to coordinate the effectiveness of the updated Filer Manual with the scheduled system upgrade in order to minimize confusion to EDGAR filers.

Statutory Basis

We are adopting the amendments to Regulation S–T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act,[9] Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,[10] Section 20 of the Public Utility Holding Company Act of 1935,[11] Section 319 of the Trust Indenture Act of 1939,[12] and Sections 8, 30, 31, and 38 of the Investment Company Act.[13]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

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

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

1. The authority citation for Part 232 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77sss(a), 78c(b), 78*l*, 78m, 78n, 78o(d), 78w(a), 78*ll*(d), 79t(a), 80a–8, 80a–29, 80a–30 and 80a–37.

2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. For the period during which Legacy EDGAR will be available, prior to the complete transition to the use of Modernized EDGAR, the EDGAR Filer Manual will consist of three parts. For filers using Legacy EDGAR, the requirements are set forth in EDGAR Filer Manual (Release 7.0), Volume I—Legacy EDGARLink. For filers using modernized EDGARLink, the requirements are set forth in EDGAR Filer Manual (Release 7.0), Volume II—Modernized EDGARLink. Additional provisions applicable to Form N–SAR filers are set forth in EDGAR Filer Manual (Release 7.0), Volume III—N–SAR Supplement. All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. You must comply with these requirements in order for documents to be timely received and accepted. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549–0102 or by calling Disclosure Incorporated at (800) 638–8241. Electronic format copies are available on the SEC's Web Site. The SEC's Web Site address for the Manual is http://www.sec.gov/asec/ofis/filerman.htm. Information on becoming an EDGAR e-mail/electronic bulletin board subscriber is available by contacting TRW/UUNET at (703) 345–8900 or at www.trw-edgar.com.

Dated: June 14, 2000.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00–15489 Filed 6–22–00; 8:45 am]

BILLING CODE 8010–01–U

[9] 15 U.S.C. 77f, 77g, 77h, 77j and 77s(a).

[10] 15 U.S.C. 78c, 78*l*, 78m, 78n, 78o, 78w and 78*ll*.

[11] 15 U.S.C. 79t.

[12] 15 U.S.C. 77sss.

[13] 15 U.S.C. 80a–8, 80a–29, 80a–30 and 80a–37.

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 171

[T.D. 00–41]

RIN 1515–AC08

Guidelines for the Imposition and Mitigation of Penalties for Violations of 19 U.S.C. 1592

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document revises Appendix B to Part 171 of the Customs Regulations, which sets forth the guidelines for remitting and mitigating penalties relating to violations of section 592 of the Tariff Act of 1930, as amended. A violation of section 592 involves the entry or introduction or attempted entry or introduction of merchandise into the commerce of the United States by fraud, gross negligence, or negligence. Many of the changes to Appendix B reflect the Customs Modernization Act and its themes of ''informed compliance'' and ''shared responsibility.''

EFFECTIVE DATE: July 24, 2000.

FOR FURTHER INFORMATION CONTACT: Charles D. Ressin, Penalties Branch (202) 927–2344.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 1993, the President signed the North American Free Trade Agreement Implementation Act (Public Law 103–182). The Customs Modernization portion of this Act (Title VI), popularly known as the Customs Modernization Act or ''the Mod Act'', became effective when it was signed. The Mod Act emphasizes the themes of ''shared responsibility'' and ''informed compliance'' for Customs and the public.

Consistent with the Mod Act, Customs has initiated a thorough examination and review of its procedures and processes relating to importer compliance with Customs laws, regulations, and policies. In this review, the agency has considered a number of innovative approaches to improving the service it provides the importing public as well as new approaches to encourage compliance and address incidents of non-compliance.

With regard to compliance, Customs is dedicated to educating its personnel to improve agency selection of appropriate remedies to address incidents of non-compliance. In keeping with the Mod Act theme of informed compliance, Customs is also attempting to educate the importing public about its requirements, particularly in areas involving complex import transactions. A more informed public promotes an overall greater level of compliance than the threat of an occasional and often ineffective penalty.

In Appendix B to Part 171 of the Customs Regulations (19 CFR part 171) Customs has guidelines for remitting and mitigating penalties relating to violations of section 592 of the Tariff Act of 1930, as amended (19 U.S.C. 1592) (hereinafter referred to as section 592). A violation of section 592 involves the entry or introduction or attempted entry or introduction of merchandise into the United States by fraud, gross negligence or negligence. In accordance with the ''shared responsibility'' and ''informed compliance'' approach of the Mod Act, Customs proposed a revision of these guidelines in a notice of proposed rulemaking published in the **Federal Register** (63 FR 57628) on October 28, 1998. This proposed revision consisted of a reorganization of the content of the current guidelines into a new format intended to more clearly identify important provisions which are contained in the present text.

Below is a summary of the proposed revised guidelines.

Summary of Proposed Revised Guidelines

After the introductory text, the proposed revised guidelines broke current section (A) into 2 paragraphs. Proposed section (A) discussed what constitutes section 592 violations and proposed section (B) discussed what is meant by materiality.

Proposed section (A) clarified that placing merchandise in-bond is considered entering or introducing merchandise into the United States for purposes of section 592. The paragraph also made it clear that if one unintentionally transmits a clerical error to Customs electronically, and that clerical error is transmitted repetitively by the electronic system, Customs will not consider repetitions of the non-intentional electronic transmission of the initial clerical error as constituting a pattern, unless Customs has drawn the error to the party's attention.

In proposed section (B), defining materiality under section 592, that definition was clarified by providing that a document, statement, act, or omission is material if it significantly impairs Customs ability to collect and report accurate trade statistics, deceives the public as to the source, origin or quality of the merchandise, or constitutes an unfair trade practice in violation of federal law.

Proposed section (C) discussed the degrees of culpability under section 592. The degrees of culpability are currently discussed in section (B).

A section (D) was proposed to be added to include terms used throughout the guidelines. Included in this section were discussions of the terms: duty loss violations; non-duty loss violations; actual loss of duty; potential loss of duty; reasonable care; clerical error; and mistake of fact.

A section (E) was proposed to be added which tracked the administrative penalty process in chronological order. Proposed section (E) was a revision of current section (C). It began with the case initiation and proceeded to describe the considerations pertinent to the decision to issue a pre-penalty notice and how the different types of violations can produce different proposed claim amounts depending upon the level of culpability and the presence of mitigating and/or aggravating factors. The proposed guidelines contained express guidance regarding statute of limitations considerations and Customs policy regarding waivers when the issuance of pre-penalty and penalty notices are involved.

Continuing in their chronological progression, the proposed guidelines next addressed steps to be taken when Customs decides whether to close a case or issue a penalty notice. Most of this material is contained in paragraph (C)(2) of the current guidelines. However, the proposed guidelines provided that penalty notices can indicate higher degrees of culpability and proposed penalty amounts than were contained in the original pre-penalty notice if less than 9 months remain before the expiration of the statute of limitations, and a waiver of the statute has not been received. The current guidelines provide that such increased penalty notices would only be issued if less than 3 months remained.

Section (F) of the proposed guidelines covered the procedures that are to be followed and elements that Customs will consider as part of the case record for any mitigating and/or aggravating factors. The current guidelines discuss mitigating factors in section (F) and aggravating factors in section (G). Proposed section (F) was arranged so the various types and degrees of violations are explained and respective mitigation considerations are explained. The section also informed the reader who within Customs has the authority to cancel or remit penalty claims.

Proposed paragraph (F)(2)(f) provided a discussion of prior disclosure and the reduced penalties based upon the different levels of culpability for a valid prior disclosure. Prior disclosure is discussed in section (E) of the current guidelines.

Proposed section (G) of the guidelines discussed the factors that are considered by Customs in proposing a penalty or mitigating an assessed penalty claim. Among these factors are: an error by Customs that contributed to the violation; the extent of cooperation by the violator with the investigation by Customs into the alleged violation; whether or not the violator takes immediate steps to remedy the situation that caused the violation; inexperience in importing; and the prior record of the violator in its dealings with Customs. This proposed section combined the factors located in sections (F) and (H) of the current guidelines. It was felt that a separate section was no longer necessary for ''extraordinary'' factors such as the ability of Customs to obtain personal jurisdiction over the violator, the violator's financial status, and whether Customs had actual knowledge of repeated violations but failed to inform the violator thus depriving him of the opportunity to take corrective action. All these factors were contained in the one section. The proposed section allowed that additional factors may be considered in appropriate circumstances.

Proposed section (H) contained the factors that Customs believes are to be treated as aggravating factors when considering mitigation of proposed or assessed penalties. Most of these factors are found in section (G) of the current guidelines. While the list of factors was not intended to be all-inclusive, two new factors were proposed to be added. They were: the discovery of evidence of a motive to evade a prohibition or restriction on the admissibility of merchandise, and failure to comply with a lawful demand for records or a Customs summons.

