

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 703

Investment and Deposit Activities

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed Rule; extension of comment period.

SUMMARY: On November 29, 1995 (60 FR 61219) the National Credit Union Administration (NCUA) published a rule regarding natural person credit union investment and deposit activities. The comment period for this proposed rule was to have expired on March 28, 1996. To encourage additional comments, the NCUA Board has decided to extend the comment period on the proposed rule for an additional 90 days. The extended comment period now expires June 26, 1996.

DATES: The comment period has been extended and now expires June 26, 1996. Comments must be received on or before June 26, 1996.

ADDRESSES: Comments should be directed to Becky Baker, Secretary of the Board. Mail or hand-deliver comments to: National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314-3428. Fax comments to (703) 518-6319. Post comments on NCUA's electronic bulletin board by dialing (703) 518-6480. Please send comments by one method only.

FOR FURTHER INFORMATION CONTACT: David M. Marquis, Director, Office of Examination and Insurance, (703) 518-6360, or Daniel Gordon, Senior Investment Officer, (703) 518-6620, or at the above address.

By the National Credit Union Administration Board on February 23, 1996.
Becky Baker,
Secretary of the Board.

[FR Doc. 96-5110 Filed 3-4-96; 8:45 am]

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FEDERAL TRADE COMMISSION

16 CFR Part 405

Trade Regulation Rule on Misbranding and Deception as to Leather Content of Waist Belts

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Trade Commission ("Commission") announces the commencement of a rulemaking proceeding for the trade regulation rule on Misbranding and Deception as to Leather Content of Waist Belts ("Leather Belt Rule" or "Rule"). The proceeding will address whether or not the Leather Belt Rule should be repealed. The Commission invites interested parties to submit written data, views, and arguments on how the Rule has affected consumers, businesses and others, and on whether there currently is a need for the Rule. This document includes a description of the procedures to be followed, an invitation to submit written comments, a list of questions and issues upon which the Commission particularly desires comments, and instructions for prospective witnesses and other interested persons who desire to participate in the proceeding.

DATES: Written comments must be submitted on or before April 4, 1996.

Notifications of interest in testifying must be submitted on or before April 4, 1996. If interested parties request the opportunity to present testimony, the Commission will publish a document in the Federal Register stating the time and place at which the hearings will be held and describing the procedures that will be followed in conducting the hearings. In addition to submitting a request to testify, interested parties who wish to present testimony must submit, on or before April 4, 1996, a written comment or statement that describes the issues on which the party wishes to testify and the nature of the testimony to be given.

ADDRESSES: Written comments and requests to testify should be submitted to Office of the Secretary, Federal Trade Commission, Room H-159, Sixth Street and Pennsylvania Avenue, NW., Washington, DC 20580, telephone number (202) 326-2506. Comments and requests to testify should be identified at "16 CFR Part 405—Comment—

Leather Belt Rule" and "16 CFR Part 405—Request to Testify—Leather Belt Rule," respectively. If possible, submit comments both in writing and on a personal computer diskette in Word Perfect or other word processing format (to assist in processing, please identify the format and version used). Written comments should be submitted, when feasible and not burdensome, in five copies.

FOR FURTHER INFORMATION CONTACT: Lemuel Dowdy or Edwin Rodriguez, Attorneys, Federal Trade Commission, Division of Enforcement, Bureau of Consumer Protection, Sixth Street and Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-2981 or (202) 326-3147.

SUPPLEMENTARY INFORMATION:

I. Introduction

Pursuant to the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 41-58, and the Administrative Procedure Act, 5 U.S.C. 551-59, 701-06, by this Notice of Proposed Rulemaking ("NPR") the Commission initiates a proceeding to consider whether the Leather Belt Rule should be repealed or remain in effect.¹ The Commission is undertaking this rulemaking proceeding as part of the Commission's ongoing program of evaluating trade regulation rules and industry guides to determine their effectiveness, impact, cost and need. This proceeding also responds to President Clinton's National Regulatory Reinvention Initiative, which, among other things, urges agencies to eliminate obsolete or unnecessary regulations.

