

amendment will simplify the application process and reduce work required of the exporter in submitting applications.

EFFECTIVE DATE: September 13, 1977.

FOR FURTHER INFORMATION CONTACT:

Charles C. Swanson, Director, Operations Division, Office of Export Administration, Department of Commerce, Washington, D.C. 20230 (202-377-4196).

SUPPLEMENTARY INFORMATION: This revision eliminates all requirements for use of Form DIB-623P, Application Processing Card, in order to simplify the application process and reduce work required of the exporter in submitting applications.

Accordingly, the Export Administration Regulations (15 CFR Part 368 et seq.) are amended as follows:

PART 372—INDIVIDUAL VALIDATED LICENSES AND AMENDMENTS

1. In § 372.4, paragraph (a) is revised, paragraph (a) (5), excluding "Note", is deleted, and the second sentence of (b) is deleted. As revised, paragraph (a) reads as follows:

§ 372.4 How to apply for a validated license.

(a) *Form and Manner of Filing—(1) Application Form.* An application for a validated license must be submitted on Form DIB-622P, Application for Export License. Since January 1, 1976, only Forms DIB-622P revised March 1975 or later are acceptable. Earlier versions will be returned without action. An application that omits essential information, or is otherwise incomplete, will be returned without action to the applicant. (See § 370.12 for instructions on obtaining forms.)

PART 373—SPECIAL LICENSING PROCEDURES

§ 373.2 [Amended]

2. Paragraph (c) (2) (i) of § 373.2 is deleted and reserved.

§ 373.3 [Amended]

3. Paragraphs (d) (2) (i) and (d) (3) (i) are deleted and reserved.

4. By revising § 373.5(d) (1) to read as follows:

§ 373.5 Periodic Requirements (PRL) License.

(d) *Application Procedure—(1) Application Form.* An application for a PRL Licensee shall be prepared and submitted on Form DIB-622P, Application for Export License, in accordance with instructions contained in § 372.4(a), except as modified below.

5. By revising § 373.6(b) (1) to read as follows:

§ 373.6 Time Limit (TL) License.

(b) *Preparation of a TL License Application—(1) Application form.* An application for a Time Limit License shall be prepared and submitted on an Application for Export License, Form DIB-622P, in accordance with instructions in § 372.4(a), except that the applicant shall: * * *

§ 373.7 [Amended]

6. By deleting and reserving §§ 373.7(d) (1) (ii) (a) and 373.7(d) (1) (iv) (a).

PART 379—TECHNICAL DATA

§ 379.5 [Amended]

7. By amending § 379.5 as follows: Section 379.5(a) (2) is deleted, and § 379.5(a) (3) is renumbered as § 379.5(a) (2).

Section 379.5(c) is deleted and reserved.

(Sec. 4 Pub. L. 91-184, 83 Stat. 842 (50 U.S.C. App. 2403), as amended; E.O. 12002, 42 FR 35623 (1977); Department Organization order 10-3, dated Nov. 17, 1975, 40 FR 58876 (1975), as amended; and Domestic and International Business Administration Organization and Function Orders 46-1, dated November 17, 1975, 40 FR 59761 (1975), as amended and 46-2, dated November 17, 1975, 40 FR 59761 (1975) as amended.)

RAUER H. MEYER,
Director,

Office of Export Administration.

[FR Doc. 77-27027 Filed 9-13-77; 3:39 pm]

Title 16—Commercial Practice

CHAPTER I—FEDERAL TRADE COMMISSION

PART 433—PRESERVATION OF CONSUMERS' CLAIMS AND DEFENSES

Two-Party Open End Consumer Credit Contracts

AGENCY: Federal Trade Commission.

ACTION: Modification of exemption from trade regulation rule; denial of proposed permanent exemption—Forty-five day extension of exemption.

SUMMARY: On April 14, 1977 the Commission issued a limited exemption from certain requirements of the Trade Regulation Rule concerning the Preservation of Consumers' Claims and Defenses (42 FR 19487), for two-party open end consumer credit contracts that were executed before August 1, 1977 and do not involve the use of negotiable instruments or waivers of claims and defenses. That exemption was subsequently extended for a period of 45 days beyond August 1, 1977 (42 FR 40426). The Commission when it issued the exemption also invited comment on the exemption issued and on a proposed, permanent exemption.

Based on its review of the comments received, the Commission has decided to modify the exemption so that the definitions make it clear that "30 day accounts", which do not allow the consumer the option of paying in installments, fall within the exemption issued. The Commission has also carefully reviewed the record and has decided that the arguments and data presented by commenters do not support the issuance of a permanent exemption. The Commission is however, further extending the limited exemption for another 45 days beyond September 14, 1977. Thus, the Rule will apply to all consumer credit contracts taken or received by sellers after October 31, 1977.

FOR FURTHER INFORMATION CONTACT:

Walter Diercks, Deputy Assistant Director, Division of Compliance, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580 (202-254-9491).

DATES: The Rule will apply to all consumer credit contracts taken or received by sellers after October 31, 1977.

SUPPLEMENTARY INFORMATION:

Section 433.2(a) of the Trade Regulation Rule on Preservation of Consumers' Claims and Defenses requires that a short Notice be included in all consumer credit contracts used by sellers. The required Notice expressly preserves the consumers' right to assert against any third party which subsequently acquires the contract any legally sufficient claims and defenses that the consumer may have against the seller.

On April 14, 1977 (42 FR 19847) the Commission issued a limited exemption from the Rule for two-party open end consumer credit contracts that were executed before August 1, 1977 and do not involve the use of negotiable instruments or waivers of claims and defenses. The Commission subsequently extended the exemption for a period of 45 days beyond August 1, 1977 (42 FR 40426). The Commission is further extending its limited exemption for an additional 45 day period. Thus, as of November 1, 1977 the Rule will apply to all consumer credit contracts taken or received by sellers.

The Commission also, in its April 14 1977 FEDERAL REGISTER Notice, invited interested parties to comment on the exemption, as issued, as well as a permanent exemption proposed in a petition filed by the National Retail Merchants Association (NRMA) and the American Retail Federation (ARF). The proposed exemption would have applied to two-party open end consumer credit contracts which do not involve the use of negotiable instruments or waivers of claims and defenses. Further, upon transfer of the contract, the Notice required by the Rule would become a term of the consumer credit contracts.