Section (I) of the proposed guidelines addressed offers in compromise (settlement offers). This was a new element not contained in the current guidelines. The proposed section instructed parties who wish to submit a civil offer in compromise pursuant to 19 U.S.C. 1617 to follow procedures outlined in 161.5 of the Customs Regulations (19 CFR 161.5). The section summarized what steps will be taken by both parties once such an offer has been made.

Section (J) of the proposed guidelines contained instructions to be followed in instances where Customs makes a demand for payment of actual loss of duties pursuant to section 592(d). This is a subject not addressed in the current guidelines. The section provided that Customs will follow the procedures set forth in § 162.79b of the Customs Regulations (19 CFR 162.79b) and stated that no such demand will be issued unless the record establishes the presence of a violation of section 592(a). The section stated that, absent statute of limitations problems, Customs will endeavor to issue section 592(d) demands to concerned sureties and non-violator importers only after default by principals.

Section (K) of the proposed guidelines addressed violations of section 592 by brokers. The current guidelines discuss brokers in section (I). The section proposed to continue the present practice of applying the overall mitigation guidelines in instances of fraud or where the broker shares in the financial benefits of a violation. However, where there has been no fraud or sharing of the financial benefits, the proposed section removed the dollar limitations contained in the current guidelines and advised that Customs may charge the broker under 19 U.S.C. 1641.

Section (L) of the proposed guidelines covered arriving travelers and consisted of a reordering of the provisions of section (J) of the current guidelines.

Section (M) of the proposed guidelines referred Customs officers to other Federal agencies for recommendations in instances where violations of laws administered by other agencies are discovered. These provisions are the same as those contained in section (K) of the current guidelines.

Analysis of Comments

The notice of proposed rulemaking invited public comments. The comment period closed on December 28, 1998. Seventeen comments were received. Many commenters applauded Customs efforts to re-organize and simplify the existing guidelines. Nine of the commenters set forth similar concerns and objections to Customs change in the guidelines relating to penalty assessment of customs brokers who violate section 592. Also, eight of the commenters voiced concerns and recommendations regarding the proposed guidelines on a section by section basis. Three commenters also made general comments which were not directly related to a specific section of the proposal.

The specific ''section by section'' recommendations and/or suggestions, general recommendations and/or suggestions, and the Customs responses to the comments, are set forth below.

Proposed Introductory Paragraph of the Guidelines

Comment: Three commenters object to the language in the introductory paragraph that indicates that ''a mitigated penalty is conditioned upon payment of any actual loss of duty as well as a *release by the party that indicates that the mitigation decision constitutes full accord and satisfaction*.'' The commenters believe that if other statutory remedies are available to importers, the importers should have the right to pursue those remedies separately and distinctly from the settlement of any civil penalty for violation of section 592.

Also, one commenter takes issue with Customs statement in the introduction that the guidelines ''may supplement, and are not intended to preclude application of, any other special guidelines promulgated by Customs.'' The commenter believes that the language is unclear and would permit Customs to issue, without prior notice, draconian special guidelines to fit the immediate needs of the agency.

Customs Response: Customs does not agree that an alleged violator who seeks mitigation of a civil penalty initiated by Customs under section 592 is deprived of other statutory remedies or judicial recourse in the event that the party chooses not to comply with the agency decision. In other words, the party *elects* to pay the mitigated amount. The agency must, in turn, sue the party to collect an assessed penalty in the event that the violator decides not to comply with the agency decision. Consequently, given the elective nature of the mitigation proceedings and the availability of judicial recourse, we do not agree with the commenters' objections.

Also, we do not share the commenter's concern regarding issuance of ''special guidelines'' inasmuch as these guidelines merely reflect policies issued pursuant to the discretionary authority of the Customs Service pursuant to 19 U.S.C. 1618 to remit and mitigate penalties. As such, the Customs Service may depart from the guidelines as appropriate circumstances warrant, including the application of special guidelines.

Proposed Section (A) Violations of Section 592

Comment: One commenter takes issue with Customs characterization of ''in-bond'' movements as encompassed within the language ''entry, introduction, or attempted entry or introduction.'' The commenter believes that the in-bond language is an impermissible expansion of section 592. In the commenter's view, a mere transportation movement should not be considered an ''entry'' under section 592 because nothing has been presented to Customs for entry or introduction into the commerce of the United States.

Two commenters express concern regarding Customs discussion of clerical error and pattern of negligent conduct. Specifically, one commenter believes that the section is contradictory because Customs initially states that ''an unintentional repetition by an electronic system of an initial clerical error, generally shall not constitute a pattern of negligent conduct'' unless Customs has brought the error to the party's attention. In the next sentence the commenter feels that Customs contradicts itself where it is stated that ''* * * the unintentional repetition of a clerical mistake over a significant period of time or involving many entries could indicate a pattern of negligent conduct and a failure to exercise reasonable care.'' Both commenters believe that this language should be clarified.

Customs Response: With respect to the objection regarding inclusion of ''in bond'' applications within the meaning of entry, introduction, or attempted entry or introduction, Customs does not believe that such inclusion contradicts either statute or regulation. For example, if merchandise entered under bond is subsequently diverted (*i.e.*, ''introduced'' into the commerce of the United States contrary to the terms of the bond, the penalty provisions of section 592 may apply.

We also disagree with the two comments relating to Customs language concerning ''clerical error'' and ''pattern of negligent conduct.'' Clearly, in those cases where Customs calls the error to the attention of the party and the error is not corrected, the party may be subject to potential section 592 penalty. Similarly, in those cases where the repetition of a clerical mistake occurs over a significant period of time or involves many entries, a violation may occur if the facts and circumstances surrounding the transactions indicate a failure to exercise reasonable care. In the latter instance, the proposed language does not mandate assessment of a penalty, but rather, contemplates the possibility of a penalty depending on the facts and circumstances of the transactions at issue.

Proposed Section (B) Definition of Materiality Under Section 592

Comment: Three commenters object to Customs definition of materiality as either ''too subjective'' or not within the scope of section 592. One of the commenters is of the opinion that the Court of Appeals' decision in *Pentax Corp.* v. *Robinson,* 125 F.3d 1457 (Fed. Cir. 1997), amended, 135 F.3d 760 (1998), does not permit Customs to include an importer's liability for marking duties in the agency definition of materiality. Two commenters also expressed concern that the language ''whether an unfair trade practice has been committed under the anti-dumping or countervailing duty laws or a similar statute'' is too broad and may result in Customs adding its penalty on top of other agencies' statutory remedies. Similarly, one of these commenters also believes that the definition of materiality should not include a determination of whether an unfair act has been committed involving patent, trademark or copyright infringement, in view of other remedies available to Customs for such intellectual property rights infractions. Lastly, one of the commenters believes that the definition's inclusion of ''collection and reporting of accurate trade statistics'' exceeds the statutory limits of section

592. This commenter is involved with oil and gas importations and is of the opinion that statistical discrepancies for the majority of these products bear no relevance to the entry of such products, and that therefore, Customs definition of materiality should not include statistical errors.

Customs Response: Customs is of the opinion that the definition of materiality set forth in the proposed guidelines comports with law and judicial precedent. With respect to the inclusion of a marking duties assessment as an example of a ''Customs action'' that could be influenced by a false statement, omission, or act, in Customs view, the *Pentax* decision does not preclude liability for marking duties in connection with section 592 violations in all cases.

We note that in cases involving either antidumping, other agency or intellectual property rights infractions, the law does not preclude the use of section 592 in appropriate cases, despite the availability of other government remedies. Further, with respect to that part of the definition of materiality involving collection and reporting of accurate trade statistics, we note that there is judicial precedent that supports this aspect of Customs definition.

Proposed Section (D) Discussion of Additional Terms

Comment: Two commenters suggest that Customs include fees and taxes in the definition of loss of duty in the paragraph entitled ''(1) Duty Loss Violations'' so that there is consistency with the definition of loss of duty as set forth in the paragraphs entitled ''(3) Actual Loss of Duties,'' and ''(4) Potential Loss of Duties.'' Two other commenters object to including marking duties in the definition of ''duty loss'' based on the same objections expressed above regarding materiality and the *Pentax* decision.

One commenter is of the opinion that the last sentence in section (D) paragraph (4) ''Potential Loss of Duties'', should be deleted. The commenter points out that if an entry summary is filed without inclusion of information regarding antidumping or countervailing duty investigations the regulations provide that the entry should be rejected. The commenter believes that such a case should not give rise to a potential loss of duties inasmuch as Customs is not discovering a violation but rather merely enforcing a regulation.

The same commenter suggests that Customs revise section (D) paragraph (6) ''Reasonable Care'', to include language that failure to follow a binding Customs ruling pertaining to its merchandise evidences a failure to exercise reasonable care.