II. Background Information

The Leather Belt Rule was promulgated on June 27, 1964, to remedy deceptive practices involving misrepresentations about the leather content of waist belts that are not offered for sale as part of a garment. The Rule prohibits representations that belts not made from the hide or skin of an animal are made of leather or that belts are made of a specified animal hide or skin when such is not the case. In addition, the Rule requires that belts

¹ In accordance with section 18 of the FTC Act, 15 U.S.C. 57a, the Commission submitted this NPR to the Chairman of the Committee on Commerce, Science, and Transportation, United States Senate, and the Chairman of the Subcommittee on Commerce, Trade and Hazardous Materials, United States House of Representatives, 30 days prior to its publication in the Federal Register.

made of split leather, and ground, pulverized or shredded leather bear a label or tag disclosing the kind of leather of which the belt is composed. The Rule also requires that non-leather belts having the appearance of leather bear a tag or label disclosing their composition or disclosing that they are not leather.

As part of its continuing review of its trade regulation rules to determine their current effectiveness and impact, the Commission published a Federal Register notice² on March 27, 1995,³ asking questions about the benefits and burdens of the Rule to consumers and industry. The request for comments elicited ten comments.⁴ Six comments were from consumers⁵ and four from leather or leather goods manufacturers.⁶

The consumer comments expressed continuing support for the Rule, contending that its disclosure requirements help consumers make informed purchasing decisions. One industry comment supported the Rule for the same reason.⁷ These commenters stated that the Rule helps consumers identify belts made of different types of cowhide leather, such as top grain leather, and split leather.⁸ In addition, the comments stated that the disclosures required by the Rule allow consumers to identify belts made of vinyl, plastic, polyurethane, paper and other synthetic materials that can be made to look like

leather.⁹ The consumer commenters stated that, without the required disclosures, consumers cannot be certain of the quality of the leather used in belts, or that belts are made of leather at all.¹⁰

Three comments recommended that the Commission amend the Rule to allow the use of the term "bonded leather" when a leather good is made of ground, pulverized, or shredded leather that is bonded with an adhesive.¹¹ Seven comments supported the continuation of the Leather Belt Rule as it currently exists.¹² Two comments from industry members expressed support for consolidating the Rule and the Guides into one set of guidelines that apply to all finished leather goods.¹³

On September 18, 1995, the Commission announced that, to eliminate unnecessary duplication, it had rescinded the three separate guides for various leather products¹⁴ and sought comment on one set of proposed, consolidated guidelines: the Guides for Select Leather and Imitation Leather Products.¹⁵ Because the proposed Guides would cover belts, the Commission published, on the same day, an Advance Notice of Proposed Rulemaking ("ANPR") stating that it had tentatively determined that a separate Leather Belt Rule is no longer

necessary, and seeking comments on the proposed repeal of the Rule.¹⁶ In accordance with section 18 of the FTC Act, 14 U.S.C. 57a, the ANPR was sent to the Chairman of the Committee on Commerce, Science, and Transportation, United States Senate, and the Chairman of the Subcommittee on Commerce, Trade and Hazardous Materials, United States House of Representatives.

The ANPR comment period closed on October 18, 1995. The Commission received two comments in response to the ANPR.¹⁷ One of these comments supports retention of the existing Leather Belt Rule. The commenter believes that rescission of the Rule may decrease the accuracy of the labeling of waist belts, making the selection and purchase of belts more difficult for consumers.¹⁸ The other comment supports consolidating the Rule into one set of guidelines governing disclosures of the leather content of leather goods, and recommends that the term "bonded leather" be allowed by those guidelines.¹⁹

After reviewing the comments submitted, the Commission has determined that the benefits of the Rule are retained through the inclusion of belts in the proposed Guides for Select Leather and Imitation Leather Products. While repealing the Rule would eliminate the Commission's ability to obtain civil penalties for any future misrepresentations of the leather content of belts, the Commission has determined that it would not seriously jeopardize the Commission's ability to act effectively. Any significant problems that might arise could be addressed on a case-by-case basis, administratively under Section 5 of the FTC Act, 15 U.S.C. 45, or through court actions under Section 13(b), 15 U.S.C. 53(b), in federal district court. Prosecuting serious or knowing misrepresentations in district court allows the Commission to seek injunctive relief as well as equitable remedies, such as redress or disgorgement.

The Commission believes that the proposed Guides serve the public

² 60 FR 15725. The Commission's Office of the Secretary has assigned document number B172445 to this notice. All comments submitted in response to this notice are sequentially numbered and filed under number B172445 in the public record, starting with number B17244500001. Any request for copies or inspection of the comments to this notice should refer to document number B172445.

³ On the same date, the Commission published a Federal Register notice soliciting comment on its Industry Guides for luggage, shoes, and Ladies' handbags. 60 FR 15724. See Guides for the Luggage and Related Products Industry, 16 CFR Part 24; Guides for Shoe Content Labeling and Advertising, 16 CFR Part 231; and Guides for the Ladies' Handbag Industry, 16 CFR Part 247.