Twenty-six comments were received by the Commission in response to its April 14, 1977 FEDERAL REGISTER Notice. Industry commenters basically argued that the Commission should issue the broader exemption proposed by the National Retail Merchants Association (NRMA) and the American Retail Federation (ARF) in their petitions for exemption. Industry commenters argued that because the proposed exemption is confined to contracts that are not negotiable and do not contain waiver provisions, and because they would agree to include the required Notice in the event of transfer, consumers would receive equivalent protections. The National Consumer Law Center objected to the issuance of any exemption for two-party credit contracts.

After analyzing the views, arguments and data, the Commission has decided that the exemption, as issued, should be slightly modified and, further, that the petitions submitted by NRMA and ARF should be denied.

In denying the NRMA/ARF petitions the Commission carefully weighed the costs of prospective compliance with the Rule against the potential for consumer injury that might result from exempting two-party open end consumer credit contracts from the Rule. Major compliance costs put forth by industry commenters were those costs associated with disposing of obsolete inventories of forms, typically a six-month supply, and reprinting new forms—a total of \$3 million. The Commission decided that the costs of prospective compliance, especially in light of the extension of the exemption through October 31, 1977, would be substantially less than \$3 million and further that these costs did not outweigh the potential for consumer injury that might result if the exemption were extended permanently. The potential for consumer injury stems mainly from the state laws that may operate to cut off consumers' claims and defenses despite non-negotiability and the absence of a waiver. Several commenters conceded that certain state laws may have such an effect. The Commission has further reviewed these state laws and determined that the uncertainties of the state laws of assignment suggests the desirability of denying the proposed permanent exemption.

In order to give all sellers an adequate opportunity to come into compliance with the Rule, the Commission is extending its limited exemption for an additional 45 days beyond September 14, 1977. Thus, the Rule will apply to all consumer credit contracts taken or received by sellers after October 31, 1977.

The Commission is also modifying 16 CFR 433.3(b)(3), the definition of "open end credit," to track the language of 202.2(w) of Federal Reserve Board Regulation B, as amended March 23, 1977 (12 CFR Part 202), to include so-called "30 day accounts," extensions of credit which do not allow the consumer the privilege of paying in installments, within the exemption, issued on April 14, 1977.

The primary purpose of the exemption, as issued, was to avoid costs involved in modifying existing two-party open end credit agreements. The Commission decided that there was no justification for distinguishing "30 day accounts" from other two-party open end credit contracts that are exempted through October 31, 1977.

Accordingly, pursuant to the Federal Trade Commission Act, as amended, 15 U.S.C. 41, et seq., the provisions of Part I, Subparts B and C of the Commission's Procedures and Rules of Practice, 16 CFR 1.7, et seq., and 553 of Subchapter II, Chapter 5, Title 5 of the U.S. Code (Administrative Procedures), the Commission hereby modifies §§ 433.3(a) and 433.3(b)(3) of 16 CFR Part 433:

§ 433.3 Exemption of sellers taking or receiving open end consumer credit contracts before November 1, 1977, from requirements of § 433.2(a).

(a) Any seller who has taken or received an open end consumer credit contract before November 1, 1977, shall be exempt from the requirements of 16 CFR Part 433 with respect to such contract: *Provided*, The contract does not cut off consumers' claims and defenses.

(b) Definitions. The following definitions apply to this exemption: * * *

(3) "Open end credit": Consumer credit extended pursuant to a plan under which a creditor may permit an applicant to make purchases or make loans from time to time directly from the creditor or indirectly by use of a credit card, check or other device as the plan may provide. The term does not include negotiated advances under an open end real estate mortgage or a letter of credit.

By direction of the Commission.

CAROL M. THOMAS,
Secretary.

**SEPARATE STATEMENT OF COMMISSIONER
CALVIN J. COLLIER**

Commissioner Collier dissented from the Commission's decision to deny the permanent exemption, stating:

Although I agree with the Commission's decision to grant a further temporary exemption, I dissent from its decision to refuse a permanent (conditional) exemption from the "Holder-in-Due-Course Rule" for open-end credit and 30-day accounts. I would grant such an exemption where:

The debt instrument is not a negotiable instrument;

It does not contain a waiver or limitation of consumer claims or defenses; and

It is not transferred, sold, pledged or assigned.

This exemption would require the addition of the notice prior to any subsequent assignment.

By its terms, the exemption would unquestionably provide the same measure

¹ Trade Regulation Rule Concerning Preservation of Consumers Claims and Defenses, 16 CFR Part 433 (1977).

of consumer protection as the rule itself. The rule has relevance only where obligations are assigned to third persons; and, among other things, the exemption would be unavailable if an assignment were made. The possibility for lesser consumer protection can therefore arise only if the exemption is exceeded and the rule is violated. Conversely, neither the rule nor the exemption is violation-proof, although the prospect of substantial civil penalties and litigation expenses, far in excess of the likely profit from violating the rule (with or without the exemption), should hold in check the risks of this behavior.

The central issue, in my view, is whether the exemption will make it significantly easier to both violate the law and get away with it. An affirmative answer, it seems to me, requires a showing that: (1) Detection of law violations will be more difficult; (2) the cutting off of consumer claims or defenses will be more likely; and (3) sellers and assignees will perceive these advantages as sufficiently attractive to offer a premium price for these consumer obligations. Some discussion on each of these conditions is required.

At the outset, however, it is important to note that the failure to grant an exemption will add to the costs of supplying credit. The costs in wasted forms alone are estimated to be between \$0.5 million and \$3 million, depending on various assumptions.² There are also the intangible costs of aggravation that invariably attend compliance with the latest government regulatory command. Finally, the exemption proposed would reduce the inevitable costs of consumer confusion that surely will result when a consumer applying for an open-end or 30-day account reads the required notice; inquires with a raised eyebrow whether the seller plans to assign his obligation to a third party; is told, "no"; asks then what the reason for the notice is; and is told that it serves no purpose except that it is required by law. The Commission can ill afford to incur unnecessary costs of this kind.

The staff has argued that violations of the rule will be more difficult to detect as a result of the exemption. The principal approach to policing compliance with the rule will apparently be subpoenas of credit agreements to assure that the required notice is included.³ But policing compliance with the rule with the exemption could be just as easily achieved by demanding the credit agreements (to be sure that they contained either the required notice or the absence

² The smaller estimates depend on the assumption that sellers have been depleting their inventories of old forms during the pendency of our deliberations. Moreover, today's action of the Commission to extend the temporary exemption will reduce these costs even further. These costs, like all other costs, must be passed through to consumers, no matter what the state of competition in the regulated industry. (Economic theory tells us that there would be a proportionately greater passing through of these costs the more competitive the industry.)

of waiver language) and by further demanding a list of those that had been assigned. The absence of the notice on the assigned agreements would, of course, indicate a violation of the rule.⁴ In short, I do not see how the task of policing compliance with the rule would be rendered more costly by the exemption,⁵ how detection would be made more difficult, or how sellers or assignees would perceive a more valuable temptation to violate the rule.