Customs Response: Customs agrees that the definition of duty loss set forth in section (D) paragraph (1) ''Duty Loss Violations'', should be amended to conform to the definition of duty loss set forth in section (D) paragraph (3) ''Actual Loss of Duties'', and has made the necessary change.

As indicated in our response to comments regarding materiality, section 592 liability may arise in certain cases where the government has been deprived of marking duties. Consequently, Customs believes that the inclusion of marking duties in the definition of duty loss is appropriate.

With regard to the suggestion that Customs delete the last sentence of section (D) paragraph (4) ''Potential Loss of Duties'', we note that the failure to provide required information on the entry documents may give rise to section 592 liability and that Customs may ''discover'' such an omission after the filing of the documents. Therefore, it is accurate to state that a potential loss of duties equals the amount of the duties, taxes, and fees that would have occurred had Customs not discovered the violation prior to liquidation and taken steps to correct the entry.

With regard to the commenter's suggestion involving ''Reasonable Care'', we believe that the suggested revision is unnecessary. Customs notes that the regulations already establish the requirement that an importer who receives a ruling from Customs regarding the tariff classification of merchandise shall set forth in connection with a subsequent entry of that merchandise the tariff classification set forth in the ruling.

Proposed Section (E) Penalty Assessment

Comment: A commenter recommends that section (E) be revised to require the Customs field officer to include copies of the evidence relied upon for issuance of the prepenalty notice with appropriate deletions based on Freedom of Information Act exemptions. This commenter also believes that if Customs agrees to a waiver of the statute of limitations, the guidelines should reflect a requirement that the Customs officer signing the waiver has the contractual authority to sign the waiver. Also, the commenter is of the opinion that the guidelines should be amended to require that penalty notices provide explanations why a petitioner's prepenalty response arguments are defective or without merit. Lastly, the commenter believes that the guidelines should require that the Customs field officer promptly notify the alleged violator in cases where the officer has determined that the statute of limitations has expired.

Another commenter questions Customs approach to the ''parking ticket'' penalties of up to $10,000, set forth in paragraph (E)(1)(c). The commenter believes that $10,000 is an excessive penalty for per entry infractions especially when the case involves a number of entries. The same commenter expresses concern regarding Customs approach to statute of limitations waivers. The commenter is of the opinion that the paragraphs in section (E) relating to statute of limitations waivers override the clear legislative intent underlying the statute of limitations applicable to section 592 violations—*i.e.,* that the agency identify and resolve the violations within a specified period of time. For example, the commenter objects to Customs Headquarters recently requiring agents to obtain waivers of the statute of limitations immediately upon initiating a case.

Another commenter objects to Customs lengthening the time during which Customs can lawfully indicate a degree of culpability and penalty amount higher than were set forth in the original prepenalty notice, without having to issue a new prepenalty notice (*i.e.,* from the current 3 months to the proposed 9 months before expiration of the statute of limitations). The commenter believes that the proposed revision needlessly extends the period of time within which Customs may claim higher levels of culpability without providing the alleged violator full due process. The commenter believes that this proposal provides a strong incentive for Customs to delay its section 592 investigation.

Customs Response: Customs does not agree with the commenter's recommendation to include copies of evidence with the prepenalty notice. Neither the statute nor corresponding regulations authorize release of evidence at the time of issuance of the prepenalty notice, and to require its production would be tantamount to engaging in unauthorized pre-trial discovery. Also, Customs does not agree with this commenter's suggestions to establish a requirement that the Customs officer signing a waiver of the statute of limitations has the contractual authority to sign such a waiver. Such signing authority already has been established through the appropriate Customs delegation procedures. Moreover, waivers involve the unilateral action of the involved party and such

action has nothing to do with any contractual authority with Customs. Further, inasmuch as section 592 does not require the agency to furnish explanations why a prepenalty response is deficient or defective, Customs does not believe that such a requirement is necessary. In Customs view, the statute provides adequate safeguards for the alleged violator by requiring the agency ultimately to furnish the party with its findings of fact and conclusions of law in the agency decision. Lastly, because the statute of limitations is an affirmative defense available to an alleged violator, we do not agree with the commenter's recommendation that Customs should be required to notify the alleged violator in cases where the statute has expired.

With respect to the commenter's concern regarding Customs approach to technical violations and ''parking ticket'' penalties of up to $10,000, Customs notes that this paragraph does not mandate a $10,000 fixed sum penalty per entry violation, but rather provides for ranges of fixed sum penalties—generally $1,000 to $2,000 per infraction where there are no prior violations. The higher fixed sum amounts may be appropriate in cases of multiple or repeat violations, and Customs does not believe that these fixed sum amounts are excessive. In response to this commenter's concern regarding statute of limitations waivers, Customs notes that an alleged violator is not required to provide a waiver to Customs, and the guidelines merely serve to advise the alleged violator of the consequences of providing a waiver, as well as the consequences of choosing not to provide a waiver of the statute of limitations. Customs notes that the guidelines, for the most part, reiterate already established regulatory provisions.

Customs also does not agree with the comment raising a due process objection to Customs lengthening the time in which Customs can lawfully indicate a higher degree of culpability and penalty amount than were set forth in the original prepenalty notice without having to issue a new prepenalty notice. Customs notes that the guidelines do not affect the alleged violator's due process rights, inasmuch as the party may file a petition to contest the allegations set forth in the penalty notice. Customs would also like to point out that this provision affects only those few cases where evidence is uncovered at a point in time where the statute of limitations poses a significant concern to the government's ability to timely process the penalty action.

Proposed Section (F) Administrative Penalty Disposition

Comment: One commenter believes that the penalty dispositions for non-duty loss violations (based on a percentage of the dutiable value) are unfair to importers of duty-free articles. The commenter is of the opinion that the penalty disposition in non-duty loss cases should be under 10 percent of the dutiable value (plus interest), including cases of fraud.

Customs Response: Customs disagrees. Some of the most egregious violations involve non-dutiable articles (*e.g.,* quota evasion).

Proposed Section (G) Mitigating Factors

Comment: Two commenters object to the proposed requirement that ''Contributory Customs Error'' may only be claimed where the misleading or erroneous advice given by a Customs officer is given in writing. The commenters believe that the writing requirement will have the effect of eliminating the ability to claim this factor, and one of the commenters expresses the view that because the alleged violator has the burden of proof, a writing requirement is unnecessary.

One commenter objects to Customs elimination of ''Inexperience in Importing'' as a mitigating factor, and believes that the Customs Modernization Act's concept of ''reasonable care'' suggests that the factor should be included in the guidelines. This commenter also believes that Customs should not require the cooperation with an investigation be ''extraordinary'' to be entitled to mitigation; that the ''inability to obtain jurisdiction'' factor should not be eliminated as a mitigating factor and that there should not be an increase in penalties in non-duty loss cases where Customs knew of the infraction but failed to take action.

Finally, with respect to the mitigating factor of ''Customs Knowledge'' another commenter recommends deletion of the qualifying language ''without justification,'' that precedes the requirement that Customs ''failed to inform the violator so that it could have taken earlier corrective action.'' The commenter is of the opinion that the qualifying language makes the benefit of this factor unobtainable.

Customs Response: Customs disagrees with the two commenters' objections to the ''Contributory Customs Error'' writing requirement. In view of the responsibility of the importer to act with reasonable care (as set forth in the Customs Modernization Act), Customs believes it is reasonable to require that the importer demonstrate ''Contributory Customs Error'' by tangible written evidence.

With regard to the commenter's concern involving the proposal to eliminate ''Inexperience in Importing,'' as a mitigating factor, Customs has reconsidered the proposal and decided to retain the factor. With respect to the commenter's concern regarding cooperation, Customs believes that it is appropriate that the cooperation be extraordinary, as it is expected that the party does more than merely cure the defect or problem that resulted in the violative conduct. Customs also believes that ''inability to obtain jurisdiction'' (*i.e.,* personal jurisdiction) is a matter that is better addressed at the litigation stage of the proceedings in the event of non-compliance with the agency decision. As for the commenter's question regarding the rationale for increasing the ''Customs Knowledge'' non-duty loss penalties, we note that the change is being made so that the non-duty loss penalty amounts are consistent with the corresponding duty loss penalty amounts.

Finally, Customs disagrees with the commenter's opinion regarding the suggested deletion of the ''without justification'' language set forth in the ''Customs Knowledge'' mitigating factor. Customs notes that there may be circumstances (such as an open investigation) that warrant delay in notifying the alleged violator of the purported infraction.

Proposed Section (H) Aggravating Factors

Comment: One commenter believes that because the new proposed aggravating factors of ''evading a quota restriction'' and ''failure to comply with a lawful demand for records'' are themselves subject to penalty, these factors should not be considered to increase the penalty or proposed penalty of an alleged violator.

