

INTERNATIONAL INTELLECTUAL PROPERTY ALLIANCE®



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November 7, 2007

Via Email traderelations@dhs.gov

Ms. Wanda Tate
Office of International Affairs and Trade Relations
U.S. Customs and Border Protection,
Department of Homeland Security, Room 8.5C
Washington, DC 20229

Comment docket: USCBP-2007-0089

Re: Request to Add Intellectual Property Rights (IPR) Item to the Agenda of the Meeting of The Departmental Advisory Committee on Commercial Operations of Customs and Border Protection and Related Homeland Security Functions (COAC), 72 Fed. Reg. 60871 (October 26, 2007)

To Ms. Tate and the COAC:

The International Intellectual Property Alliance (IIPA) takes this opportunity to request that a specific intellectual property rights item be added to the November 16, 2007 meeting agenda and that DHS officials brief the members of the COAC and the public on the status of this particular docket.

The IIPA is a private sector coalition formed in 1984 to represent the U.S. copyright-based industries in bilateral and multilateral efforts to improve international protection of copyrighted materials. The IIPA is comprised of seven trade associations (listed below), which in turn represent over 1,900 U.S. companies producing and distributing materials protected by copyright laws throughout the world – all types of computer software including business applications software and entertainment software; theatrical films, television programs, home videos and digital representations of audiovisual works; music, records, CDs, and audiocassettes; and textbooks, tradebooks, reference and professional publications and journals (in both electronic and print media). IIPA members and their member companies enforce their copyrights at the U.S. border, and have worked with and trained U.S. border enforcement officials on identifying and intercepting suspected infringing copyrighted goods at U.S. borders.

Request: The public notice of the November COAC meeting indicates that Intellectual Property Rights (IPR) is number 9 on the tentative agenda. IIPA requests that this IPR agenda item remain on the agenda, and specifically asks that DHS officials brief the COAC and the public regarding the status of pending amendments to customs recordation procedures which have been pending, without action, for three years.

The IPR Issue for the COAC Agenda: In October 2004, the CBP issued a notice of proposed rulemaking involving proposed changes affecting the recordation of copyrights under the CPR Regulations (see 69 Fed. Reg. 59562, October 5, 2004, and attached). To quote this 2004 Federal Register notice:


The CBP Regulations currently require that in order to be eligible for border protection all claims to copyright, foreign and domestic, be registered with the U.S. Copyright Office. This document proposes to allow sound recordings and motion pictures or similar audio-visual works to be recorded with CBP while pending registration with the U.S. Copyright Office. This document also proposes to amend the CBP Regulations to enhance the protection of all non-U.S. works by allowing recordation without requiring registration with the U.S. Copyright Office. Lastly, the proposed regulations set forth changes to CBP's enforcement procedures, including, among other things, enhanced disclosure provisions, protection for live musical performances and provisions to enforce the Digital Millennium Copyright Act.

Several IIPA members provided comments supporting the need for these changes, and furthermore, proposed some important modifications to enhance the operational efficiency of the proposed regulations, as proposed in this 2004 docket. To be clear, these members do not support adoption of the proposed amendments as written; further refinements to the proposed regulations are necessary before promulgation.

Later, several IIPA members met with various CBP and DHS officials to discuss these proposed recordation amendments and their progress toward finalization. In brief, to our knowledge there has been no movement toward promulgating any revised regulations in this docket.

Three years have passed. IIPA and its members request that the status of these proposed amendments regarding regulations affecting copyright recordation be discussed at the upcoming COAC meeting. Thank you.

Respectfully submitted,



Maria Strong
on behalf of the
International Intellectual Property Alliance (IIPA)

Attachment

the compliance times specified, unless the actions have already been done.

Modification

(f) Within 30 months after the effective date of this AD: Modify the wiring for the master dim test system in accordance with the Accomplishment Instructions of Boeing

Special Attention Service Bulletin 737-33-1132, Revision 1, dated March 4, 2004 (for Model 737-300, -400, -500 series airplanes); and Boeing Service Bulletin 737-33-1133, Revision 2, dated December 4, 2003 (for Model 737-600, -700, -700C, -800, and -900 series airplanes); as applicable.