Neither do I believe that the exemption would increase the likelihood that consumers' claims and defenses would be cut off by the exemption. Sellers who are not deterred by the prospects of heavy civil penalties but who wish to cut off consumers' claims might just as well do so by ignoring the rule altogether.

The staff is concerned, however, about the situation where the seller (in excess of the exemption and thus in violation of the rule) assigns an open-end or 30-day account that is not on its face a negotiable instrument and that does not contain a waiver of defenses. Under the Uniform Commercial Code the consumer's claims and defenses against the seller could be asserted against the assignee.⁶ But under some recently enacted state consumer protection statutes the consumer's rights are less clear. My research has disclosed eleven such statutes that could be interpreted to abrogate consumer rights. Of these, eight seem to be triggered by the presence of a waiver clause of the kind that the exemption would absolutely forbid.⁷ Be-

hind each of these statutes there seems to have been a clear attempt to expand consumer rights in the face of a purported waiver, not to restrict them in the absence of one. In three other states, the statutory language is more susceptible of a perverse interpretation that would limit, rather than expand the consumer rights granted by ordinary commercial law.⁸ No court to my knowledge, or, apparently to the staff's, has ever interpreted any of these statutes to the feared effect. Should a court ever do so, I do not see why we could not cancel the exemption or limit its geographic application for that reason.

The staff also argues that open-end consumer obligations might be transferred to a bankruptcy trustee without the notice (again, in violation of the rule). The trustee, it is thought, might retransfer, without adding the notice, to a third party. If these obligations did not bear a waiver of the kind that the exemption would forbid, I do not clearly see how consumer claims and defenses could be cut off. Nor do I see any reason why a bankrupt, bankruptcy judge or trustee⁹ would fail to respect the legal obligation to include the notice at the time of assignment.

Each variety of potential consumer injury hypothesized by the staff requires conduct in excess of the exemption and in violation of the rule. Undoubtedly, rule violations will occur in spite of the prospect of civil penalties and some¹⁰ consumers will suffer injury. But I fail to see how the proposed exemption will enlarge this class of violators or aggravate that injury. The prospects of detection are the same and the potential for incremental profit is remote.

Indeed, the information at hand indicates that the chances for consumer injury by cutting off consumer claims and defenses in the case of open-end or 30-

day accounts is especially remote. These arrangements typically signal a continuing relationship between consumer and seller grounded in part on the seller's hope that the consumer will be a repeat, if not a regular, customer. This phenomenon is consistent with the information we have indicating that such accounts are seldom assigned (except to bill collectors against whom claims and defenses are available in any event). In contrast, the rule itself was principally directed at so-called fly-by-night sellers and sellers engaged in occasional, non-repeat sales of big-ticket items. In short, there is no reason to suspect that the proposed exemption would aggravate such compliance problems as may otherwise arise.

Finally, we are urged to reject the exemption because the required notice may contribute to consumer education. The short answer to this question is that the rule is drafted in legal jargon¹¹ to serve a legal, not an educational, purpose.¹² For example, the rule does not advise consumers of their substantive rights, but only that they are preserved in an assignment, whatever they are. Moreover, if no assignment occurs, no educational purpose can possibly be served, and only confusion—as opposed to education—can result.

For these reasons, I believe that the Commission's action in failing to grant a conditional exemption for open-end credit will oblige consumers to pay more for credit with no added protection. I would grant an exemption conditioned along the lines suggested in the first part of my statement.

SEPARATE STATEMENT OF THE COMMISSION

The Commission in denying the petition issued the following statement:

The Commission has carefully reviewed the petitioners' request for a permanent exemption from the requirements of the Trade Regulation Rule Concerning Preservation of Consumers' Claims and Defenses (16 CFR Part 433) and has determined to deny it.

When promulgated the Rule was designed to ensure that consumers purchasing on credit would not, as a result of negotiation or assignment of their credit instruments, be deprived as to third party holders of those instruments of defenses which the consumers would have been able to assert against the original sellers. In fashioning the Rule the Commission determined that its requirements should apply to "consumer credit contracts" (as defined in the Rule), a category somewhat broader than negotiable instruments or contracts containing waiver of defenses clauses. One concern of the Commission in taking this approach was that certain State laws

⁴It is possible that some portion of law violators will compound their misconduct by failing to produce any noncomplying documents.

⁵Once again, and presumably to the same extent, a violator could compound his misconduct by falsifying his return. See previous footnote.

⁶Although efficiency of enforcement is an important consideration, we ought to strive to confine violations of our law to those situations in which consumers may be injured. Failing to grant the exemption when the vast bulk of open-end obligations are not assigned could divert resources to policing "technical" violations that have little possibility of ripening into actual consumer injury. We might in this way actually reduce, not increase, our enforcement efficiency.

⁷U.C.C. § 9-318(1) (1972 version). Claims and defenses arising from the contract are good against the assignee whether they accrue before or after assignment. U.C.C. § 9-318(1)(a) (1972 version). Consumers' claims not arising from the contract (such as a personal injury claim against the seller) are good against the assignee if they accrue before assignment. U.C.C. § 9-318(1)(b) (1972 version). In addition, it is extremely likely that an assignee of any debt instrument not bearing the required notice would be held to have taken the instrument with actual knowledge (implied by law) that the obligation is conditional on the seller's preference.

⁸In some of these eight states there is also an issue whether the relevant statutes apply at all to open-end. 2 Consumer Credit Guide (CCH) (Del.) §6012, §6042; 3 Consumer Credit Guide (CCH) (Kan.) §5154; 3 Consumer Credit Guide (CCH) (Ohio) §6016; Id. (Pa.) §§6225, 6275; Id. (S.C.) §5104; Id. (Tex.) §6023; Id. (W. Va.) §5032; Id. (Wis.) §5107. Of these the Kansas statute is most troublesome.

⁹1 Consumer Credit Guide (CCH) (Ariz.) §6152. Even here, however, most consumers will find a strong counter-argument in Id., §6151. See also 3 Consumer Credit Guide (CCH) (N.C.) §6325; 3 Consumer Credit Guide (CCH) (S.D.) §6185A.