Another commenter expresses reservations about the aggravating factor that involves ''textile imports that have been the subject of illegal transshipment, whether or not the merchandise bears false country of origin markings.'' The commenter asks how goods can be transshipped if they are properly marked—and implies that this factor should be deleted.

Customs Response: With regard to the first commenter, it should be noted that the guidelines indicate that the ''presence of one or more aggravating factors may not be used to raise the level of culpability attributable to the alleged violations, but may be utilized to offset the presence of mitigating factors.''

Consequently, although we agree that the offenses may be subject to separate penalties, the inclusion of these two aggravating factors do not serve to potentially increase the section 592 penalties, but rather, may serve to offset the presence of mitigating factors in the action.

With respect to the second commenter's question concerning the aggravating factor involving transshipped textile products, Customs notes that the factor's qualifying language indicates ''whether or not the merchandise bears false country of origin markings.'' Therefore, although the textile article may not bear a false country of origin marking, it does not necessarily follow that the article is properly marked. For example, an imported textile product may bear no country of origin marking at all, and therefore be improperly marked as well as possibly illegally transshipped.

Proposed Section (J) Section 592(d) Demands

Comment: One commenter believes that Customs should make it very clear that where an entry has been finally liquidated, that absent proof of a violation of section 592, no further duties may be collected.

Customs Response: Customs believes that no additional language to the proposed section is warranted inasmuch as the second sentence of the section makes clear that with respect to finally liquidated entries ''information must be present establishing a violation of section 592(a),'' before a section 592(d) demand may be issued.

Proposed Section (K) Customs Brokers

Comment: Nine commenters object to the change of Customs position regarding the applicability of section 592 to Customs brokers in ''non-fraud'' cases and in those cases where the broker does not share in the benefits of the violation to an extent over and above customary brokerage fees. In sum, in these cases, the commenters object to the proposed language requiring that Customs ''shall'' proceed against the Customs broker pursuant to the remedies provided under 19 U.S.C. 1641. The commenters believe that this language is a clear invitation for Customs field offices to make every suspected negligent violation of section 592 by a broker into a 19 U.S.C. 1641 broker penalty case. Most of the commenters believe that adoption of such a change would result in the maximum $30,000 broker penalty for such infractions. Two of the nine commenters believe that the current broker guidelines should be retained while one of the commenters is of the opinion that Customs should amend the proposed language to provide discretion to local field offices by substituting the words ''may'' for ''shall'' before the remaining language ''proceed against the Customs broker pursuant to the remedies provided under 19 U.S.C. 1641.

Customs Response: In view of the comments received in connection with this proposed section, Customs has reconsidered its position and adopted the commenter's suggestion to substitute the word ''may'' for ''shall'' in the language relating to broker penalty assessment pursuant to 19 U.S.C. 1641. The agency notes that the existing Customs Directive regarding 19 U.S.C. 1641 penalties already provides for incremental assessment of broker penalties in appropriate cases (*e.g.,* initial warning letters). Therefore, Customs believes that apprehensions about immediate $30,000 penalty assessments in every broker negligence case are unwarranted.

Proposed Section (L) Arriving Travelers

Comment: One commenter believes that this section should be clarified to indicate that alleged violators that are arriving travelers will be assessed only one penalty under either section 592, 19 U.S.C. 1497 or 19 U.S.C. 1595(a) so that the traveler will know how to prepare his or her petition.

Customs Response: Inasmuch as the law does not provide that section 592 is the exclusive remedy available to the agency in cases involving violations by arriving travelers, the commenter's suggestion cannot be adopted. More than one statute can be violated by the arriving traveler. However, the seizure or penalty notice will indicate the statute underlying the alleged violation.

Proposed Section (M) Violations of Laws Administered by Other Federal Agencies

Comment: One commenter recommends that this section be clarified so that Customs cannot impose a penalty for the release of seized merchandise for laws administered by other federal agencies.

Customs Response: Customs notes that in cases where merchandise is legally seized for violations of laws administered by other federal agencies, Customs may, by law, require payment of a penalty in order to remit the forfeiture in appropriate cases. Therefore, we cannot adopt the commenter's suggestion.

General Comments

Comment: One commenter recommends the proposed guidelines include a definition of the term ''domestic value,'' since that term is used frequently within the guidelines.

Customs Response: Customs notes that the term ''domestic value'' already is defined in the Customs Regulations in 19 CFR 162.43(a) and clearly is applicable to penalty assessments. Therefore, we do not believe that adoption of the commenter's suggestion is warranted.

Comment: One commenter believes that Customs should explicitly provide that the agency has the authority to mitigate section 592 ''interest'' penalties in non-fraudulent actual duty loss cases involving a valid prior disclosure. The commenter feels that the proposed guidelines' failure to expressly provide for such mitigation authority diminishes the agency's policy position of encouraging valid prior disclosures.

Customs Response: Although the language in the proposed guidelines does not explicitly rule out the possibility of affording mitigation in extraordinary cases involving valid prior disclosures, the agency believes that the current language best reflects Congressional intent—namely, that the monetary benefits of a valid prior disclosure are those reduced penalties provided for by law.

Comment: A commenter suggests that the first sentence of proposed Appendix B providing for remission or mitigation of section 592 penalties pursuant to section 1618 of the Tariff Act of 1930, be added to the Customs Regulations. The commenter believes that the subjects of remission and mitigation discussed in the guidelines are not found in the regulations, and that by including these subjects in the regulations, Customs would have greater discretion regarding the use and application of the guidelines.

Customs Response: Customs notes that the regulations already discuss the mitigation and remission authority of the agency in connection with penalties and forfeitures in 19 CFR 162.31.

Comment: A commenter expresses concern that the proposed guidelines do not explicitly address the situation where a party makes a false statement, or engages in an omission or act that results in the overpayment of duty and taxes. The commenter is unclear whether such a case could result in the imposition of penalties under section 592.

Customs Response: Customs notes that liability under section 592 may arise in cases involving an overpayment of duty and taxes (*e.g.,* an overpayment to evade a tariff rate quota or an established government trigger-price mechanism). In Customs view, the

proposed guidelines adequately addressed these situations. For example, section (F) provides for penalty dispositions for such infractions as non-duty loss violations.

Comment: One commenter expresses reservations about the Customs field officer's ability to take into account the presence of mitigating factors when considering the issuance of a section 592 prepenalty notice. The commenter believes that this may be an unproductive use of the field officer's time and appears to be premature since the necessary information from the alleged violator has not yet been received.

The commenter also questions the need for sending ''information copies'' of section 592(d) demands to sureties in all cases except in those cases where less than a year remains under the statute of limitations. In the commenter's view, this can be a time-consuming task for Customs field officers where there are many entries and multiple sureties. The commenter also would like the ''shortened response times'' discussed in proposed section (E) made applicable to section 592(d) demands.

Finally, this commenter suggests that the ''arriving travelers'' section be re-lettered and moved closer in location to the section involving liability for penalties so that the Customs officer, in a rushed situation, will not miss the section on arriving travelers because the officer did not read far enough along in the guidelines.

Customs Response: With respect to the first suggestion, Customs notes that the proposed guidelines set forth that the field officer consider whether mitigating factors are *present* at the pre-penalty stage regardless of the level of culpability. Customs is not instructing the field officer at the pre-penalty stage of the proceedings to manufacture mitigating factors or speculate regarding their existence, but rather is attempting to promote development of realistic initial penalty assessments commensurate with the level of available evidence.

With respect to the commenter's concern involving the need for furnishing information copies of section 592(d) demands to sureties, Customs believes that in view of statute of limitations concerns associated with section 592(d) demands, and in order to assist sureties in tracking contingent liabilities, the benefits derived from such practice for both the government and the sureties outweighs any administrative burden imposed upon the Customs field office. Also, inasmuch as the Customs regulations do not provide for a shortened response time in connection with section 592(d) demands, the commenter's recommendation is rejected.

Lastly, to reduce the likelihood of the problem discussed in the commenter's last recommendation, we have added a sentence to the end of proposed section (E)(1)(a) to direct parties to the special assessments and dispositions section in cases involving arriving travelers.

Conclusion

Accordingly, based on the comments received and the analysis of those comments as set forth above, and after further review of this matter, Customs believes that the proposed revised guidelines should be adopted with the changes discussed above. Certain other clarifying changes are made as well.

Regulatory Flexibility Act

Because this revision of the guidelines relates to rules of agency procedure and policy, and no notice of proposed rulemaking was required pursuant to 5 U.S.C. 553, the document is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Executive Order 12866

Because the document is not regulatory in nature, but merely serves to inform the public about certain agency procedures and practices, the revised guidelines do not meet the criteria for a ''significant regulatory action'' under E.O. 12866.

List of Subjects in 19 CFR Part 171

Customs duties and inspection, Law enforcement, Penalties, Seizures and forfeitures.