Actions Required To Be Accomplished Prior to or Concurrently With Paragraph (f) of This AD

(g) Prior to or concurrently with accomplishment of paragraph (f) of this AD, do the actions specified in Table 1 of this AD, as applicable.

TABLE 1—PRIOR/CONCURRENT ACTIONS

For—	Accomplish all actions associated with—	According to the Accomplishment Instructions of—
Group 57 airplanes identified in Boeing Service Bulletin 737-33-1132, Revision 1, dated March 4, 2004.	Installing an engine instrument system (EIS) and.	Boeing Service Bulletin 737-77-1022, Revision 1, dated October 26, 1989.
	Modifying the advisory system for the EIS	Boeing Service Bulletin 737-77-1023, Revision 1, dated November 9, 1989.
Group 4, 5, 7, 15, 16, 20, 24, 25, 29, 30, 33, 37, 39, 40, 41, and 46 airplanes identified in Boeing Service Bulletin 737-33-1133, Revision 2, dated December 4, 2003.	Installing wiring for the test system for the audio control panel lamp.	Boeing Service Bulletin 737-33-1121, Revision 1, dated December 19, 2002.
Group 2 airplanes identified in Boeing Service Bulletin 737-33-1121, Revision 1, dated December 19, 2002.	Installing splice SP896	Boeing Service Bulletin 737-26A1083, Revision 1, dated November 15, 2001.
Group 39 airplanes identified in Boeing Service Bulletin 737-33-1133, Revision 2, dated December 4, 2003.	Installing a smoke detection and fire extinguishing system in the cargo compartment.	Boeing Service Bulletin 737-26A1083, Revision 1, dated November 15, 2001.

Actions Accomplished per Previous Issue of Service Bulletins

(h) Actions accomplished before the effective date of this AD in accordance with Boeing Special Attention Service Bulletin 737-33-1132, dated March 20, 2003; Boeing Service Bulletin 737-33-1133, dated December 19, 2002; or Boeing Service Bulletin 737-33-1133, Revision 1, dated April 17, 2003, as applicable, are considered acceptable for compliance with the corresponding actions specified in this AD.

Alternative Methods of Compliance (AMOCs)

(i) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on September 27, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04-22355 Filed 10-4-04; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

19 CFR 133

RIN 1505-AB51

Recordation of Copyrights and Enforcement Procedures To Prevent the Importation of Piratical Articles

AGENCY: Bureau of Customs and Border Protection, Department of Homeland Security.

ACTION: Proposed rule.

SUMMARY: As a result of technological advances available to those pirating copyrighted works, there has been a global increase in the importation of piratical works. Because of this increased risk to owners of protected copyrighted works and because most owners of copyrights in non-U.S. works do not register their copyrights as a matter of course, the Bureau of Customs and Border Protection (CBP) is proposing regulations that allow CBP to be more responsive to claims of piracy.

The CBP Regulations currently require that in order to be eligible for border protection all claims to copyright, foreign and domestic, be registered with the U.S. Copyright Office. This document proposes to allow sound recordings and motion pictures or similar audio-visual works to be recorded with CBP while pending registration with the U.S. Copyright

Office. This document also proposes to amend the CBP Regulations to enhance the protection of all non-U.S. works by allowing recordation without requiring registration with the U.S. Copyright Office. Lastly, the proposed regulations set forth changes to CBP's enforcement procedures, including, among other things, enhanced disclosure provisions, protection for live musical performances and provisions to enforce the Digital Millennium Copyright Act.

DATES: Written comments must be submitted on or before November 4, 2005.

ADDRESSES: You may submit comments, identified by RIN 1505-AB51, by either of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Regulations Branch, Office of Regulations and Rulings, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW. (Mint Annex), Washington, DC 20229.

Comments submitted may be inspected at the Regulations Branch, Office of Regulations and Rulings, Bureau of Customs and Border Protection, 799 9th Street, NW., 5th Floor, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Paul Pizzeck, Esq. or George F. McCray, Esq., Intellectual Property Rights Branch, Office of Regulations and Rulings, (202) 572-8710.