¹⁰It is at least doubtful that those concerned with administering the bankrupt's estate would violate our rule and subject themselves to personal liability for civil penalties, all for the benefit of creditors. To be sure, the bankruptcy law may require that the consumer have a provable claim against the estate, but this would appear to be so whether the notice is included in the underlying agreement or not.

¹¹In order for consumers to be injured (with or without the exemption) the following events must conjoin: (1) The consumer must have a valid claim against the seller. (2) The consumer must not be in a position to assert this claim against the seller prior to assignment. (3) There must be an assignment. (4) The seller and the assignee must both refuse to adjust the claim. (5) The buyer must be willing to litigate the claim (as such or as a defense). (6) There must be a violation of the rule. (7) Ordinary operation of law, in face of the violation, must cut off the claim on assignment.

Open-end is distinguishable from other forms of credit covered by the rule because of the greater infrequency of events (3) and (7), to say nothing of (1).

¹²The required notice has already achieved the dubious distinction of appearing in the Gobbledygook column of the Washington Star, Washington Star, July 1, 1978.

¹³Moreover, consumers would not have access to the notice when it is included in a master two-party credit card agreement, as would be permitted.

might operate to limit or curtail defenses of consumers against assignees of "consumer credit contracts" even though such contracts might not be negotiable in form nor contain a waiver of defenses clause.

In seeking an exemption for open-end credit contracts, petitioners have not denied the possibility that in some states assignment of these contracts may result in that very loss of claims and defenses which the Rule is intended to prevent. While there is some dispute over the extent to which this may occur—and a precise evaluation is clearly not possible because of uncertainty over the interpretation of various state laws which, notwithstanding benign purposes may be construed to pernicious effect—it is conceded by both petitioners and Commissioner Collier in his dissent that consumers will be deprived of their claims. We believe that if the problem were indeed trivial or purely speculative that fact would and should have been documented in the petitions of those intimately involved in the extension of credit whose burden it is to justify the requested exemption.

In lieu of hard data, the petitions merely suggest that there is a better way than the Rule to prevent the possibility of loss of defenses as a result of assignment. Petitioners contend that rather than requiring inclusion of the Rule's prescribed notice in all open-end contracts it should only be required in such contracts at the time those contracts are assigned.¹³

The Commission determined when it promulgated the Trade Regulation Rule that the best way to prevent loss of consumer claims and defenses against third parties was to require the notice in all "consumer credit contracts." The instant petitions do not demonstrate that this original determination was incorrect. Our principal concern with the exemption proposed by petitioners is that it places the burden of compliance upon retailers at a time when they may be least likely to shoulder it or be detected if they do not. A requirement that the notice be placed in all consumer credit contracts is unambiguous, easily adhered to, and readily monitored. Compliance is likely to be widespread. Compliance with a requirement that the notice be incorporated into the contract only at the time of assignment is much more problematic. It is not apparent to us that a contract may be unilaterally modified by the creditor, and the process of contract modification upon assignment might, therefore, necessitate preassignment contact with the debtor. Diminishing the likelihood that this will occur is the fact that assignments often take place when the assignor is least concerned with the technical requirements of the law or least fearful of the scrutiny of the law enforcer, i.e., when its financial fortunes are in decline or when it faces bankruptcy.

¹³ The Rule would still apply under petitioners' proposal to such open-end contracts as might be negotiable in form or contain a waiver of defenses clause.

A creditor required in the normal course of business to place the notice in all contracts will do so as a matter of routine procedure and face ready detection if it fails. A creditor making an occasional assignment, or making numerous assignments in the face of financial trauma or bankruptcy may not be aware of the requirement of a rule by which it has never before been affected, and if aware may be less apprehensive of detection. Indeed, its violations will be more difficult to detect. In light of these considerations and on the basis of the petitions before us, we find no reason to alter the Commission's earlier conclusion that requiring inclusion of the notice in all consumer credit contracts is more likely than alternative approaches to minimize the harm which the Rule is designed to prevent.

At the same time, the Commission recognizes that the issue is a difficult one and that some misunderstanding as to the scope of the Rule's provisions may have occurred. As a result, the Commission has made every effort to minimize or eliminate the costs attendant upon compliance with the Rule. In April 1977 the Commission granted a limited exemption for pre-existing open-end credit contracts and open-end contracts signed prior to August 1, 1977. Subsequently the Commission granted an additional extension of 45 days in order to minimize or eliminate the costs of compliance and has now authorized an additional 45 day period during which petitioners may bring themselves into compliance.¹⁴

Under these circumstances, the Commission believes, and has been given no reason to doubt, that the costs of adding the required notice to future form contracts will be insignificant, and do not justify dilution of the protections thereby afforded. Accordingly, the Commission has declined to grant the requested permanent exemption for two-party open-end credit contracts.

[FR Doc. 77-27075 Filed 9-15-77; 8:45 am]

Title 17—Commodity and Securities Exchanges

CHAPTER II—SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33-5863, 34-13938, 35-20166, AS-226]

PART 210—FORM AND CONTENT OF FINANCIAL STATEMENTS, SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934, PUBLIC UTILITY HOLDING COMPANY ACT OF 1935, AND INVESTMENT COMPANY ACT OF 1940

Marketable Securities and Other Security Investments

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

¹⁴ While Commissioner Dole concurs in the portion of the Commission's decision denying the permanent exemption, she continues to believe that the costs of immediate compliance have not been shown to outweigh the value of the protection to consumers that will be lost due to the extensions granted by the Commission.

SUMMARY: The Commission has adopted amendments to its rules regarding disclosures by commercial and industrial companies of investments in marketable securities and other security investments. Current economic conditions and events have indicated a need for more detailed information on material concentrations of investments in the securities. The requirements of the amended rules will result in improved disclosures of these concentrations of investments by commercial and industrial companies.

DATE: Effective for financial statements for fiscal years ending after December 24, 1977.

FOR FURTHER INFORMATION CONTACT:

Robert R. Love, Office of the Chief Accountant, Securities and Exchange Commission, 500 North Capitol Street, Washington, D.C. 20549 (202-755-1773).

