methyl or ethyl esters of fatty acids.

(2) Not more than 1.5 percent unsaponifiable matter.

(b) The additive is used or intended for use at the level not to exceed 3 percent by weight in an aqueous emulsion in dehydrating grapes to produce raisins, whereby the residue of the additive on the raisins does not exceed 200 parts per million.

3. New § 172.270 is added to subpart C to read as follows:

§ 172.270 Sulfated butyl oleate.

Sulfate butyl oleate may be safely used in food, subject to the following prescribed conditions:

(a) The additive is prepared by sulfation, using concentrated sulfuric acid, of a mixture of butyl esters produced by transesterification of an edible vegetable oil using 1-butanol. Following sulfation, the reaction mixture is washed with water and neutralized with aqueous sodium or potassium hydroxide. Prior to sulfation, the butyl oleate reaction mixture meets the following specifications:

(1) Not less than 90 percent butyl oleate.

(2) Not more than 1.5 percent unsaponifiable matter.

(b) The additive is used or intended for use at a level not to exceed 2 percent by weight in an aqueous emulsion in dehydrating grapes to produce raisins, whereby the residue of the additive on the raisins does not exceed 100 parts per million.

Dated: April 1, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-8401 Files 4-10-92; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 510 and 546

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Vetri-Tech, Inc., to Arkansas Micro Specialties, Inc.

EFFECTIVE DATE: April 13, 1992.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8646.

SUPPLEMENTARY INFORMATION: Vetri-Tech, Inc., P.O. Box 324, Montvale, NJ 07645, had informed FDA that it has transferred ownership of, and all rights and interests in, approved NADA 140-578 (tetracycline hydrochloride soluble powder) to Arkansas Micro Specialties, Inc., P.O. Box 308, Highway 71 North, Lowell, AR 72745. Accordingly, FDA is amending the regulations in 21 CFR 510.600 (c)(1) and (c)(2) by removing Vetri-Tech, Inc., because the firm is no longer the sponsor of any approved NADA's. Also, the regulations are amended in 21 CFR 546.180d to reflect the change of sponsor.

List of Subjects in 21 CFR

Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Part 546

Animal drugs, Antibiotics.

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, 21 CFR parts 510 and 546 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing "Vetri-Tech, Inc." and in the table in paragraph (c)(2) by removing "058752".

PART 546—TETRACYCLINE ANTIBIOTIC DRUGS FOR ANIMAL USE

1. The authority citation for 21 CFR part 546 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 546.180d [Amended]

2. Section 546.180d *Tetracycline soluble powder* is amended in paragraph (c)(6)(iv)(*d*)(*3*) by removing "058752" and adding in its place "047863".

Dated: April 6, 1992.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 92-8403 Filed 4-10-92; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; Tilmicosin Phosphate Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly and Co. The NADA provides for the subcutaneous use of tilmicosin phosphate injection for the treatment of bovine respiratory disease in cattle. The regulations are also amended to provide for a tolerance for tilmicosin residues in edible cattle tissues.

EFFECTIVE DATE: April 13, 1992.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8659.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, a Division of Eli Lilly