SUPPLEMENTARY INFORMATION:

Background

Due to a global increase in piracy and an increased risk to owners of protected copyrighted works as a result of technological advances available to those pirating such works, the Bureau of Customs and Border Protection (CBP) is proposing regulations that allow CBP to be more responsive to claims of piracy. In this document, CBP is proposing changes designed to better facilitate the recordation process with CBP for certain works and to strengthen the enforcement procedures to protect those rights.

Recordation of Protected Copyrighted Works

CBP is proposing several changes to subpart D of part 133 of the CBP Regulations regarding the recordation process, as set forth below.

Protection of Sound Recordings and Motion Pictures or Similar Audio-Visual Works Pending Registration With the U.S. Copyright Office

Presently, the CBP Regulations provide that only those claims to copyright, foreign and domestic, which have been registered with the U.S. Copyright Office may be recorded with CBP. Subparts D and E of part 133, CBP Regulations (19 CFR part 133, subparts D and E) prohibit the importation of piratical works that have been properly registered and recorded. However, piratical copies of sound recordings and motion pictures or similar audio-visual works are often found in the market before the owner of a copyright in those works can effect registration of the copyright with the U.S. Copyright Office. Although the copyrightability of these types of works is rarely a substantive issue, because of the time lapse between the application for registration and the granting of registration with the U.S. Copyright Office, significant imports of piratical articles can often occur before the copyright owner is able to secure registration with the U.S. Copyright Office.

For these types of works, it is during the periods of time prior to and immediately following the release of the work in which piracy is most likely to occur. As a result, pre-release copyright registration applications are generally avoided due to concerns about leaks arising from the sample copies submitted with the application which are made available to the public.

Securing border protection simultaneously with (or in some cases prior to) the commercial release of sound recordings and motion pictures

or similar audio-visual works should help to prevent the importation into the U.S. of piratical goods. As a result, CBP is proposing to revise subparts D and E of part 133, CBP Regulations, in order to provide for border enforcement of U.S. copyrights for sound recordings and motion pictures or similar audio-visual works in which copyrightability is rarely a substantive issue, that are pending registration with the U.S. Copyright Office.

Concerning sound recordings and motion pictures or similar audio-visual works, CBP intends to accept a copy of a valid application for registration that has been filed with the U.S. Copyright Office as evidence of a copyrightable interest entitled to protection by CBP. The proposed regulations require that an applicant provide to CBP proof of registration with the U.S. Copyright Office no later than six months after the date of the application for recordation. If the applicant fails to provide proof of registration in a timely manner, CBP would cancel the related recordation. In addition, CBP proposes to reserve the right to cancel any recordation which it determines to have been obtained in any manner contrary to law. Permitting copyright owners of those certain categories of works for which copyrightability is rarely a substantive issue to make an initial recordation with CBP based on a filed, pending application for copyright registration rather than a perfected certificate of registration, will allow CBP to prevent the importation of piratical goods prior to the completion of the registration process.

Accordingly, in § 133.32 which covers the recordation procedure for protected copyrighted works, a new paragraph (b)(4) is proposed to include claims to copyright in sound recordings and motion pictures or similar audio-visual works which are not yet registered with the U.S. Copyright Office.

CBP notes that the above proposed change may result in an increased number of applications for recordation and, as each application is required to be accompanied by a \$190 fee, an increased administrative burden in the processing of an increased number of individual payments. In order to mitigate processing costs for business and government, we are considering allowing alternative fee arrangements. For example, one annual payment may be made in lieu of individual application fees. The difference between the amount paid per recordation under the alternative arrangement and the standard single recordation fee (currently, \$190) would not exceed the difference in processing costs. We are

particularly interested in any comments on the fairness, equity, and potential administrative efficiency of such arrangements under 31 U.S.C. 9701.