SUPPLEMENTARY INFORMATION:

BACKGROUND

The Commission originally issued a proposal in Securities Act Release No. 5668 (34-11986, IC-9116) [41 FR 4833] on January 7, 1976, to require disclosure in a footnote to the financial statements of information regarding concentrations of investments in marketable securities and other investment securities. Basically, the proposal would have required footnote disclosure by all registrants of the investments in such securities of any issues for which the aggregate book value exceeded five percent of stockholders' equity. This proposal was issued at the time Accounting Series Release No. 188 [41 FR 4817] was issued which mandated certain special disclosures for registrants' holdings of New York City securities because of the unusual risks and uncertainties pertaining to them, and, as stated in that release, the proposal was part of a longer term and more generalized effort to deal with the fact that, because other issuers of securities may suffer financial difficulties severely affecting a registrant's holdings of such securities, material concentration of holdings of any security may warrant disclosure.

After consideration of the comments on the proposal, the Commission issued a revised proposal in Securities Act Release No. 5825 (34-13500, 35-20016) [42 FR 23853] on May 2, 1977. In the revised proposal major changes were made (1) to change the criterion for the required footnote disclosures to a basis of the investments in the securities of any issuer for which the aggregate market value exceeds one percent of total assets, and (2) to limit the applicability of the requirements to commercial and industrial companies which prepare financial statements in accordance with Article 5 of Regulation S-X [17 CFR Part 210].

Other technical revisions were made in the proposal, including amendments of the instructions to the schedule prescribed under Rule 12-02 [§ 210.12-02] of Regulation S-X, "Marketable securi-

ties—other security investments," to provide for segregation of the securities required to be listed by issuers in the schedule on the same basis as specified in the proposed footnote disclosure requirement. It was noted in the release that the information called for by the proposed footnote disclosure requirement might duplicate to some extent the disclosures required to be provided in the schedule under Rule 12-02. Comments were solicited regarding how to reduce or eliminate such duplication.

COMMENT ON THE SECOND PROPOSAL

Comments on the proposal in Release No. 33-5825 have been carefully considered. Most commentators generally supported the concept embodied in the proposal of disclosure of concentrations of investments in the securities of particular issuers with the objective of providing better information for evaluating the risks of investments as between issuers. However, almost all stated that the criterion for disclosure of the concentrations, specified in the proposal as one percent of total assets, was too low and would result in disclosure in the notes to financial statements of considerable detailed information which is immaterial. It was suggested that, as a minimum, the basis for disclosure should be increased to two percent of total assets to conform to the criterion for grouping of securities by issuers presently specified in Rule 12-02, and in any event, footnote disclosures should not be required for investments in securities of the U.S. Government and its agencies because of their nearly risk-free nature.

It was also suggested that, if a requirement for footnote disclosure of material concentrations of investments is adopted by the Commission, the Rule 12-02 schedule requirement should be eliminated, inasmuch as the information included in the Rule 12-02 schedule on material investments and material concentrations would also be provided in the footnote, and therefore the disclosures in the Rule 12-02 schedule regarding such material investments and concentration would be duplicative and unnecessary.

Other commentators suggested that the proposed requirement for footnote disclosure of the concentrations of investments be withdrawn and instead the requirements for the schedule under Rule 12-02 be revised to insure that all disclosures called for in the proposed new rule will be included in the schedule. They reasoned that many of the securities and the concentrations thereof itemized in the schedule would involve no unusual risks or uncertainties, particularly securities of the U.S. Government and its agencies, and other requirements exist for specific discussions or disclosures in the financial statements regarding unusual risks or uncertainties relating to any material concentrations

of investments in securities and accordingly a requirement for footnote disclosure of all such material concentrations is unnecessary.

ADOPTION OF AMENDMENTS

After consideration of the comments, the Commission has determined to withdraw the proposal contained in Release No. 33-5825 and instead amend Rule 12-02 and Rule 5-04 (17 CFR 210.5-04), which specifies when the schedule prescribed by Rule 12-02 shall be filed for disclosures of securities included under caption 2, Marketable securities, and caption 12, Other security investments, of a balance sheet, to require detailed disclosures in the Rule 12-02 schedule regarding each issue of securities of any issuer where the greater of the aggregate cost or market value of the securities of the issuer constitutes two percent or more of total assets, and to permit summarized disclosures of the other security holdings of the registrant in the marketable securities and other security investments accounts, the amounts of which, for any issuer, do not exceed two percent of total assets. The detailed disclosures required include a description of each security issue, the cost, the market value, and the amounts at which carried in the balance sheet.

The Commission is persuaded by the comments that inclusion in one schedule of these data regarding all of the securities held under these two accounts by a registrant will facilitate a better analysis of the securities holdings, particularly in the comparison of risk factors as between securities. Furthermore, generally accepted accounting principles presently require write-downs or accrual of provisions for losses on securities, as well as disclosure regarding other unquantified loss contingencies in the financial statements, and the Commission would require discussion, in "Management's Discussion and Analysis of Summary of the Earnings" included in reports filed with the Commission, of any unusual risks and uncertainties relating to any material investments or concentration of investments, as discussed and illustrated in Accounting Series Release No. 166 (40 FR 2878). Therefore, requirements beyond those specified above and in the revised Rule 12-02 schedule regarding material concentrations of investments are not considered necessary for commercial and industrial companies subject to Article 5 of Regulation S-X.

Other technical revisions are effected in Rule 5-02 (§ 210.5-02), captions 2 and 12; Rule 5-04 (§ 210.5-04), Schedule I; and the captions and instructions of Rule 12-02 (§ 210.12-02) to clarify the basis for valuation of securities including recognition of requirements under generally accepted accounting principles for determination of the carrying amounts of marketable equity securities

on a portfolio basis; and, with regard to caption 2 of Rule 5-02, to clarify the exclusion of securities from the caption.

COMMISSION ACTION: The Commission hereby amends Part 210 of 17 CFR Chapter II, by revisions of (1) captions 2 and 12 of § 210.5-02, (2) Schedule I of § 210.5-04, and (3) the captions and instructions of § 210.12-02 to read as given below.

§ 210.5-02 Balance sheets.

2. *Marketable securities.* Include only securities having a ready market and which represent the investment of cash available for current operations; securities which are intended to be used for nonworking capital purposes shall be excluded. Securities of affiliates and of other persons the investments in which are accounted for by the equity method shall not be included here. State, parenthetically, or otherwise, the basis of determining the aggregate amounts shown in the balance sheet for the portfolio of equity securities and for all other securities, and for each category state the alternative of the aggregate cost or the aggregate market value at the balance sheet date. When the original cost of securities purchased on a yield basis has been properly adjusted to reflect amortization of premium or accumulation of discount since acquisition, the basis of determining their amount may be described "at cost."