Amendment to the Regulations

Part 171 of the Customs Regulations (19 CFR part 171) is amended as set forth below:

PART 171—FINES, PENALTIES, AND FORFEITURES

1. The general authority citation for Part 171 continues to read as follows:

Authority: 19 U.S.C. 66, 1592, 1618, 1624. The provisions of subpart C also issued under 22 U.S.C. 401; 46 U.S.C. App. 320 unless otherwise noted.

2. Appendix B to Part 171 is revised to read as follows:

Appendix B to Part 171—Customs Regulations, Guidelines for the Imposition and Mitigation of Penalties for Violations of 19 U.S.C. 1592

A monetary penalty incurred under section 592 of the Tariff Act of 1930, as amended (19 U.S.C. 1592; hereinafter referred to as section 592) may be remitted or mitigated under section 618 of the Tariff Act of 1930, as amended (19 U.S.C. 1618), if it is determined that there are mitigating circumstances to justify remission or mitigation. The guidelines below will be used by the Customs Service in arriving at a just and reasonable assessment and disposition of liabilities arising under section 592 within the stated limitations. It is intended that these guidelines shall be applied by Customs officers in pre-penalty proceedings and in determining the monetary penalty assessed in any penalty notice. The assessed penalty or penalty amount set forth in Customs administrative disposition determined in accordance with these guidelines does not limit the penalty amount which the Government may seek in bringing a civil enforcement action pursuant to section 592(e). It should be understood that any mitigated penalty is conditioned upon payment of any actual loss of duty as well as a release by the party that indicates that the mitigation decision constitutes full accord and satisfaction. Further, mitigation decisions are not rulings within the meaning of part 177 of the Customs Regulations (19 CFR part 177). Lastly, these guidelines may supplement, and are not intended to preclude application of, any other special guidelines promulgated by Customs.

(A) Violations of Section 592

Without regard to whether the United States is or may be deprived of all or a portion of any lawful duty, tax or fee thereby, a violation of section 592 occurs when a person, through fraud, gross negligence, or negligence, enters, introduces, or attempts to enter or introduce any merchandise into the commerce of the United States by means of any document, electronic transmission of data or information, written or oral statement, or act that is material and false, or any omission that is material; or when a person aids or abets any other person in the entry, introduction, or attempted entry or introduction of merchandise by such means. It should be noted that the language ''entry, introduction, or attempted entry or introduction'' encompasses placing merchandise in-bond (*e.g.,* filing an immediate transportation application). There is no violation if the falsity or omission is due solely to clerical error or mistake of fact, unless the error or mistake is part of a pattern of negligent conduct. Also, the unintentional repetition by an electronic system of an initial clerical error generally will not constitute a pattern of negligent conduct. Nevertheless, if Customs has drawn the party's attention to the unintentional repetition by an electronic system of an initial clerical error, subsequent failure to correct the error could constitute a violation of section 592. Also, the unintentional repetition of a clerical mistake over a significant period of time or involving many entries could indicate a pattern of negligent conduct and a failure to exercise reasonable care.

(B) Definition of Materiality Under Section 592

A document, statement, act, or omission is material if it has the natural tendency to

influence or is capable of influencing agency action including, but not limited to a Customs action regarding: (1) Determination of the classification, appraisement, or admissibility of merchandise (*e.g.,* whether merchandise is prohibited or restricted); (2) determination of an importer's liability for duty (including marking, antidumping, and/or countervailing duty); (3) collection and reporting of accurate trade statistics; (4) determination as to the source, origin, or quality of merchandise; (5) determination of whether an unfair trade practice has been committed under the anti-dumping or countervailing duty laws or a similar statute; (6) determination of whether an unfair act has been committed involving patent, trademark, or copyright infringement; or (7) the determination of whether any other unfair trade practice has been committed in violation of federal law. The ''but for'' test of materiality is inapplicable under section 592.

(C) Degrees of Culpability Under Section 592

The three degrees of culpability under section 592 for the purposes of administrative proceedings are:

(1) *Negligence.* A violation is determined to be negligent if it results from an act or acts (of commission or omission) done through either the failure to exercise the degree of reasonable care and competence expected from a person in the same circumstances either: (a) in ascertaining the facts or in drawing inferences therefrom, in ascertaining the offender's obligations under the statute; or (b) in communicating information in a manner so that it may be understood by the recipient. As a general rule, a violation is negligent if it results from failure to exercise reasonable care and competence: (a) to ensure that statements made and information provided in connection with the importation of merchandise are complete and accurate; or (b) to perform any material act required by statute or regulation.

(2) *Gross Negligence.* A violation is deemed to be grossly negligent if it results from an act or acts (of commission or omission) done with actual knowledge of or wanton disregard for the relevant facts and with indifference to or disregard for the offender's obligations under the statute.

(3) *Fraud.* A violation is determined to be fraudulent if a material false statement, omission, or act in connection with the transaction was committed (or omitted) knowingly, *i.e.,* was done voluntarily and intentionally, as established by clear and convincing evidence.

(D) Discussion of Additional Terms

(1) *Duty Loss Violations.* A section 592 duty loss violation involves those cases where there has been a loss of duty including any marking, anti-dumping, or countervailing duties, or any tax and fee (*e.g.,* merchandise processing and/or harbor maintenance fees) attributable to an alleged violation.

(2) *Non-duty Loss Violations.* A section 592 non-duty loss violation involves cases where the record indicates that an alleged violation is principally attributable to, for example, evasion of a prohibition, restriction, or other non-duty related consideration involving the importation of the merchandise.

(3) *Actual Loss of Duties.* An actual loss of duty occurs where there is a loss of duty including any marking, anti-dumping, or countervailing duties, or any tax and fee (*e.g.,* merchandise processing and/or harbor maintenance fees) attributable to a liquidated Customs entry, and the merchandise covered by the entry has been entered or introduced (or attempted to be entered or introduced) in violation of section 592.

(4) *Potential Loss of Duties.* A potential loss of duty occurs where an entry remains unliquidated and there is a loss of duty, including any marking, anti-dumping or countervailing duties or any tax and fee (*e.g.,* merchandise processing and/or harbor maintenance fees) attributable to a violation of section 592, but the violation was discovered prior to liquidation. In addition, a potential loss of duty exists where Customs discovers the violation and corrects the entry to reflect liquidation at the proper classification and value. In other words, the potential loss in such cases equals the amount of duty, tax and fee that would have occurred had Customs not discovered the violation prior to liquidation and taken steps to correct the entry.

(5) *Total Loss of Duty.* The total loss of duty is the sum of any actual and potential loss of duty attributable to alleged violations of section 592 in a particular case. Payment of any actual and/or potential loss of duty shall not affect or reduce the total loss of duty used for assessing penalties as set forth in these guidelines. The ''multiples'' set forth below in paragraph (F)(2) involving assessment and disposition of cases shall utilize the ''total loss of duty'' amount in arriving at the appropriate assessment or disposition.

(6) *Reasonable Care.* General Standard: All parties, including importers of record or their agents, are required to exercise reasonable care in fulfilling their responsibilities involving entry of merchandise. These responsibilities include, but are not limited to: providing a classification and value for the merchandise; furnishing information sufficient to permit Customs to determine the final classification and valuation of merchandise; taking measures that will lead to and assure the preparation of accurate documentation, and determining whether any applicable requirements of law with respect to these issues are met. In addition, all parties, including the importer, must use reasonable care to provide accurate information or documentation to enable Customs to determine if the merchandise may be released. Customs may consider an importer's failure to follow a binding Customs ruling a lack of reasonable care. In addition, unreasonable classification will be considered a lack of reasonable care (*e.g.,* imported snow skis are classified as water skis). Failure to exercise reasonable care in connection with the importation of merchandise may result in imposition of a section 592 penalty for fraud, gross negligence or negligence.

(7) *Clerical Error.* A clerical error is an error in the preparation, assembly or submission of import documentation or information provided to Customs that results from a mistake in arithmetic or transcription that is not part of a pattern of negligence. The mere non-intentional repetition by an electronic system of an initial clerical error does not constitute a pattern of negligence. Nevertheless, as stated earlier, if Customs has drawn a party's attention to the non-intentional repetition by an electronic system of an initial clerical error, subsequent failure to correct the error could constitute a violation of section 592. Also, the unintentional repetition of a clerical mistake over a significant period of time or involving many entries could indicate a pattern of negligent conduct and a failure to exercise reasonable care.

(8) *Mistake of Fact.* A mistake of fact is a false statement or omission that is based on a bona fide erroneous belief as to the facts, so long as the belief itself did not result from negligence in ascertaining the accuracy of the facts.