Non-U.S. Works Entitled to Border Enforcement Protection

Under the current regulations, in order to seek protection from the importation of piratical copies, non-U.S. claimants holding a copyright entitled to enforcement are required to provide CBP with a valid certificate of registration issued by the U.S. Copyright Office and to record such registration with CBP. However, because most countries do not have registration systems and most non-U.S. copyright claimants do not register their works in the U.S. as a matter of course, and at the same time, due to technological advances available for pirating such works, there is an overall global increase in piracy and increased risk to owners of protected copyrighted works originating from throughout the world. Accordingly, CBP believes that it would be appropriate for non-U.S. claimants holding copyrights in such works to be entitled to record their claims with CBP regardless of whether they have registered their copyrights with the U.S. Copyright Office at the time of recordation.

Accordingly, in § 133.31(a) covering protected copyrighted works eligible for recordation, new regulatory text is proposed to include, among other things, certain claims to copyright in non-U.S. works that have not been registered with the U.S. Copyright Office, but which are recognized under the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention).

Recordation Application Process

Based on the above described changes, CBP is also proposing to amend § 133.32 of the CBP Regulations (19 CFR 133.32) which outlines the procedure for recordation and the information required in all applications to record a copyright with CBP. To carry out CBP protection of claims to copyright in certain U.S. works pending registration with the U.S. Copyright Office and claims to copyright in non-U.S. works which are entitled to protection under 17 U.S.C. 104, new paragraphs (b)(3) and (4) are proposed to be added to expand § 133.32 to provide for such claims.

New paragraph (b)(3) would permit owners of claims to copyrights in non-U.S. works to apply for recordation with CBP for the enforcement of such claims, even if not registered with the U.S. Copyright Office. This new paragraph

sets forth that non-U.S. works will be entitled to border enforcement protection when sufficient evidence of ownership of copyright in those works is provided to CBP through recordation with CBP. Sufficient evidence of ownership consists of a written affidavit (in English), appropriately sworn to by a duly authorized party, validating the existence, ownership, and nature of the rights claimed.

New paragraph (b)(4) would allow owners of claims to copyrights in U.S. sound recordings and motion pictures or similar audio-visual works for which copyrightability is rarely a substantive issue and for which securing border protection on an immediate basis is essential for purposes of preventing the importation of piratical articles, to record these works with CBP when registration is pending with the U.S. Copyright Office. The filing of such a claim will require the submission to CBP of a copy of a valid registration application officially filed with the U.S. Copyright Office for the specific work. Claims for protection made pursuant to either provision ((b)(3) or (4)) will be subject to independent verification by CBP, which will maintain sole discretion as to whether to accept such claims for enforcement.

In addition, to further clarify and simplify the recordation process and reduce the burden on those applying for recordation of claims to copyright, CBP is proposing other changes to §§ 133.32 and 133.33 which would: (1) Allow a "duly appointed representative" to record a claim to copyright for the copyright owner thereby eliminating the need for the copyright owner to personally file the application; (2) eliminate the requirement that an applicant supply four additional photocopies (or likenesses) of the protected copyrighted work with the application; (3) update the address to which completed applications are submitted; and (4) update the name of the agency to which fees are submitted for recordation of copyright to reflect the new name of the former U.S. Customs Service.

CBP is also proposing to require information regarding the citizenship of a copyright owner. Moreover, the current regulation requires that photographic or other likenesses be provided with an application for recordation in order to ensure that CBP has adequate information regarding a claim to copyright to enforce such rights. Works such as books, magazines, periodicals and sound recordings are excepted from this requirement. CBP is proposing to require that, as appropriate, either a sample, a digital

image, or photograph of the protected work be submitted with the application to record the copyright. CBP is further proposing to require samples of sound recordings.

Enforcing the Prohibition on the Importation of Piratical Articles

CBP is proposing several changes to subpart E of part 133 of the CBP Regulations to achieve consistency with the above proposed changes concerning subpart D of part 133. The proposed changes, as set forth below, also serve to strengthen CBP's ability to enforce the prohibition against the importation of piratical articles.

