completely independent pricing may be difficult to obtain. In such cases, operational units may need to use prices provided by the portfolio manager. For unique instruments where the pricing is being provided by a single source (e.g., the dealer providing the instrument), the institution should review and understand the assumptions used to price the instrument.

Personnel. The increasingly complex nature of securities available in the marketplace makes it important that operational personnel have strong technical skills. This will enable them to better understand the complex financial structures of some investment instruments.

Documentation. Institutions should clearly define documentation requirements for securities transactions, saving and safeguarding important documents, as well as maintaining possession and control of instruments purchased.

An institution's policies should also provide guidelines for conflicts of interest for employees who are directly involved in purchasing and selling securities for the institution from securities dealers. These guidelines should ensure that all directors, officers, and employees act in the best interest of the institution. The board may wish to adopt policies prohibiting these employees from engaging in personal securities transactions with these same securities firms without specific prior board approval. The board may also wish to adopt a policy applicable to directors, officers, and employees restricting or prohibiting the receipt of gifts, gratuities, or travel expenses from approved securities dealer firms and their representatives.

Legal Risk

Legal risk is the risk that contracts are not legally enforceable or documented correctly. Institutions should adequately evaluate the enforceability of its agreements before individual transactions are consummated. Institutions should also ensure that the counterparty has authority to enter into the transaction and that the terms of the agreement are legally enforceable. Institutions should further ascertain that netting agreements are adequately documented, executed properly, and are enforceable in all relevant jurisdictions. Institutions should have knowledge of relevant tax laws and interpretations governing the use of these instruments.

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BILLING CODE 7535–01–U

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 703 and 704

Investment and Deposit Activities; Corporate Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: NCUA is adopting as final the interim final amendments to the investment regulation as issued last year. The final amendments revise the broker-dealer and safekeeping provisions. NCUA is also deleting the references to the High Risk Securities Test for CMOs/REMICs in its regulations on investments and corporate credit unions. These amendments will clarify certain procedures related to credit unions' involvement with broker-dealers and safekeeping of securities.

DATES: The interim final amendments published at 62 FR 64146 are adopted as final effective May 1, 1998. Amendments in this rule to part 703 are effective October 1, 1998. Amendments in this rule to part 704 are effective May 1, 1998.

ADDRESSES: National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

FOR FURTHER INFORMATION CONTACT: Daniel Gordon, Senior Investment Officer, Office of Investment Services, (703) 518–6620 or Kim Iverson (Program Officer), Office of Examination and Insurance (703) 518–6360, or at the above address.

SUPPLEMENTARY INFORMATION:

A. Interim Final Rule

On November 24, 1997, NCUA issued an interim final rule that made substantive revisions and technical changes to part 703. 62 FR 64146, December 4, 1997. NCUA received eleven comment letters, three from trade associations, two from credit union leagues, three from federal credit unions, two from corporate credit unions, and one from a state-chartered credit union. Five commenters supported the technical changes and offered no other comments. The remaining six had specific comments, as discussed below.

The interim final rule amended § 703.50 to state that a federal credit union may use a third party that is not rregistered with the Securities and Exchange Commission (SEC) or is not a federally regulated depository institution to purchase a certificate of deposit (CD) as long as the credit union purchases the CD directly from a bank, credit union, or other depository institution. One commenter requested clarification that wiring funds to a correspondent bank for further credit to the issuing institution is an acceptable practice. Another suggested that the rule should simply state whether credit unions are prohibited from using third-parties, passing their funds through third parties, or passing funds through unregistered brokers. Another commenter suggested the reason for the amendment was that entities that sell only CDs are not usually subject to comprehensive regulatory oversight, and NCUA should not inadvertently force credit unions to stop buying CDs from legitimate, regulated CD brokers (banks and registered broker-dealers).

NCUA wishes to clarify that it is permissible to send funds to an agent depository institution either of the credit union (credit union's correspondent) or of the issuing depository institution (issuer's correspondent) for credit to an issuing depository institution (issuer). For example, a credit union can send its funds directly to the issuer's correspondent. Alternatively, it is permissible for a credit union to send funds to its correspondent and this correspondent can send those funds to the issuer's correspondent or the issuer. A federal credit union may not wire, or send in any manner, funds to an agent depository institution of an unregistered entity to purchase a CD. The account relationship must be directly with the issuer unless the credit union is using a broker-dealer that is SEC-registered or is a federally regulated depository institution. NCUA believes that the amendment made by the interim final rule is sufficiently clear in this area and is not making additional changes to the provision in this final rule.