(E) Penalty Assessment

(1) *Case Initiation—Pre-penalty Notice.*

(a) *Generally.* As provided in § 162.77, Customs Regulations (19 CFR 162.77), if the appropriate Customs field officer has reasonable cause to believe that a violation of section 592 has occurred and determines that further proceedings are warranted, the Customs field officer will issue to each person concerned a notice of intent to issue a claim for a monetary penalty (*i.e.,* the ''pre-penalty notice''). In issuing such a pre-penalty notice, the Customs field officer will make a tentative determination of the degree of culpability and the amount of the proposed claim. Payment of any actual and/or potential loss of duty will not affect or reduce the total loss of duty used for assessing penalties as set forth in these guidelines. The ''multiples'' set forth in paragraphs (F)(2)(a)(i), (b)(i) and (c)(i) involving assessment and disposition of duty loss violation cases will use the amount of total loss of duty in arriving at the appropriate assessment or disposition. Further, where separate duty loss and non-duty loss violations occur on the same entry, it is within the Customs field officer's discretion to assess both duty loss and non-duty loss penalties, or only one of them. Where only one of the penalties is assessed, the Customs field officer has the discretion to select which penalty (duty loss or non-duty loss) shall be assessed. Also, where there is a violation accompanied by an incidental or nominal loss of duties, the Customs field officer may assess a non-duty loss penalty where the incidental or nominal duty loss resulted from a separate non-duty loss violation. The Customs field officer will propose a level of culpability in the pre-penalty notice that conforms to the level of culpability suggested by the evidence at the time of issuance. Moreover, the pre-penalty notice will include a statement that it is Customs practice to base its actions on the earliest point in time that the statute of limitations may be asserted (*i.e.,* the date of occurrence of the alleged violation) inasmuch as the final resolution of a case in court may be less than a finding of fraud. A pre-penalty notice that is issued to a party in a case where Customs determines a claimed prior disclosure is not valid—owing to the

disclosing party's knowledge of the commencement of a formal investigation of a disclosed violation—will include a copy of a written document that evidences the commencement of a formal investigation. In addition, a pre-penalty notice is not required if a violation involves a non-commercial importation or if the proposed claim does not exceed $1,000. Special guidelines relating to penalty assessment and dispositions involving ''Arriving Travelers,'' are set forth in section (L) below.

(b) *Pre-penalty Notice—Proposed Claim Amount*

(i) *Fraud.* In general, if a violation is determined to be the result of fraud, the proposed claim ordinarily will be assessed in an amount equal to the domestic value of the merchandise. Exceptions to assessing the penalty at the domestic value may be warranted in unusual circumstances such as a case where the domestic value of the merchandise is disproportionately high in comparison to the loss of duty attributable to an alleged violation (*e.g.,* a total loss of duty of $10,000 involving 10 entries with a total domestic value of $2,000,000). Also, it is incumbent upon the appropriate Customs field officer to consider whether mitigating factors are present warranting a reduction in the customary domestic value assessment. In all section 592 cases of this nature regardless of the dollar amount of the proposed claim, the Customs field officer will obtain the approval of the Penalties Branch at Headquarters prior to issuance of a pre-penalty notice at an amount less than domestic value.

(ii) *Gross Negligence and Negligence.* In determining the amount of the proposed claim in cases involving gross negligence and negligence, the appropriate Customs field officer will take into account the gravity of the offense, the amount of loss of duty, the extent of wrongdoing, mitigating or aggravating factors, and other factors bearing upon the seriousness of a violation, but in no case will the assessed penalty exceed the statutory ceilings prescribed in section 592. In cases involving gross negligence and negligence, penalties equivalent to the ceilings stated in paragraphs (F)(2)(b) and (c) regarding disposition of cases may be appropriate in cases involving serious violations, *e.g.,* violations involving a high loss of duty or significant evasion of import prohibitions or restrictions. A ''serious'' violation need not result in a loss of duty. The violation may be serious because it affects the admissibility of merchandise or the enforcement of other laws, as in the case of quota evasions, false statements made to conceal the dumping of merchandise, or violations of exclusionary orders of the International Trade Commission.

(c) *Technical Violations.* Violations where the loss of duty is nonexistent or minimal and/or that have an insignificant impact on enforcement of the laws of the United States may justify a proposed penalty in a fixed amount not related to the value of merchandise, but an amount believed sufficient to have a deterrent effect: *e.g.,* violations involving the subsequent sale of merchandise or vehicles entered for personal use; violations involving failure to comply with declaration or entry requirements that do not change the admissibility or entry status of merchandise or its appraised value or classification; violations involving the illegal diversion to domestic use of instruments of international traffic; and local point-to-point traffic violations. Generally, a penalty in a fixed amount ranging from $1,000 to $2,000 is appropriate in cases where there are no prior violations of the same kind. However, fixed sums ranging from $2,000 to $10,000 may be appropriate in the case of multiple or repeated violations. Fixed sum penalty amounts are not subject to further mitigation and may not exceed the maximum amounts stated in section 592 and in these guidelines.

(d) *Statute of Limitations Considerations—Waivers.* Prior to issuance of any section 592 pre-penalty notice, the appropriate Customs field officer will calculate the statute of limitations attributable to an alleged violation. Inasmuch as section 592 cases are reviewed de novo by the Court of International Trade, the statute of limitations calculation in cases alleging fraud should assume a level of culpability of gross negligence or negligence, *i.e.,* ordinarily applying a shorter period of time for statute of limitations purposes. In accordance with section 162.78 of the Customs Regulations (19 CFR 162.78), if less than 1 year remains before the statute of limitations may be raised as a defense, a shortened response time may be specified in the notice—but in no case, less than 7 business days from the date of mailing. In cases of shortened response times, the Customs field officer should notify alleged violators by telephone and use all reasonable means (*e.g.,* facsimile transmission of a copy of the notice) to expedite receipt of the notice by the alleged violators. Also in such cases, the appropriate Customs field officer should advise the alleged violator that additional time to respond to the pre-penalty notice will be granted only if an acceptable waiver of the statute of limitations is submitted to Customs. With regard to waivers of the statute of limitations, it is Customs practice to request waivers concurrently both from all potential alleged violators and their sureties.

(2) *Closure of Case or Issuance of Penalty Notice.*

(a) *Case Closure.* The appropriate Customs field officer may find, after consideration of the record in the case, including any pre-penalty response/oral presentation, that issuance of a penalty notice is not warranted. In such cases, the Customs field officer will provide written notification to the alleged violator who received the subject pre-penalty notice that the case is closed.

(b) *Issuance of Penalty Notice.* In the event that circumstances warrant issuance of a notice of penalty pursuant to § 162.79 of the Customs Regulations (19 CFR 162.79), the appropriate Customs field officer will give consideration to all available evidence with respect to the existence of material false statements or omissions (including evidence presented by an alleged violator), the degree of culpability, the existence of a prior disclosure, the seriousness of the violation, and the existence of mitigating or aggravating factors. In cases involving fraud, the penalty notice will be in the amount of the domestic value of the merchandise unless a lesser amount is warranted as described in paragraph (E)(1)(b)(i). In general, the degree of culpability or proposed penalty amount stated in a pre-penalty notice will not be increased in the penalty notice. If, subsequent to the issuance of a pre-penalty notice and upon further review of the record, the appropriate Customs field officer determines that a higher degree of culpability exists, the original pre-penalty notice should be rescinded and a new pre-penalty notice issued that indicates the higher degree of culpability and increased proposed penalty amount. However, if less than 9 months remain before expiration of the statute of limitations or any waiver thereof by the party named in the pre-penalty notice, the higher degree of culpability and higher penalty amount may be indicated in the notice of penalty without rescinding the earlier pre-penalty notice. In such cases, the Customs field officer will consider whether a lower degree of culpability is appropriate or whether to change the information contained in the pre-penalty notice.

(c) *Statute of Limitations Considerations.* Prior to issuance of any section 592 penalty notice, the appropriate Customs field officer again shall calculate the statute of limitations attributable to the alleged violation and request a waiver(s) of the statute, if necessary. In accordance with part 171 of the Customs Regulations (19 CFR part 171), if less than 180 days remain before the statute of limitations may be raised as a defense, a shortened response time may be specified in the notice—but in no case less than 7 business days from the date of mailing. In such cases, the Customs field officer should notify an alleged violator by telephone and use all reasonable means (*e.g.,* facsimile transmission of a copy) to expedite receipt of the penalty notice by the alleged violator. Also, in such cases, the Customs field officer should advise an alleged violator that, if an acceptable waiver of the statute of limitations is provided, additional time to respond to the penalty notice may be granted.

(F) Administrative Penalty Disposition

(1) *Generally.* It is the policy of the Department of the Treasury and the Customs Service to grant mitigation in appropriate circumstances. In certain cases, based upon criteria to be developed by Customs, mitigation may take an alternative form, whereby a violator may eliminate or reduce his or her section 592 penalty liability by taking action(s) to correct problems that caused the violation. In any case, in determining the administrative section 592 penalty disposition, the appropriate Customs field officer will consider the entire case record—taking into account the presence of any mitigating or aggravating factors. All such factors should be set forth in the written administrative section 592 penalty decision. Once again, Customs emphasizes that any penalty liability which is mitigated is conditioned upon payment of any actual loss of duty in addition to that penalty as well as a release by the party that indicates that the mitigation decision constitutes full accord and satisfaction. Finally, section 592 penalty

dispositions in duty-loss and non-duty-loss cases will proceed in the manner set forth below.