Definition of "Protected Copyrighted Works"

Section 133.42(a) currently provides that "Infringing copies or phonorecords are 'piratical' articles." In order to more accurately and completely define "piratical articles," CBP is proposing to revise paragraph (a) of § 133.42 to define "piratical articles" as those which constitute unlawful copies (made without the authorization of the copyright owner) or phonorecords of "protected copyrighted works." The proposed amended language defines "protected copyrighted works" to encompass works registered with the U.S. Copyright Office and recorded with CBP, non-U.S. works which are entitled to protection under 17 U.S.C. 104 (including sound recordings and motion pictures or similar audio-visual works) for which relevant ownership information is recorded with CBP, and certain U.S. works pending registration with the U.S. Copyright Office that are duly recorded with CBP.

Disclosure to Copyright Owners Upon Infringement

CBP has determined that, in order to pursue all avenues of relief from copyright infringement, including seeking criminal prosecution of violators and pursuing private civil remedies for copyright infringement, an affected copyright owner must have access to certain information regarding parties attempting to import infringing piratical articles. In cases involving seizures of articles that circumvent copyright protection systems (technological measures) under the Digital Millennium Copyright Act (Pub. L. 105-304, 112 Stat. 2860, DMCA) (see Other Proposed Changes to the Regulations below), such information would be provided to the producers, or their duly authorized agents, of such copyright protection systems. Accordingly, CBP is proposing to amend its disclosure provisions regarding

copyright violations in order to expand the information provided to copyright owners, or, in the case of articles seized pursuant to 19 CFR 133.42(c)(3) information provided to duly authorized agents of producers of copyright protection systems (technical measures), when merchandise violating their rights is seized at the border including information regarding articles seized for violation of the DMCA.

Currently § 133.42(d) provides that, when CBP seizes goods under that section, CBP will disclose to the owner of the copyright:

- (1) The date of importation;
- (2) The port of entry;
- (3) A description of the merchandise;
- (4) The quantity involved;
- (5) The name and address of the manufacturer;
- (6) The country of origin of the merchandise;
- (7) The name and address of the exporter; and
- (8) The name and address of the importer.

CBP is proposing to amend § 133.42(d) to provide that, in addition to the information above, when CBP seizes goods under that section, CBP will also disclose to the copyright owner or, for merchandise seized pursuant to § 133.42(c)(3), to the producer of the copyright protection system:

- (9) Information from available shipping documents (such as manifests, air waybills, and bills of lading), including mode or method of shipping (such as airline carrier and flight number) and the intended final destination of the merchandise.

Procedures on the Suspicion of Piratical Copies

Section 133.43 contains the current procedures to be employed when CBP suspects that certain articles may be piratical articles. The current § 133.43 provides for: (1) Notice of detention of suspected articles to an importer and to a copyright owner, including the disclosure of certain information; (2) the disclosure of samples of suspected articles to the copyright owner; (3) the release of the goods in the case of inaction by the copyright owner and in cases where the copyright owner makes a written demand for the exclusion of the suspected articles, a bonding requirement and exchange of briefs process; and (4) alternative procedures to the administrative process (court action). In general, the current regulations provide that upon notification by a port director that CBP has reason to believe that an imported article may be a piratical copy or phonorecord of a copyrighted work, the

copyright owner may file a written demand for exclusion of the suspected infringing copies. Additional evidence, legal briefs, and other pertinent material to substantiate a claim or denial of piracy are then exchanged between the parties and eventually submitted to CBP for administrative review.

CBP believes that the existing procedures contained in § 133.43 are an outdated and inefficient mechanism to address the situation where CBP has a suspicion that certain goods may be piratical. These provisions are rarely used and unduly burdensome on CBP and all other parties involved. Essentially, these procedures interfere with CBP's ability to conduct the required investigation in a timely and efficient manner. Moreover, the process inhibits CBP from applying its expertise in an expedient manner to determine whether or not merchandise is piratical. Most importantly, these procedures are ineffective in aiding CBP in resolving the issue of whether certain merchandise is indeed piratical.

Likewise, § 133.44 outlines the actions to be taken when a claim of piracy under § 133.43 is sustained or denied.

