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Acting Commissioner of Customs.

Approved: August 31, 1998.

John P. Simpson,
Deputy Assistant Secretary of the Treasury.
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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 133

[T.D. 98-75]

RIN 1515-AC10

Anticounterfeiting Consumer Protection Act: Disposition of Merchandise Bearing Counterfeit American Trademarks; Civil Penalties

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations by adopting final rules to implement two statutory changes contained in the Anticounterfeiting Consumer Protection Act of 1996 (ACPA) enacted by Congress to protect consumers and American businesses from counterfeit copyrighted and trademarked products. This document addresses the public comments submitted in response to the interim regulations which initially implemented these counterfeiting provisions, and makes certain changes to those interim regulations in response to the public comments and in order to add clarity and improve the readability of the final regulations.

EFFECTIVE DATE: October 26, 1998.

FOR FURTHER INFORMATION CONTACT:
For Entry Questions—Jerry Laderberg, Entry and Carrier Rulings Branch, (202) 927-2320, Office of Regulations and Rulings;
For Penalties and other legal Questions—Charles Ressin, Penalties Branch, (202) 927-2344, or John Atwood, Intellectual Property Rights Branch, (202) 927-2330, Office of Regulations and Rulings.

SUPPLEMENTARY INFORMATION:

Background

Finding that counterfeit products cost American businesses an estimated \$200 billion each year worldwide, Congress enacted the Anticounterfeiting Consumer Protection Act of 1996 (ACPA) to make sure that Federal law adequately addresses the scope and sophistication of modern counterfeiting. See, S.Rpt.No. 177, 104th Cong., 1st Sess. (1995), *reprinted in* (1996) 4

U.S.C.C.&A.N. 1074. On July 2, 1996, the President signed the ACPA into law (Pub.L. 104-153, 110 Stat. 1386). The ACPA was designed to provide important weapons against counterfeiters in four principal areas. First, it increases criminal penalties for counterfeiting and allows law enforcement to fight counterfeiters at the organizational level by making trafficking in counterfeit goods or services an offense under the Racketeer Influenced and Corrupt Organizations (RICO) Act, by providing increased imprisonment terms, criminal fines, and asset forfeiture against those involved in criminal counterfeiting enterprises. Second, the legislation enhances law enforcement's ability to fight counterfeiting more effectively by increasing the involvement of all levels of law enforcement and expanding their power to seize counterfeit goods and the tools of the counterfeit trade. Third, the legislation helps stem the flow of counterfeit goods by making it easier to find imported counterfeit goods and making it more difficult for seized goods to reenter the stream of commerce. Lastly, the ACPA, in part, strengthens the hand of businesses harmed by counterfeiters by updating existing statutes and providing additional civil penalties and remedies against counterfeiters.

Section 14 of the ACPA directs the Secretary of the Treasury to prescribe such regulations or amendments to existing regulations as may be necessary to implement and enforce particular provisions of the ACPA. This document concerns sections 9 and 10 of the ACPA.

Section 9 of the ACPA pertains to government disposition of merchandise bearing American trademark information and amends section 526(e) of the Tariff Act of 1930, as amended, (19 U.S.C. 1526(e)) to ensure that counterfeits of American products are routinely destroyed, unless there is no public safety risk and the trademark owner agrees to some other disposition of the merchandise. The provisions of section 526(e) are provided for, in part, at § 133.52(c) of the Customs Regulations (19 CFR 133.52(c)).

Section 10 of the ACPA pertains to civil penalties and further amends section 526 of the Tariff Act of 1930 (19 U.S.C. 1526) by adding a new subsection (f) that provides for civil fines on persons involved in the importation of merchandise bearing a counterfeit American trademark and are in addition to any other civil or criminal penalty or other remedy authorized by law. Since this provision is new, there were no Customs Regulations that addressed civil fines for those involved

in the importation of counterfeit trademark goods.

To implement these statutory provisions as soon as possible to afford the protection legislated to trademark owners and the public from imported merchandise bearing a counterfeit trademark, on November 17, 1997, Customs published interim regulations in the **Federal Register** (62 FR 61231). These interim regulations amended the Customs Regulations at § 133.52(c) to implement the provisions of section 9 of the ACPA, and created a new § 133.25 to implement the provisions of section 10 of the ACPA. The document also solicited comments concerning these changes.

The comment period closed on January 16, 1998. Two comments were received. The comments and Customs responses to them follow.

Discussion of Comments

The comments received were from a professional association and a law firm representing a foreign trade association. Both commenters supported the interim regulations, with one commenter suggesting modifications. The suggested modification is discussed below.

Comment: One commenter urged Customs to modify the text of § 133.25 concerning use of the phrase "American trademark." This commenter states that the phrase is arguably ambiguous, as it is not defined anywhere, and could lead to misunderstandings concerning the scope of the protection afforded. The commenter cites the legislative history of the ACPA (the Act) to show that Congress intended to extend coverage of the Act to all entities, foreign as well as domestic, holding a trademark properly registered with the Patent and Trademark Office and recorded with Customs. Accordingly, the commenter recommends that Customs modify the text of this regulatory provision to provide for "counterfeit mark or name (within the meaning of § 133.21 of this part)" in lieu of the present "counterfeit American trademark."