⁴ For purposes of this NPR, we cite these ten comments using the name of the commenter and the sequential number of the comment in parentheses, without repeating the B172445 prefix.

⁵ The following is a list of the consumer commenters: Stephen Toso (1), Ross E. Kettering (2), Matt Anderson (3), Marilyn Raeth (4), James A. McGarry (5), and Lenna Mae Gara (8).

⁶ The following is a list of comments received from industry members: Enger Kress Company (manufactures mens and ladies wallets and occasionally leather belts) (6), Cromwell leather Company, Inc. (produces leather that is sold to producers of finished leather goods) (7), Humphreys, Inc. (manufacturer of leather belts) (9), and Leather Industries of America, Inc. (trade association representing the leather tanning industry) (10).

⁷ Enger Kress (6).

⁸ Toso (1), Kettering (2), Anderson (3), Raeth (4), McGarry (5), and Gara (6).

⁹ Toso (1) states that the use in belts of synthetic materials that look like leather makes it difficult to determine the true leather content of belts. The comment gives as an example the use of "P.U. Glove Leather" where the "P.U." stands for polyurethane. Kettering (2) also opposes rescinding the Leather Belt Rule because of the difficulty consumers face in identifying belts that are made of real leather when manufacturers try to pass off vinyl or other materials as leather; the comment states that the Rule's disclosures allow consumers to make informed choices by identifying the leather contents of belts. Anderson (3), p.2.

¹⁰ Toso (1) states that the discount stores are growing and that they will be tempted to deceive consumers by claiming that belts are made a higher quality leather than they actually are. Raeth (4) expresses the concern that manufacturers may pass off cheaper, inferior goods to consumers if the Rule is eliminated.

¹¹ Cromwell (7), Humphreys (9), and Leather Industries (10). These commenters recommend that the Rule include a prohibition on the use of the term "bonded leather" unless at least 75% of the fibers in the product are leather. This issue has been addressed in the proposed Guides, which allow the use of the term "bonded leather" if certain required disclosures are made.

¹² Toso (1), Kettering (2), Anderson (3), Raeth (4), McGarry (5), Enger Kress (6), and Gara (8).

¹³ Cromwell (7) and Leather Industries (10).

¹⁴ 60 FR 48027.

¹⁵ 60 FR 48056. In particular the Commission sought comment as to whether the consolidated Guides should cover leather, or imitation leather, products in addition to shoes, luggage, handbags, and belts. The deadline for comment on the proposed Guides was October 18, 1995, but it was subsequently extended until November 15, 1995. 60 FR 54316 (Oct. 23, 1995).

¹⁶ 60 FR 48070. The Commission's Office of the Secretary has assigned document number B183789 to the ANPR. All comments submitted in response to the ANPR are sequentially numbered and filed under document number B183789 in the public record, starting with number B18378900001. The comments submitted in response to the ANPR are identified in this NPR by the name of the commenter and the sequential number, without repeating the document number.

¹⁷ The comments were submitted by Larry E. Gundersen (1), a consumer, and Humphreys Inc. (2), a manufacturer of leather belts.

¹⁸ Gundersen (1).

¹⁹ Humphreys Inc. (2). See footnote 11 above regarding the term "bonded leather."

interest better than maintaining a Rule for leather belts and separate Guides for various other leather products. Accordingly, the Commission has determined that a separate Leather Belt Rule is not necessary. The Commission therefore seeks comments on the proposed repeal of the Leather Belt Rule.

III. Rulemaking Procedures

The Commission finds that the public interest will be served by using expedited procedures in this proceeding. First, there do not appear to be any material issues of disputed fact to resolve in determining whether to repeal the Rule. Second, the use of expedited procedures will support the Commission's goal of eliminating obsolete or unnecessary regulations without an undue expenditure of resources, while ensuring that the public has an opportunity to submit data, views and arguments on whether the Commission should repeal the Rule.

The Commission, therefore, has determined, pursuant to 16 CFR 1.20, to use the procedures set forth in this notice. These procedures include: (1) Publishing this Notice of Proposed Rulemaking; (2) soliciting written comments on the Commission's proposal to repeal the Rule; (3) holding an informal hearing, if requested by interested parties; (4) obtaining a final recommendation from staff; and (5) announcing final Commission action in a notice published in the Federal Register.