12. *Other security investments.* State, parenthetically or otherwise, the basis of determining the aggregate amounts shown in the balance sheet for the portfolio of equity securities and for all other securities, and for each category state the alternate of the aggregate cost or the aggregate market value at the balance sheet date.

§ 210.5-04 What schedules are to be filed.

Schedule I—Marketable securities—other security investments. The schedule prescribed by § 210.12-02 shall be filed—

(1) In support of caption 2 of a balance sheet, if the greater of the aggregate cost or the aggregate market value of marketable securities as of the balance sheet date constitutes 10 percent or more of total assets.

(2) In support of caption 12 of a balance sheet, if the greater of the aggregate cost or the aggregate market value of other security investments as of the balance sheet date constitutes 10 percent or more of total assets.

(3) In support of captions 2 and 12 of a balance sheet, if the greater of the aggregate cost or aggregate market of other security investments plus the greater of the aggregate cost or the aggregate market value of marketable securities as of the balance sheet date constitutes 15 percent or more of total assets.

(4) In support of captions 2 and 12 of a balance sheet, if the greater of the aggregate cost or aggregate market value of the securities as of the balance sheet date of any issuer reported under either caption 2 or caption 12 constitutes two percent or more of total assets.

§ 210.12-02 Marketable securities—other security investments.

Column A	Column B	Column C	Column D	Column E ¹
Name of issuer ² and title of each issue. ³	Number of shares or units—principal amount of bonds and notes.	Cost of each issue.....	Market value ⁴ of each issue at balance sheet date.	Amount at which each portfolio of equity security issues and each other security issue carried in the balance sheet.

¹ Column E shall be totaled to correspond to the respective balance sheet captions.

² For the purpose of this schedule, each of the following groups of entities shall be considered as one issuer: (a) The United States Government and its agencies; (b) any State of the United States and its agencies; (c) a political subdivision of a state of the United States and its agencies; (d) a foreign government and its agencies and political subdivisions; and (e) a corporation and its majority owned subsidiaries. If a security listed herein is guaranteed by or considered a moral obligation of another issuer named herein, provide, in a note keyed to each issuer, a brief description of the terms of such guarantee or obligation.

³ (a) Each issue shall be stated separately, except that reasonable groupings, without enumeration, may be made of securities of any issuer for which the greater of the aggregate cost or aggregate market value is less than 2 pct. of total assets. (b) In the case of bank holding companies group separately (1) securities of banks and (2) other securities, and in column C show totals for each group.

⁴ Market value shall be based on market quotations at the balance sheet date or, if such quotations are not available, on determinations of fair value made in good faith by the board of directors.

These amendments shall be effective for financial statements for fiscal years ending after December 24, 1977. The amendments are adopted pursuant to authority in Sections 6, 7, 8, 10 and 19(a) (15 U.S.C. 77f, 77g, 77h, 77j, and 77s) of the Securities Act of 1933; Sections 12, 13, 15(d) and 23(a) (15 U.S.C. 78l, 78m, 78o(d) and 78w) of the Securities Exchange Act of 1934; and Sections 5(b), 14 and 20(a) (15 U.S.C. 79e, 79n, and 79t) of the Public Utility Holding Company Act of 1935. Pursuant to Section 23 (a) (2) of the Exchange Act, the Commission has considered the effect that the proposed amendments would have on competition and is not aware, at this time, of any burden that such amendments would impose on competition not necessary or appropriate in furtherance of the purposes of the Act.

By the Commission.

GEORGE A. FITZSIMMONS,
Secretary.

SEPTEMBER 8, 1977.

[FR Doc. 77-26984 Filed 9-15-77; 8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

[Docket No. 77C-0207]

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Guanine; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of August 23, 1977, of a regulation concerning the use of guanine in externally applied drugs and in cosmetics generally, including those drugs and cosmetics intended for use in the area of the eye.

DATE: Effective date confirmed, August 23, 1977.

FOR FURTHER INFORMATION CONTACT:

Gerard L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW.,

Washington, D.C. 20204 (202-472-5740).

SUPPLEMENTARY INFORMATION: A regulation published in the FEDERAL REGISTER of July 22, 1977 (42 FR 37536) added §§ 73.1329 and 73.2329 to Subparts B and C, respectively, of Part 73 (21 CFR Part 73) to provide for the safe use of guanine in externally applied drugs and in cosmetics generally, including those drugs and cosmetics intended for use in the area of the eye. The regulation also amended § 81.1(g) (21 CFR 81.1(g)), by deleting guanine (pearl essence) from the provisionally listed colors.

Under the Federal Food, Drug, and Cosmetic Act (Sec. 706(b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), notice is given that no objections or requests for hearing were filed in response to the regulation of July 22, 1977. Accordingly, the amendments promulgated thereby became effective on August 23, 1977.

Dated: September 7, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 77-26627 Filed 9-15-77; 8:45 am]

[Docket No. 77C-0210]

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Zinc Oxide; Confirmation of Effective Date
AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of August 23, 1977, of a regulation concerning the use of zinc oxide in externally applied drugs and in cosmetics generally, including those drugs and cosmetics intended for use in the area of the eye.

DATE: Effective date confirmed, August 23, 1977.

FOR FURTHER INFORMATION CONTACT:

Gerard L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW.,

Washington, D.C. 20204 (202-472-5740).

SUPPLEMENTARY INFORMATION: A regulation published in the FEDERAL REGISTER of July 22, 1977 (42 FR 37537) added §§ 73.1991 and 73.2991 to Subparts B and C, respectively, of Part 73 (21 CFR Part 73) to provide for the safe use of zinc oxide in externally applied drugs and in cosmetics generally, including those drugs and cosmetics intended for use in the area of the eye. The regulation also amended § 81.1(g) (21 CFR 81.1(g)) by deleting zinc oxide from the provisionally listed colors.

Under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d))) and under authority delegated to the Commissioner (21 CFR 5.1), notice is given that no objections or requests for hearing were filed in response to the regulation of July 22, 1977. Accordingly, the amendments promulgated thereby became effective on August 23, 1977.

Dated: September 7, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 77-26628 Filed 9-15-77; 8:45 am]

SUBCHAPTER G—COSMETICS

[Docket No. 76N-0153]

PART 701—COSMETIC LABELING

Ingredient Designation of Cosmetics Sold by Direct Mail

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document provides for off-package declaration of ingredients for cosmetics distributed to consumers by direct mail and prescribes the requirements for this alternative method of labeling. Petitioners had requested this labeling method.