Customs response: Customs agrees in part with this recommendation to modify the text of § 133.25. Use of the term "American" could cause confusion regarding the scope of the protection afforded, since Congress did intend to confer protection to trademarks (whether or not owned by foreign interests) registered with the U.S. Patent Office. However, Customs does not feel that adding the additional term "name" is appropriate; it might also cause confusion, since one cannot register a trade name with the U.S. Patent Office. Accordingly, the text of § 133.25 is modified to read "counterfeit mark

(within the meaning of § 133.21 of this part)" in lieu of the present "counterfeit American trademark" text.

Conclusion

After analysis of the comments received and further consideration of the matter, Customs has decided to adopt the interim amendments to Part 133 of the Customs Regulations with the modification discussed above in the analysis of comments. Further, to make the text of paragraphs (a) and (b) of § 133.25 read more clearly, the phrase "as determined by" in paragraph (b) is replaced with the phrase "based on" used in paragraph (a), and the term "domestic value" used in paragraph (a) is inserted in paragraph (b). Lastly, the authority citation of part 133 is revised to add a specific authority citation for new § 133.25.

Inapplicability of the Regulatory Flexibility Act and Executive Order 12866

Because these regulatory amendments reflect existing statutory requirements or merely implement interpretations and policies that are already in effect under interim regulations to protect trademark owners and the public from imported merchandise bearing a counterfeit trademark, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the regulations will not have a significant economic impact on a substantial number of small entities. Accordingly, the regulations are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604. Further, this document does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866.

List of Subjects in 19 CFR Part 133

Copyrights, Counterfeit goods, Customs duties and inspection, Imports, Penalties, Prohibited merchandise, Reporting and recordkeeping requirements, Restricted merchandise, Seizures and forfeitures, Trademarks, Trade names, Unfair competition.

Amendments to the Regulations

For the reasons stated above, part 133 of the Customs Regulations (19 CFR part 133), is amended as set forth below:

PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

1. The general authority citation for part 133 continues, and the specific authority for § 133.52 is revised, to read as follows:

Authority: 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1624; 31 U.S.C. 9701;

Sections 133.25 and 133.52 also issued under 19 U.S.C. 1526;

2. Section 133.25 is revised to read as follows:

§ 133.25 Civil fines for those involved in the importation of counterfeit trademark goods.

In addition to any other penalty or remedy authorized by law, Customs may impose a civil fine on any person who directs, assists financially or otherwise, or aids and abets the importation of merchandise bearing a counterfeit mark (within the meaning of § 133.21 of this part) as follows:

(a) *First violation.* For the first seizure of such merchandise, the fine imposed shall not be more than the domestic value of the merchandise (*see*, § 162.43(a) of this chapter) as if it had been genuine, based on the manufacturer's suggested retail price of the merchandise at the time of seizure.

(b) *Second and subsequent violations.* For the second and each subsequent seizure of such merchandise, the fine imposed shall not be more than twice the domestic value of the merchandise as if it had been genuine, based on the manufacturer's suggested retail price of the merchandise at the time of seizure.

3. Section 133.52(c) is republished to read as follows:

§ 133.52 Disposition of forfeited merchandise.

(c) *Articles bearing a counterfeit trademark.* Merchandise forfeited for violation of 19 U.S.C. 1526 shall be destroyed, unless it is determined that the merchandise is not unsafe or a hazard to health and the Commissioner of Customs or his designee has the written consent of the U.S. trademark owner, in which case the Commissioner of Customs or his designee may dispose of the merchandise, after obliteration of the trademark where feasible, by:

(1) Delivery to any Federal, State, or local government agency that, in the opinion of the Commissioner or his designee, has established a need for the merchandise; or

(2) Gift to any charitable institution that, in the opinion of the Commissioner or his designee, has established a need for the merchandise; or

(3) Sale at public auction, if more than 90 days has passed since the forfeiture and Customs has determined that no need for the merchandise has been established under paragraph (c)(1) or (c)(2) of this section.

Approved: August 3, 1998.

Samuel H. Banks,

Acting Commissioner of Customs.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 98N-0417]

Amendment to Examination and Investigation Sample Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations regarding the collection of twice the quantity of food, drug, or cosmetic estimated to be sufficient for analysis. This action increases the dollar amount that FDA will consider to determine whether to routinely collect a reserve sample of a food, drug, or cosmetic product in addition to the quantity sufficient for analysis. Experience has demonstrated that the current dollar amount does not adequately cover the cost of most quantities sufficient for analysis plus reserve samples. This direct final rule is part of FDA's continuing effort to achieve the objectives of the President's "Reinventing Government" initiative, and is intended to reduce the burden of unnecessary regulations on food, drugs, and cosmetics without diminishing the protection of the public health. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comment and withdraws this direct final rule.

DATES: This rule is effective February 8, 1999. Comments must be received on or before December 9, 1998. If FDA receives no significant adverse comments during the specified comment period, the agency intends to publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on February 8, 1999. If the agency receives any