IV. Invitation To Comment and Questions for Comment

Interested persons are requested to submit written data, views or arguments on any issue of fact, law or policy they believe may be relevant to the Commission's decision on whether to repeal the Rule. The Commission requests that commenters provide representative factual data in support of their comments. Individual firms' experiences are relevant to the extent they typify industry experience in general or the experience of similar-sized firms. Commenters opposing the proposed repeal of the Rule should explain the reasons they believe the rule is still needed and, if appropriate, suggest specific alternatives. Proposals for alternative requirements should include reasons and data that indicate why the alternatives would better protect consumers from unfair or deceptive acts or practices under section 5 of the FTC Act, 15 U.S.C. 45.

Although the Commission welcomes comments on any aspect of the proposed repeal of the Rule, the

Commission is particularly interested in comments on questions and issues raised in this Notice. All written comments should state clearly the question or issue that the commenter is addressing.

Before taking final action, the Commission will consider all written comments timely submitted to the Secretary of the Commission and testimony given on the record at any hearings scheduled in response to requests to testify. Written comments submitted will be available for public inspection in accordance with the Freedom of Information Act, 5 U.S.C. 552, and Commission regulations, on normal business days between the hours of 8:30 a.m. to 5:00 p.m. at the Federal Trade Commission, Public Reference Room, Room H-130, Federal Trade Commission, Sixth Street and Pennsylvania Avenue, N.W., Washington, DC 20580, telephone number (202) 326-2222.

Questions

(1) Is the misrepresentation of the leather contents of belts by manufacturers and distributors of belts still a significant problem in the marketplace?

(2) What benefits do consumers derive from the Rule?

(3) Should the Rule be kept in effect or should it be repealed?

(4) How would repealing the Rule affect the benefits experienced by consumers?

(5) How would repealing the Rule affect the benefits and burdens experienced by firms subject to the Rule's requirements?

(6) Are there any other federal or state laws or regulations, or private industry standards, that eliminate the need for the Rule?

(7) Are the proposed Guides for Select Leather and Imitation Leather Products likely to provide all or most of the benefits now provided by the Rule?

(8) How, if at all, would repeal of the Rule, and the resulting elimination of civil penalty enforcement actions now available to enforce it, likely affect the accuracy of the advertising, labeling, or marketing of leather belts?

V. Requests for Public Hearings

Because there does not appear to be any dispute as to the material facts or issues raised by this proceeding and because written comments appear adequate to present the views of all interested parties, a public hearing has not been scheduled. If any person would like to present testimony at a public hearing, he or she should follow

the procedures set forth in the **DATES** and **ADDRESSES** sections of this notice.

VI. Preliminary Regulatory Analysis

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601-11, requires an analysis of the anticipated impact of the proposed repeal of the Rule on small businesses.²⁰ The analysis must contain, as applicable, a description of the reasons why action is being considered, the objectives of and legal basis for the proposed action, the class and number of small entities affected, the projected reporting, recordkeeping and other compliance requirements being proposed, any existing federal rules which may duplicate, overlap or conflict with the proposed action, and any significant alternatives to the proposed action that accomplish its objectives and, at the same time, minimize its impact on small entities.

A description of the reasons why action is being considered and the objectives of the proposed repeal of the Rule have been explained elsewhere in this Notice. Repeal of the Rule would appear to have little or no effect on any small business. The Commission is not aware of any existing federal laws or regulations that would conflict with repeal of the Rule.

In light of these reasons, the Commission certifies, pursuant to section 605 of RFA, 5 U.S.C. 605, that if the Commission determines to repeal the Rule that action will not have a significant impact on a substantial number of small entities. To ensure that no substantial economic impact is being overlooked, however, the Commission requests comments on this issue. After reviewing any comments received, the Commission will determine whether it is necessary to prepare a final regulatory flexibility analysis.

VII. Paperwork Reduction Act

The Leather Belt Rule imposes third-party disclosure requirements that constitute "information collection requirements" under the Paperwork

²⁰ Section 22 of the FTC Act, 15 U.S.C. 57b-3, also requires the Commission to issue a preliminary regulatory analysis relating to proposed rules when the Commission publishes a notice of proposed rulemaking. The Commission has determined that a preliminary regulatory analysis is not required by section 22 in this proceeding because the Commission has no reason to believe that repeal of the Rule: (1) will have an annual effect on the national economy of \$100,000,000 or more; (2) will cause a substantial change in the cost or price of goods or services that are used extensively by particular industries, that are supplied extensively in particular geographical regions, or that are acquired in significant quantities by the Federal Government, or by State or local governments; or (3) otherwise will have a significant impact upon persons subject to the Rule or upon consumers.