Accordingly, CBP is proposing to remove § 133.43 and § 133.44 in their entirety. Instead, CBP is proposing regulations allowing CBP to detain merchandise when CBP has reasonable suspicion to believe that the merchandise is piratical and to seize merchandise that it determines to be piratical. In addition, the proposed regulations would facilitate the exchange of information between the copyright owners and CBP in order to assist CBP in making this determination.

Detention of Sound Recordings and Motion Pictures or Similar Audio Visual Works

CBP is proposing to add regulatory text in a newly created paragraph (b)(2) to § 133.42 that specifies CBP's power to detain articles that appear to be piratical copies of sound recordings, motion pictures, or similar audio-visual works to conduct further investigation. Accordingly, paragraph (b)(2) in § 133.42 proposes to allow CBP to detain, for up to 30 days, sound recordings and motion pictures or similar audio-visual works prior to registration with the U.S. Copyright Office when CBP has reasonable suspicion to believe that they constitute piratical copies even though there is no underlying copyright registration or recordation on file with CBP. Reasonable suspicion that certain articles are piratical may be based upon factors such as poor product quality,

substandard packaging, irregular invoicing, methods of shipment, or other indicia of piracy.

Waiver of Bond Requirement for Samples Less Than \$50.00

Section 133.42(e) of the CBP Regulations (19 CFR 133.42(e)) allows CBP to provide a sample of suspect merchandise to the owner of the copyright. The copyright owner seeking to obtain a sample is required to furnish a bond to CBP. CBP is proposing to allow port directors, at their discretion, to waive the bond requirement where the value of the sample is less than \$50.00.

Other Proposed Changes to the Regulations

Adding DMCA Violations to Enforcement Provisions of Subpart E

In 1998, Congress enacted the DMCA. Among other things, the DMCA prohibits the circumvention of technological measures used by copyright owners to protect their works. A technological measure "effectively controls access to a work" if the measure, in the ordinary course of its operation, requires the application of information, or a process or a treatment, with the authority of the copyright owner, to gain access to the work.

Although the current CBP Regulations do not specifically provide for detention and seizure of articles that constitute violations of the DMCA, CBP has implemented the DMCA by providing CBP personnel with internal enforcement guidelines and advice on how to enforce DMCA violations. Where CBP finds that certain devices violate the DMCA, the goods are subject to seizure and forfeiture under 19 U.S.C. 1595a(c)(2)(C) for a violation of the DMCA (17 U.S.C. 1201(b)(1)).

Accordingly, CBP is proposing to include provisions for the detention and seizure of articles that constitute violations under the DMCA to the enforcement provisions of subpart E. Specifically, CBP is proposing to add paragraph (b)(3) to § 133.42 to provide for the detention of articles that CBP reasonably believes constitute violations of 17 U.S.C. 1201(b)(1). Such detentions will be limited to 30 days in duration. In the event that the Intellectual Property Rights (IPR) Branch within CBP's Office of Regulations & Rulings determines that such detained articles violate 17 U.S.C. 1201(b)(1), CBP will then seize them and institute forfeiture proceedings in accordance with part 162 of chapter I of the CBP Regulations. Articles determined by the IPR Branch

not to violate 17 U.S.C. 1201(b)(1), will be released.

CBP is also proposing to add paragraph (c)(3) to § 133.42 to provide for the seizure of articles that the IPR Branch determines to violate 17 U.S.C. 1201(b)(1). Importers may petition for relief from the seizure and forfeiture under the provisions of part 171 of chapter I. Articles that have been seized and forfeited to the U.S. Government under part 133 will be disposed of in accordance with § 133.52(b).

Adding Recordings of Live Musical Performances in Violation of 18 U.S.C. 2319A to Enforcement Provisions of Subpart E

Section 2319A of title 18 (18 U.S.C. 2319A) states that copies of live musical performance that are "fixed" outside of the U.S. without the consent of the performer or performers involved are subject to seizure and forfeiture in the same manner as property imported in violation of the customs laws. Although CBP has had enforcement guidelines in place for several years, CBP has not promulgated regulations implementing section 2319A.