EFFECTIVE DATE: October 17, 1977, except as to any provision that may be stayed by the filing of proper objections.

FOR FURTHER INFORMATION CONTACT:

Heinz J. Elermann, Bureau of Foods (HFF-440), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington D.C. 20204 (202-245-1530).

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of June 21, 1976

(41 FR 24899), the Commissioner of Food and Drugs issued a proposal to provide for off-package declaration of ingredients in the case of cosmetics distributed to consumers by direct mail. Petitioners requested this method of labeling as an alternative to the declaration of ingredients on a package label, as required in the cosmetic ingredient labeling regulations (21 CFR 701.3 (a) and (b)). Petitioners requested that distributors selling cosmetics by direct mail be permitted to list the ingredients of these cosmetics either in a descriptive catalog from which the consumer selects or orders products by mail, or, where cosmetics are mailed on consignment, in accompanying literature.

Five comments were received in response to the proposal. Four comments endorsed the proposal; namely, two explicitly and two by implication in that they proposed further amendments or other regulatory action. One comment expressed neither endorsement nor opposition. Summaries of the comments and the Commissioner's conclusions follow:

1. One comment endorsing the proposal to add a new paragraph (r) to § 701.3 expressed disappointment about the Commissioner's denial of a request for listing of ingredients in alphabetical order or listing of only "known allergens" as an alternative to the currently prescribed listing of ingredients in descending order of predominance. A second comment, which expressed preference for alphabetical ingredient listing, neither endorsed nor opposed the proposal.

The Commissioner advises that the issue of alphabetical listing of ingredients or declaration of only "known allergens" was fully discussed in the preambles to regulation published in the FEDERAL REGISTER of May 30, 1975 (40 FR 23458) and the proposal published in the FEDERAL REGISTER of June 21, 1976 (41 FR 24899). No data or other information were submitted during the comment period after the May 30, 1975, regulation, or at any time thereafter, in support of these alternate methods of declaration of ingredients. Accordingly, no rule making proceeding was initiated to change the existing requirement for listing ingredients in descending order of predominance.

2. One comment asked that cosmetics sold by direct mail and accompanied by labeling bearing ingredient declarations specifically relating to the cosmetics mailed should not be required to state that a copy of the ingredient declarations will be mailed to any person requesting it, as ordered in proposed § 701.3(r)(2)(ii). The comment argued that a copy of the brochure describing the cosmetics and listing the ingredients would likely be included in a cosmetic shipment, and the required mailing of additional brochures is burdensome, costly, and unjustified. The comment also said that this provision is more stringent than the requirement of § 701.3(k)(5), concerning certain cosmetics with off-package ingredient labeling

that are sold at retail. Section 701.3(k)(5), it was noted, merely requires that the distributor "supply sufficient declarations of ingredients so that a purchaser may obtain a copy of the declaration with each purchase."

The Commissioner is not persuaded that the requirements of proposed § 701.3(r)(2)(ii), i.e., the statement on the mail order package and the mailing of an ingredient declaration to any person requesting it, are unjustified and exceed a similar requirement for cosmetics with off-package labeling that are sold at retail. There is always the chance that some cosmetic assortments may on occasion not contain the brochure with the ingredient information. The recipients of such mailings must be assured that ingredient declarations are available from the distributor on request. In addition, consumers who have lost or inadvertently discarded their brochures must be able to obtain new ingredient lists from the distributor when needed, and the ingredient information must also be available to other consumers sharing in the use of a cosmetic assortment.

The Commissioner points out that proposed § 701.3(r) only provides for an alternate method of ingredient labeling. Cosmetics distributed by direct mail may also bear the ingredient information on the package label, should this method be more convenient and economical. Furthermore, the distributor is not required to mail a costly brochure to a person requesting ingredient information. Ingredient declarations may be provided on leaflets or other plain labeling.

As regards § 701.3(k)(5), the comment disregarded the additional provision of § 701.3(k)(6), which requires that the firm whose name appears on the label of a "shaded" product, as defined in § 701.3(l)(2), that does not bear an ingredient declaration shall promptly mail a copy of the ingredient information to any person requesting it. Accordingly, the requirements of § 701.3(r) are not discriminatory or more stringent than those applicable to "shaded" cosmetics.

3. Two comments contended that off-package ingredient labeling as proposed for cosmetics sold by direct mail should also be permitted in the case of cosmetics distributed to consumers by means of "direct selling" or "door-to-door selling." This method of selling involves solicitation of sale of a cosmetic by an independent sales agent at the consumer's home and delivery of the purchased product by the salesperson to the consumer. Both comments held that the methods of distribution of cosmetics by direct selling and direct mail have much in common, with the pertinent difference between the two methods of selling being the manner of product delivery, i.e., delivery of a product to a consumer by a sales agent as opposed to delivery by postal service.

The Commissioner advises that proposed § 701.3(r) was published in response to a petition concerning only cosmetics sold by direct mail. The request did not refer to cosmetics distributed by

means of direct selling. Moreover, the Commissioner disagrees with the contention that the two methods of distribution of cosmetics are sufficiently analogous also to permit off-package ingredient labeling for cosmetics distributed by means of direct selling. In fact, the Commissioner concludes that the two methods of distribution differ profoundly. In the case of distribution by direct mail, a cosmetic is shipped directly to the consumer and the distributor fully controls delivery to the consumer of the required ingredient information. Where a cosmetic is shipped to a sales agent for delivery or sale to a consumer, the delivery of ingredient information to the consumer cannot be controlled by a distributor in the case of off-package labeling. Direct selling, therefore, has in this regard much more in common with selling through retail outlets than selling by direct mail, and, with the exception of shaded cosmetics held for sale in tightly compartmented trays or racks, cosmetics sold through retail outlets are not permitted to declare ingredients by means of off-package labeling.

4. One comment requested clarification regarding the definition of the term "package" and placement on the package of the notice informing the consumer about the location of the declaration of ingredients and, specifically, whether the notice may be located on the face of the package platform surrounding and holding the assorted products.

The Commissioner advises that the term "package" as it applies to this regulation is defined in section 10(b) of the Fair Packaging and Labeling Act (15 U.S.C. 1459(b)) and in 21 CFR 1.20. Since a shipping container is not included in the definition of the term "package," the respective notice may not be placed on an "outer mailing container."