Reduction Act, 44 U.S.C. 3501 *et seq.* Accordingly, repeal of the Rule would eliminate any burdens on the public imposed by these disclosure requirements.

VIII. Additional Information for Interested Persons

A. Motions or Petitions

Any motions or petitions in connection with this proceeding must be filed with the Secretary of the Commission.

B. Communications by Outside Parties to Commissioners or Their Advisors

Pursuant to Rule 1.18(c) of the Commission's Rules of Practice, 16 CFR 1.18(c), communications with respect to the merits of this proceeding from any outside party to any Commissioner or Commissioner's advisor during the course of this rulemaking shall be subject to the following treatment. Written communications, including written communications from members of Congress, shall be forwarded promptly to the Secretary for placement on the public record. Oral communications, not including oral communications from members of Congress, are permitted only when such oral communications are transcribed verbatim or summarized at the discretion of the Commissioner or Commissioner's advisor to whom such oral communications are made, and are promptly placed on the public record, together with any written communications relating to such oral communications. Memoranda prepared by a Commissioner or Commissioner's advisor setting forth the contents of any oral communications from members of Congress shall be placed promptly on the public record. If the communication with a member of Congress is transcribed verbatim or summarized, the transcript or summary will be placed promptly on the public record.

List of Subjects in 16 CFR Part 405

Advertising, Clothing, Labeling, Leather and leather products industry, Trade practices.

Authority: 15 U.S.C. 41-58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96-5043 Filed 3-4-96; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860

[Docket No. 93N-0445]

Financial Disclosure by Clinical Investigators; Reopening of Comment Period and Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period and notice of meeting.

SUMMARY: The Science Board to the Food and Drug Administration (FDA), an FDA advisory committee, will hold an open committee meeting to discuss the proposed rulemaking on Financial Disclosure by Clinical Investigators, which published in the Federal Register of September 22, 1994. At the same time, FDA is reopening the comment period for the proposed rule. The proposed rule would require that the sponsor of any drug, biological product, or device submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting clinical studies to determine whether that product meets the marketing requirements specified by the agency. FDA is taking these actions in order to obtain additional comment on whether the provision on "significant payments of other sorts" should be eliminated from the proposed rule.

DATES: The comment period is reopened until April 29, 1996. Those desiring to make formal presentations to the Science Board must notify the contact person before March 14, 1996, and submit a brief statement of the general nature of the evidence or arguments they may wish to present, and the names and addresses of proposed participants. Each presenter will be limited in time and not all requests to speak may be able to be accommodated. All written statements submitted in a timely fashion will be provided to the board.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The meeting will be held at the Sheraton National Hotel, North Ballroom, 900 South Orme St. (Columbia Pike and Washington Blvd.), Arlington, VA.

FOR FURTHER INFORMATION CONTACT: Mary Gross, Office of External Affairs

(HF-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301-827-3440; or the FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area) Science Board to the Food and Drug Administration, code 12603. **SUPPLEMENTARY INFORMATION:** In the Federal Register of September 22, 1994 (59 FR 48708), FDA proposed regulations to require that the sponsor of any drug, biological product, or device submit certain information concerning the compensation to, and financial interests of any clinical investigator conducting clinical studies to determine whether that product meets the marketing requirements specified by the agency. The agency is proposing to require that sponsors either certify to the absence of certain financial interests of clinical investigators or disclose those financial interests when clinical studies are submitted to FDA in support of product marketing.

FDA has asked the Science Board to discuss, at the March 29, 1996, meeting proposed § 54.4(a)(2)(ii), which would require disclosure by clinical investigators of "significant payments of other sorts" from sponsors. The proposed definition of such payments is " * * * payments that exceed \$5,000 (e.g., grants to fund ongoing research, compensation in the form of equipment on retainers for ongoing consultation, or honoraria) or that exceed 5 percent of the total equity in a publicly held and widely traded company." FDA specifically seeks discussion of the following issues:

(1) In proposing to require disclosure of any significant equity interest held by a clinical investigator in the sponsor, the agency has defined a significant equity interest as "any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices, or any equity interest in a publicly traded corporation that exceeds 5 percent of total equity." Is 5 percent equity interest in a publicly traded corporation an appropriate threshold to trigger disclosure of financial information to FDA? Should a threshold dollar amount also be specified? If so, what might be a reasonable threshold amount?

(2) Are there financial arrangements that may be overlooked that could affect study outcome if FDA eliminates the provision entitled "significant payments of other sorts," from the proposed rule?

(3) Does it help to narrow the scope of the provision "significant payments of other sorts" by raising the current payment level that would trigger