(2) *Dispositions.*

(a) *Fraudulent Violation.* Penalty dispositions for a fraudulent violation will be calculated as follows:

(i) *Duty Loss Violation.* An amount ranging from a minimum of 5 times the total loss of duty to a maximum of 8 times the total loss of duty—but in any such case the amount may not exceed the domestic value of the merchandise. A penalty disposition greater than 8 times the total loss of duty may be imposed in a case involving an egregious violation, or a public health and safety violation, or due to the presence of aggravating factors, but again, the amount may not exceed the domestic value of the merchandise.

(ii) *Non-Duty Loss Violation.* An amount ranging from a minimum of 50 percent of the dutiable value to a maximum of 80 percent of the dutiable value of the merchandise. A penalty disposition greater than 80 percent of the dutiable value may be imposed in a case involving an egregious violation, or a public health and safety violation, or due to the presence of aggravating factors, but the amount may not exceed the domestic value of the merchandise.

(b) *Grossly Negligent Violation.* Penalty dispositions for a grossly negligent violation shall be calculated as follows:

(i) *Duty Loss Violation.* An amount ranging from a minimum of 2.5 times the total loss of duty to a maximum of 4 times the total loss of duty—but in any such case, the amount may not exceed the domestic value of the merchandise.

(ii) *Non-Duty Loss Violation.* An amount ranging from a minimum of 25 percent of the dutiable value to a maximum of 40 percent of the dutiable value of the merchandise—but in any such case, the amount may not exceed the domestic value of the merchandise.

(c) *Negligent Violation.* Penalty dispositions for a negligent violation shall be calculated as follows:

(i) *Duty Loss Violation.* An amount ranging from a minimum of 0.5 times the total loss of duty to a maximum of 2 times the total loss of duty but, in any such case, the amount may not exceed the domestic value of the merchandise.

(ii) *Non-Duty Loss Violation.* An amount ranging from a minimum of 5 percent of the dutiable value to a maximum of 20 percent of the dutiable value of the merchandise, but, in any such case, the amount may not exceed the domestic value of the merchandise.

(d) *Authority to Cancel Claim.* Upon issuance of a penalty notice, Customs has set forth its formal monetary penalty claim. Except as provided in 19 CFR part 171, in those section 592 cases within the administrative jurisdiction of the concerned Customs field office, the appropriate Customs field officer will cancel any such formal claim whenever it is determined that an essential element of the alleged violation is not established by the agency record, including pre-penalty and penalty responses provided by the alleged violator. Except as provided in 19 CFR part 171, in those section 592 cases within Customs Headquarters jurisdiction, the appropriate Customs field officer will cancel any such formal claim whenever it is determined that an essential element of the alleged violation is not established by the agency record, and such cancellation action precedes the date of the Customs field officer's receipt of the alleged violator's petition responding to the penalty notice. On and after the date of Customs receipt of the petition responding to the penalty notice, jurisdiction over the action rests with Customs Headquarters including the authority to cancel the claim.

(e) *Remission of Claim.* If the Customs field officer believes that a claim for monetary penalty should be remitted for a reason not set forth in these guidelines, the Customs field officer should first seek approval from the Chief, Penalties Branch, Customs Service Headquarters.

(f) *Prior Disclosure Dispositions.* It is the policy of the Department of the Treasury and the Customs Service to encourage the submission of valid prior disclosures that comport with the laws, regulations, and policies governing this provision of section 592. Customs will determine the validity of the prior disclosure including whether or not the prior disclosure sets forth all the required elements of a violation of section 592. A valid prior disclosure warrants the imposition of the reduced Customs civil penalties set forth below:

(1) *Fraudulent Violation.*

(a) *Duty Loss Violation.* The claim for monetary penalty shall be equal to 100 percent of the total loss of duty (*i.e.*, actual + potential) resulting from the violation. No mitigation will be afforded.

(b) *Non-Duty Loss Violation.* The claim for monetary penalty shall be equal to 10 percent of the dutiable value of the merchandise in question. No mitigation will be afforded.

(2) *Gross Negligence and Negligence Violation.*

(a) *Duty Loss Violation.* The claim for monetary penalty shall be equal to the interest on the actual loss of duty computed from the date of liquidation to the date of the party's tender of the actual loss of duty resulting from the violation. Customs notes that there is no monetary penalty in these cases if the duty loss is potential in nature. Absent extraordinary circumstances, no mitigation will be afforded.

(b) *Non-Duty Loss Violation.* There is no monetary penalty in such cases and any claim for monetary penalty which had been issued prior to the decision granting prior disclosure will be remitted in full.

(G) Mitigating Factors

The following factors will be considered in mitigation of the proposed or assessed penalty claim or the amount of the administrative penalty decision, provided that the case record sufficiently establishes their existence. The list is not all-inclusive.

(1) *Contributory Customs Error.* This factor includes misleading or erroneous advice given by a Customs official *in writing* to the alleged violator, or established by a contemporaneously created written Customs record, only if it appears that the alleged violator reasonably relied upon the information and the alleged violator fully and accurately informed Customs of all relevant facts. The concept of comparative negligence may be utilized in determining the weight to be assigned to this factor. If it is determined that the Customs error was the sole cause of the violation, the proposed or assessed penalty claim shall be canceled. If the Customs error contributed to the violation, but the violator also is culpable, the Customs error will be considered as a mitigating factor.

(2) *Cooperation with the Investigation.* To obtain the benefits of this factor, the violator must exhibit extraordinary cooperation beyond that expected from a person under investigation for a Customs violation. Some examples of the cooperation contemplated include assisting Customs officers to an unusual degree in auditing the books and records of the violator (*e.g.*, incurring extraordinary expenses in providing computer runs solely for submission to Customs to assist the agency in cases involving an unusually large number of entries and/or complex issues). Another example consists of assisting Customs in obtaining additional information relating to the subject violation or other violations. Merely providing the books and records of the violator should not be considered cooperation justifying mitigation inasmuch as Customs has the right to examine an importer's books and records pursuant to 19 U.S.C. 1508–1509.

(3) *Immediate Remedial Action.* This factor includes the payment of the actual loss of duty prior to the issuance of a penalty notice and within 30 days after Customs notifies the alleged violator of the actual loss of duties attributable to the alleged violation. In appropriate cases, where the violator provides evidence that immediately after learning of the violation, substantial remedial action was taken to correct organizational or procedural defects, immediate remedial action may be granted as a mitigating factor. Customs encourages immediate remedial action to ensure against future incidents of non-compliance.

(4) *Inexperience in Importing.* Inexperience is a factor only if it contributes to the violation and the violation is not due to fraud or gross negligence.

(5) *Prior Good Record.* Prior good record is a factor only if the alleged violator is able to demonstrate a consistent pattern of importations without violation of section 592, or any other statute prohibiting false or fraudulent importation practices. This factor will not be considered in alleged fraudulent violations of section 592.

(6) *Inability to Pay the Customs Penalty.* The party claiming the existence of this factor must present documentary evidence in support thereof, including copies of income tax returns for the previous 3 years, and an audited financial statement for the most recent fiscal quarter. In certain cases, Customs may waive the production of an audited financial statement or may request alternative or additional financial data in order to facilitate an analysis of a claim of inability to pay (*e.g.,* examination of the financial records of a foreign entity related to the U.S. company claiming inability to pay).

(7) *Customs Knowledge.* Additional relief in non-fraud cases (which also are not the

subject of a criminal investigation) will be granted if it is determined that Customs had actual knowledge of a violation and, without justification, failed to inform the violator so that it could have taken earlier corrective action. In such cases, if a penalty is to be assessed involving repeated violations of the same kind, the maximum penalty amount for violations occurring after the date on which actual knowledge was obtained by Customs will be limited to two times the loss of duty in duty-loss cases or twenty percent of the dutiable value in non-duty-loss cases if the continuing violations were the result of gross negligence, or the lesser of one time the loss of duty in duty-loss cases or ten percent of dutiable value in non-duty-loss cases if the violations were the result of negligence. This factor will not be applicable when a substantial delay in the investigation is attributable to the alleged violator.

(H) Aggravating Factors

Certain factors may be determined to be aggravating factors in calculating the amount of the proposed or assessed penalty claim or the amount of the administrative penalty decision. The presence of one or more aggravating factors may not be used to raise the level of culpability attributable to the alleged violations, but may be utilized to offset the presence of mitigating factors. The following factors will be considered ''aggravating factors,'' provided that the case record sufficiently establishes their existence. The list is not exclusive.