Placement of the notice on the face of the package platform surrounding and holding the assorted products is not considered contrary to the intent of § 701.3(r)(2). To clarify the meaning of this requirement, the Commissioner is amending its wording accordingly. Section 701.3(r)(2) now includes in the description of the location of the respective notice the additional phrase, " * * * on the face of the package platform surrounding and holding the product(s) * * * ."

5. On April 27, 1976, the Commissioner received a request for extension of the effective dates of cosmetic ingredient labeling—May 31, 1976 for ordering labels with ingredient declarations and November 30, 1976, for labeling of cosmetics with ingredient declarations (Ref. 1). The petitioner sought the extension because no action had been taken to that date by FDA on the requested permission for off-package labeling of cosmetics sold by direct mail, and the requirement for ingredient labeling was about to become effective. In the FEDERAL REGISTER of June 21, 1976 (41 FR 24899), the Commissioner issued the proposal regarding off-package ingredient labeling of cosmetics sold by direct

mail. On August 2, 1976, the petitioner was notified that the request for extension of the effective dates was denied, but because of the existing uncertainties and the petitioner's concern about full compliance with regulatory requirements, the agency notified the petitioner that it would not take regulatory action against cosmetics labeled in accordance with proposed § 701.3(r). The Commissioner advises that he will continue to abide by this commitment until the final rule becomes effective.

REFERENCES

1. Letter of April 27, 1976, by William F. Weigel, Counsel for Cosmetic Beauty Club, Inc., to the Hearing Clerk, Food and Drug Administration.

2. Letter of August 2, 1976, by the Associate Commissioner for Compliance, to William F. Weigel, Esq., Rogers, Hoge & Hills, New York, N.Y. 10016.

Therefore under the Federal Food, Drug, and Cosmetic Act (sec. 701(e), 70 Stat. 919 as amended (21 U.S.C. 371(e)), the Fair Packaging and Labeling Act (secs. 5(c), 6(a), 80 Stat. 1298, 1299 (15 U.S.C. 1454, 1455)) and under authority delegated to the Commissioner (21 CFR 5.1), Part 701 is amended in § 701.3 by adding new paragraph (r), to read as follows:

§ 701.3 Designation of ingredients.

(r) In the case of cosmetics distributed to the consumers by direct mail, as an alternative to the declaration of ingredients on an information panel, the declaration of ingredients may appear in letters not less than $\frac{1}{16}$ of an inch in height in labeling that accompanies and specifically relates to the cosmetic(s) mailed, or in labeling furnished to each consumer for his personal use and from which he orders cosmetics through the mail, e.g., a direct mail sales catalog or brochure, provided all of the following additional requirements met:

(1) The declarations of ingredients are conspicuous and presented in a way that permits the consumer to identify the declaration of ingredients applicable to each cosmetic.

(2) The package mailed to the consumer is accompanied by a notice located on, or affixed to, the top of the package or on top of the contents inside the package, or on the face of the package platform surrounding and holding the product(s), readily visible to the consumer on opening of the package, and provides the following information in letters not less than $\frac{3}{16}$ of an inch in height:

(i) The location of the declarations of ingredients, e.g., in an accompanying brochure, or in a sales catalog used for ordering;

(ii) A statement that a copy of the declaration of ingredients will be mailed promptly to any person requesting it; and

(iii) The name and place of business of the mail order distributor.

(3) The mail order distributor promptly mails a copy of the declaration of ingredients to any person requesting it.

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 17, 1977, submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m. Monday through Friday.

Effective date. This regulation shall become effective October 17, 1977, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be given by publication in the FEDERAL REGISTER.

(Sec. 701(e), 70 Stat. 919, as amended (21 U.S.C. 371(e)); secs. 5(c), 6(a), 80 Stat. 1298, 1299 (15 U.S.C. 1454, 1455).)

Dated: September 9, 1977.

JOSEPH P. HILE,
Associate Commissioner for
Compliance.

[FR Doc. 77-26755 Filed 9-15-77; 8:45 am]

SUBCHAPTER H—MEDICAL DEVICES

[Docket No. 76N-0355]

ESTABLISHMENT REGISTRATION AND
PREMARKET NOTIFICATION PROCEDURES

Corrections

In FR Doc. 77-24147 appearing as Part III at page 42519 in the issue for Tuesday, August 23, 1977, the following corrections should be made.

1. On Page 42521, second column, line 19, the word, "modification", should read, "notification".

2. On page 42525, third column, 4th line from the bottom, the date, "October 25, 1977", should be changed to, "October 24, 1977".

3. On page 42526, first column, the dates on lines 7 and 12 of paragraph d., now reading, "October 21, 1977", should read, "October 24, 1977".

Title 22—Foreign Relations

CHAPTER I—DEPARTMENT OF STATE

[Dept. Reg. 108.745]

PART 9A—CLASSIFICATION OF CERTAIN
INFORMATION AND MATERIAL OBTAINED
FROM ADVISORY BODIES
CREATED TO IMPLEMENT THE INTER-
NATIONAL ENERGY PROGRAM

Security Information Regulations Applicable to Certain International Energy Program, Related Material

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule establishes regulations for the classification and safeguarding of certain information and material obtained from advisory bodies created to implement the International Energy Program (TIAS 8278). EO 11932 directs the Department of State to promulgate such regulations which will provide for the protection of classified information taking into account the special circumstances under which such information is generated and utilized and will reflect the character of certain records which may be in the possession of the United States Government.

EFFECTIVE DATE: September 16, 1977.

FOR FURTHER INFORMATION CONTACT:

Gerald A. Rosen, Director, Office of Fuels and Energy, Bureau of Economic and Business Affairs, Department of State, Washington, D.C. 20520.

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking was published in the FEDERAL REGISTER (42 FR 17142, March 31, 1977) inviting interested persons to submit comments regarding the proposed regulation. Relevant comments have been considered and in order to clarify the regulations, a new § 9a.1 is added and the remaining section headings are renumbered.

Accordingly, Part 9a is adopted as set forth below.

Dated: September 6, 1977.

BEN H. READ,
Deputy Under Secretary
for Management.

Sec.

9a.1 Security of certain information and material related to the International Energy Agency.

9a.2 General policy.

9a.3 Scope.

9a.4 Classification

9a.5 Declassification and downgrading.

9a.6 Marking.

9a.7 Access.

9a.8 Physical protection.

AUTHORITY: E. O. 11932 (41 FR 32691), E. O. 11652 (37 FR 5209), National Security Council Directive of May 17, 1972 (37 FR 10053).