This interim final rule also established that a credit union may safekeep securities with a selling broker-dealer as long as the safekeeper used by the broker-dealer is regulated by the SEC. Two commenters suggested that the preamble recommend that a safekeeping agreement prohibit a third party from pledging or lending the credit union's securities without notice of each specific transaction. Without notice of each specific transaction, the credit union would have an unknown counterparty exposure. The NCUA Board agrees it is a sound business practice for every credit union to carefully read and understand the details of any agreement it enters into and encourages credit unions to do so. In the absence of a delegation of authority, a credit union must specifically authorize any actions its

broker-dealer may take with its securities (purchases, sales, pledges, securities lending, etc.), and must not sign an account agreement with a broker-dealer that permits the broker-dealer to take any action with its securities without the credit union's consent and knowledge. The credit union must participate in the monetary gains derived from such actions.

The interim final rule also clarified that the requirement to obtain two price quotes prior to purchasing a security does not apply to new issues issued at original issue discount, in addition to those issued at par. Two commenters suggested that the preamble encourage credit unions to compare prices regardless of whether new issue securities are offered at par or at discount. The commenters believe securities purchase decisions should be made within the context of how they compare to similar Treasury securities.

In the interim final rule, the original issue discount securities that NCUA was primarily concerned with were Treasury securities. Credit unions certainly should consider whether other securities sold at original issue discount compare to similar Treasurys. NCUA encourages price comparisons to comparable Treasurys even for new issues issued at original issue discount or at par.

Two commenters requested that NCUA clarify the applicability of Section 703.60(d) to CDs. That provision requires a credit union to obtain and reconcile monthly a statement of purchased investments and repurchase collateral held in safekeeping. The commenters were concerned about CD investments, since monthly safekeeping statements are generally not received from depository institutions. The NCUA Board wishes to clarify that this requirement does not apply to CDs where the credit union has made the investment (deposit) directly with the depository institution and where there is no third party safekeeping of the CD.

In summary, the NCUA Board is adopting the interim final amendments in final, without any changes.

B. Deletion of MDP High Risk Tests

NCUA is deleting the requirements regarding mortgage derivative product (MDP) high risk tests in parts 703 and 704. NCUA no longer believes that the pass/fail criteria of the high risk tests as applied to specific instruments are necessary to constitute effective monitoring of investment activities. The rescission of the high risk tests as a constraint on a credit union's investment activities does not signal that MDPs with high levels of price risk are either appropriate or inappropriate investments. NCUA continues to believe that the stress testing of MDP investments, as well as other investments, is prudent and has significant value for risk management purposes.

An effective risk management process, through which an institution identifies, measures, monitors, and controls the risks of all its investment activities, provides a better framework. Whether a security, MDP or others, is an appropriate investment depends upon a variety of factors, including the credit union's capital level, the security's impact on the aggregate risk of the portfolio, and management's ability to measure and manage risk. Credit unions should employ valuation methodologies that take into account all of the risk elements necessary to price these investments.

For natural person federal credit unions that purchase securities having certain characteristics, as defined in paragraph 703.90(b), in an amount exceeding the credit union's net capital, part 703 requires a reasonable and supportable estimate of the potential impact of an immediate and sustained parallel shift in market interest rates of plus and minus 300 basis points.

Part 704 requires corporate credit unions to subject all their assets and liabilities to a 300 basis point instantaneous, parallel, and sustained shock in interest rates for purposes of generating "net economic value" (NEV) volatility measures. Proper NEV calculations will capture the risk of the underlying cash-flows and their corresponding price sensitivity.

C. Corrections

Section 703.50(b)(2) of the current rule refers to the North American State Administrators Association. The correct reference is the North American Securities Administrators Association and the final amendments reflect the proper terminology.

Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact any final regulation may have on a substantial number of small credit unions, defined as those having less than $1 million in assets. The NCUA Board has determined and certifies that the final rule will not have a significant economic impact on a substantial number of small credit unions.

Paperwork Reduction Act

NCUA has determined that the final amendments do not increase paperwork requirements under the Paperwork Reduction Act of 1995 and regulations of the Office of Management and Budget (OMB).

Executive Order 12612

Executive Order 12612 requires NCUA to consider the effect of its actions on state interests. The final rule applies directly only to federal credit unions. NCUA has determined that the final rule does not constitute a "significant regulatory action" for purposes of the Executive Order.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) provides generally for congressional review of agency rules. The reporting requirement is triggered in instances where NCUA issues a final rule as defined by Section 551 of the Administrative Procedure Act, 5 U.S.C. 551. NCUA is currently awaiting the Office of Management and Budget's decision on whether this is a major rule.

List of Subjects

12 CFR Part 703

Credit unions, Investments, Reporting and recordkeeping requirements.

12 CFR Part 704

Credit union, Reporting and recordkeeping requirements.

The National Credit Union Administration Board approved the final amendments to Part 703 and Part 704 on April 16, 1998 and approved as final the interim final amendments to Part 703 on April 22, 1998.