(1) Obstructing an investigation or audit,

(2) Withholding evidence,

(3) Providing misleading information concerning the violation,

(4) Prior substantive violations of section 592 for which a final administrative finding of culpability has been made,

(5) Textile imports that have been the subject of illegal transshipment (*i.e.*, false country of origin declaration), whether or not the merchandise bears false country of origin markings,

(6) Evidence of a motive to evade a prohibition or restriction on the admissibility of the merchandise (*e.g.*, evading a quota restriction),

(7) Failure to comply with a lawful demand for records or a Customs summons.

(I) Offers in Compromise (''Settlement Offers'')

Parties who wish to submit a civil offer in compromise pursuant to 19 U.S.C. 1617 (also known as a ''settlement offer'') in connection with any section 592 claim or potential section 592 claim should follow the procedures outlined in § 161.5 of the Customs Regulations (19 CFR 161.5). Settlement offers do not involve ''mitigation'' of a claim or potential claim, but rather ''compromise'' an action or potential action where Customs evaluation of potential litigation risks, or the alleged violator's financial position, justifies such a disposition. In any case where a portion of the offered amount represents a tender of unpaid duties, taxes and fees, Customs letter of acceptance may identify the portion representing any such duty, tax and fee. The offered amount should be deposited at the Customs field office responsible for handling the section 592 claim or potential section 592 claim. The offered amount will be held in a suspense account pending acceptance or rejection of the offer in compromise. In the event the offer is rejected, the concerned Customs field office will promptly initiate a refund of the money deposited in the suspense account to the offeror.

(J) Section 592(d) Demands

Section 592(d) demands for actual losses of duty ordinarily are issued in connection with a penalty action, or as a separate demand without an associated penalty action. In either case, information must be present establishing a violation of section 592(a). In those cases where the appropriate Customs field officer determines that issuance of a penalty under section 592 is not warranted (notwithstanding the presence of information establishing a violation of section 592(a)), but that circumstances do warrant issuance of a demand for payment of an actual loss of duty pursuant to section 592(d), the Customs field officer shall follow the procedures set forth in section 162.79b of the Customs Regulations (19 CFR 162.79b). Except in cases where less than one year remains before the statute of limitations may be raised as a defense, information copies of all section 592(d) demands should be sent to all concerned sureties and the importer of record if such party is not an alleged violator. Also, except in cases where less than one year remains before the statute of limitations may be raised as a defense, Customs will endeavor to issue all section 592(d) demands to concerned sureties and non-violator importers of record only after default by principals.

(K) Customs Brokers

If a customs broker commits a section 592 violation and the violation involves fraud, or the broker commits a grossly negligent or negligent violation and shares in the benefits of the violation to an extent over and above customary brokerage fees, the customs broker will be subject to these guidelines. However, if the customs broker commits either a grossly negligent or negligent violation of section 592 (without sharing in the benefits of the violation as described above), the concerned Customs field officer may proceed against the customs broker pursuant to the remedies provided under 19 U.S.C. 1641.

(L) Arriving Travelers

(1) *Liability.* Except as set forth below, proposed and assessed penalties for violations by an arriving traveler must be determined in accordance with these guidelines.

(2) *Limitations on Liability on Non-commercial Violations.* In the absence of a referral for criminal prosecution, monetary penalties assessed in the case of an alleged first-offense, non-commercial, fraudulent violation by an arriving traveler will generally be limited as follows:

(a) *Fraud—Duty Loss Violation.* An amount ranging from a minimum of three times the loss of duty to a maximum of five times the loss of duty, provided the loss of duty is also paid;

(b) *Fraud—Non-duty Loss Violation.* An amount ranging from a minimum of 30 percent of the dutiable value of the merchandise to a maximum of 50 percent of its dutiable value;

(c) *Gross Negligence—Duty Loss Violation.* An amount ranging from a minimum of 1.5 times the loss of duty to a maximum of 2.5 times the loss of duty provided the loss of duty is also paid;

(d) *Gross Negligence—Non-duty Loss Violation.* An amount ranging from a minimum of 15 percent of the dutiable value of the merchandise to a maximum of 25 percent of its dutiable value;

(e) *Negligence—Duty Loss Violation.* An amount ranging from a minimum of .25 times the loss of duty to a maximum of 1.25 times the loss of duty provided that the loss of duty is also paid;

(f) *Negligence—Non-duty Loss Violation.* An amount ranging from a minimum of 2.5 percent of the dutiable value of the merchandise to a maximum of 12.5 percent of its dutiable value;

(g) *Special Assessments/Dispositions.* No penalty action under section 592 will be initiated against an arriving traveler if the violation is not fraudulent or commercial, the loss of duty is $100.00 or less, and there are no other concurrent or prior violations of section 592 or other statutes prohibiting false or fraudulent importation practices. However, all lawful duties, taxes and fees will be collected. Also, no penalty under section 592 will be initiated against an arriving traveler if the violation is not fraudulent or commercial, there are no other concurrent or prior violations of section 592, and a penalty is not believed necessary to deter future violations or to serve a law enforcement purpose.

(M) Violations of Laws Administered by Other Federal Agencies.

Violations of laws administered by other federal agencies (such as the Food and Drug Administration, Consumer Product Safety Commission, Office of Foreign Assets Control, Department of Agriculture, Fish and Wildlife Service) should be referred to the appropriate agency for its recommendation. Such recommendation, if promptly tendered, will be given due consideration, and may be followed provided the recommendation would not result in a disposition inconsistent with these guidelines.

(N) Section 592 Violations by Small Entities

In compliance with the mandate of the Small Business Regulatory Enforcement Fairness Act of 1996, under appropriate circumstances, the issuance of a penalty under section 592 may be waived for businesses qualifying as small business entities.

Procedures established for small business entities regarding violations of 19 U.S.C. 1592 were published as Treasury Decision

97–46 in the **Federal Register** (62 FR 30378) on June 3, 1997.

Raymond W. Kelly,

Commissioner of Customs.

Approved: June 19, 2000.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 00–15874 Filed 6–22–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 00P–1117]

Medical Devices; Anesthesiology Devices; Classification of Devices to Relieve Upper Airway Obstruction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying devices to relieve upper airway obstruction into class II (special controls). The special control that will apply to this device is a labeling and design control guidance document. This action is being taken in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). The agency is classifying this device into class II in order to provide a reasonable assurance of the safety and effectiveness of the device.

DATES: This rule is effective July 24, 2000.

FOR FURTHER INFORMATION CONTACT: Carroll O'Neill, Center for Devices and Radiological Health (CDRH) (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8262, ext. 170.

SUPPLEMENTARY INFORMATION:

I. Background

The act, as amended by the amendments (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(f)(1) of the act, devices that were not in commercial distribution before May 28, 1976, the date of enactment of the amendments, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or class II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the FDA regulations (21 CFR part 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on December 29, 1999, classifying the Quickair Choke Reliever, Model 59–001A in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On December 20, 1999, FDA filed a petition from Maet, Industries, Inc., requesting classification of the device into class II under section 513(f)(2) of the act.

After review of the information submitted in the petition, FDA determined that the Quickair Choke Reliever, Model 59–001A can be classified in class II with the establishment of special controls. FDA believes that class II special controls, in addition to the general controls, provide reasonable assurance of the safety and effectiveness of the device. On February 29, 2000, FDA issued an order to the petitioner classifying the Quickair Choke Reliever, Model 59–001A, and substantially equivalent devices of this generic type into class II under the generic name, ''Devices to relieve upper airway acute obstruction.'' In addition to the general controls of the act, the Quickair Choke Reliever, Model 59–001A is subject to the following special control: ''Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices.'' The guidance document covers:

(1) Labeling that includes instructions for reporting complications resulting from the use of the device directly to the manufacturer, as well as any applicable medical device reporting requirements (21 CFR part 803).

(2) Labeling for the lay user that includes adequate instructions for use including: (a) A clear identification of the minimum victim size threshold (weight), as well as any device-specific limitations identified through application of design controls, and (b) instructions for use of the Heimlich maneuver.

(3) Design controls that satisfactorily evaluate:

(a) The potential for excessive generation and application of pressure to the abdomen that can result in damage to the internal organs;

(b) The generated pressures and their distributions over the abdomen as compared to the Heimlich maneuver in a variety of victim sizes and user strengths;

(c) The initial and peak airway pressures and the duration of pressure application of the device as compared to the Heimlich maneuver;

(d) Bench testing to include static load, mechanical shock, fatigue and intra-abdominal pressure simulation; and

(e) Human factors testing to demonstrate that the lay user is able to understand and follow the device instructions for use with respect to device placement and applied force. The testing should include a range of rescuer's sizes, ages and educational levels, as well as an appropriate range of victim size and position.

In order to receive the document entitled ''Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381