Becky Baker,

Secretary of the Board.

Accordingly NCUA adopts the interim final rule amending 12 CFR part 703 which was published at 62 FR 64146 on December 4, 1997, as a final rule without change and amends 12 CFR parts 703 and 704 as follows:

PART 703—INVESTMENT AND DEPOSIT ACTIVITIES

1. The authority citation for part 703 continues to read as follows:

Authority: 12 U.S.C. 1757(7), 1757(8), 1757(15).

§ 703.30 [Amended]

2. Section 703.30 is amended by removing paragraph (g) and redesignating paragraphs (h), (i), (j), (k),

and (l) as paragraphs (g), (h), (i), (j), and (k).

3. Section 703.50 is amended by revising paragraph (b)(2) to read as follows:

§ 703.50 What rules govern my dealings with entities I use to purchase and sell investments (''broker-dealers'')?

* * * * *

(b) * * *

(2) Information available from state or federal securities regulators and securities industry self-regulatory organizations, such as the National Association of Securities Dealers and the North American Securities Administrators Association, about any enforcement actions against the broker-dealer, its affiliates, or associated personnel.

* * * * *

4. Section 703.100 is amended by revising paragraph (e) to read as follows:

§ 703.100 What investments and investment activities are permissible for me?

* * * * *

(e) You may invest in fixed or variable rate CMOs/REMICs.

* * * * *

5. Section 703.130 is revised to read as follows:

§ 703.130 May I continue to hold investments purchased before January 1, 1998, that will be impermissible after that date?

(a) Subject to safety and soundness considerations, you may hold a CMO/REMIC residual, SMBS, or zero coupon security with a maturity greater than 10 years, if you purchased the investment:

(1) Before December 2, 1991; or

(2) On or after December 2, 1991, but before January 1, 1998, if for the purpose of reducing interest rate risk and you meet the following:

(i) You have a monitoring and reporting system in place that provides the documentation necessary to evaluate the expected and actual performance of the investment under different interest rate scenarios;

(ii) You use the monitoring and reporting system to conduct and document an analysis that shows, before purchase, that the proposed investment will reduce your interest rate risk;

(iii) After purchase, you evaluate the investment at least quarterly to determine whether or not it actually has reduced your interest rate risk; and

(iv) You classify the investment as either trading or available-for-sale.

(b) All grandfathered investments are subject to the valuation and monitoring requirements of §§ 703.70, 703.80, and 703.90.

PART 704—CORPORATE CREDIT UNIONS

6. The authority citation for part 704 continues to read as follows:

Authority: 12 U.S.C. 1757(7), 1757(8), 1757(15).

7. Section 704.5 is amended by revising paragraph (c)(6) to read as follows:

§ 704.5 Investments.

* * * * *

(c) * * *

(6) CMOs/REMICs.

* * * * *

Appendix B to Part 704—[Amended]

8. Appendix B to part 704 is amended as follows:

a. A heading is added to the beginning of the Appendix; and

b. In Part I paragraph (c)(6) is removed and paragraphs (c)(7) through (c)(9) are redesignated as paragraphs (c)(6) through (c)(8); and

c. In Part II paragraph (c)(6) is removed and paragraphs (c)(7) and (c)(8) are redesignated as paragraphs (c)(6) and (c)(7).

The addition reads as follows:

Appendix B to Part 704—Expanded Authorities and Requirements

Part I

* * * * *

[FR Doc. 98–11450 Filed 4–30–98; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

Certain Other Dosage Form New Animal Drugs; Isoflurane

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 an abbreviated new animal drug application (ANADA) filed by Marsam Pharmaceuticals, Inc. The ANADA provides for inhalational use of isoflurane USP for induction and maintenance of general anesthesia in horses and dogs.

EFFECTIVE DATE: May 1, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Marsam Pharmaceuticals, Inc., Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034, filed ANADA 200–187 that provides for inhalational use of isoflurane USP for induction and maintenance of general anesthesia in horses and dogs. The drug is limited to use by or on the order of a licensed veterinarian.

Approval of ANADA 200–187 for Marsam Pharmaceuticals, Inc.'s, isoflurane is as a generic copy of Ohmeda Pharmaceutical Product's NADA 135–773 AErrane® (isoflurane, USP). The ANADA is approved as of February 11, 1998, and the regulations are amended in 21 CFR 529.1186(b) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Marsam Pharmaceuticals, Inc., has not been previously listed in § 510.600 (21 CFR 510.600) as sponsor of an approved application. The regulations are amended in § 510.600(c)(1) and (c)(2) to reflect the new sponsor.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20855, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(1) 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

21 CFR Part 510

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

21 CFR Part 529

Animal drugs.

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 529 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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