Accordingly, CBP is proposing to add, at § 133.52(c)(2)(iii), recordings of live musical performances determined by CBP to be in violation of 18 U.S.C. 2319A to the types of sound recordings subject to seizure.

Comments

Before adopting this proposed regulation as a final rule, consideration will be given to any written comments timely submitted to CBP, including comments on the clarity of this proposed rule and how it may be made easier to understand. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552) and § 103.11(b), CBP Regulations (19 CFR 103.11(b)), on normal business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, Bureau of Customs and Border Protection, 799 9th Street, NW., 5th Floor, Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 572-8768.

Executive Order 12866

This document does not meet the criteria for a "significant regulatory action" as specified in E.O. 12866.

Regulatory Flexibility Act

Pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that these

proposed amendments will not have a significant economic impact on a substantial number of small entities. The regulatory amendments reflect, implement, or clarify existing statutory and regulatory requirements created to protect the rights of legitimate copyright owners. Accordingly, the amendments are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Signing Authority

The authority to approve regulations concerning copyright enforcement, was retained by the Secretary of the Treasury. The signing authority for these amendments, therefore, falls under § 0.1(a)(1), CBP Regulations (19 CFR 0.1(a)(1)). Accordingly, this document is signed by the Secretary of Homeland Security (or his or her delegate) and the Secretary of the Treasury (or his or her delegate).

Paperwork Reduction Act

The collection of information in this document is contained in § 133.32(b) of title 19 (19 CFR 133.32(b)). Under § 133.32(b), the information would be required and used to record copyrights with CBP for border enforcement protection of copyrights. The collection of this information would ensure that CBP has adequate information regarding a claim to copyright in order to protect the copyright owner's rights.

The collection of information encompassed within this proposed rule has been submitted to the Office of Management and Budget (OMB) for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

Estimated annual reporting and/or recordkeeping burden: 4,000 hours.

Estimated average annual burden per respondent/recordkeeper: 2 hours.

Estimated number of respondents and/or recordkeepers: 2,000.

Estimated annual frequency of responses: 1.

Comments on the collection of information should be sent to the Office of Management and Budget, Attention: Desk Officer of the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to the Regulations Branch, Office of Regulations and Rulings, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW. (Mint Annex), Washington, DC 20229.

Comments should be submitted within the time frame that comments are due regarding the substance of the proposal.

Comments are invited on: (a) Whether the collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or startup costs and costs of operations, maintenance, and purchases of services to provide information.

Part 178, CBP Regulations (19 CFR part 178), containing the list of approved information collections, would be revised to add an appropriate reference to 133.32(b), upon adoption of the proposal as a final rule.

List of Subjects in 19 CFR Part 133

Copying or simulating trademarks, Copyrights, Counterfeit trademarks, Customs duties and inspection, Detentions, Fees assessment, Imports, Labeling, Penalties, Piratical articles, Prohibited merchandise, Reporting and recordkeeping requirements, Restricted merchandise, Seizures and forfeitures, Trademarks.

Proposed Amendments to the Regulations

It is proposed to amend part 133 of the Customs and Border Protection Regulations (19 CFR part 133), as discussed above and set forth below. For the reasons stated in the preamble, part 133 of the CBP Regulations (19 CFR part 133) is proposed to be amended to read as follows:

PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

1. The general authority citation for part 133 and the specific citation for § 133.42 is revised to read as follows:

Authority: 15 U.S.C. 1124, 1125; 17 U.S.C. 101, 106, 501, 601, 602, 603; 19 U.S.C. 66, 1499, 1595a, 1526, 1624; 31 U.S.C. 9701.

* * * * *

Section 133.42 also issued under 17 U.S.C. 1201(b), 18 U.S.C. 2319A.

* * * * *

2. The heading to subpart D is revised to read as follows:

Subpart D—Recordation of Protected Copyrighted Works

3. Section 133.31 is revised to read as follows:

§ 133.31 Recordation of protected copyrighted works.

(a) *Eligible works.* The following works, collectively referred to in this part as “protected copyrighted works”, when properly recorded with the Bureau of Customs and Border Protection (CBP) in accordance with the provisions of § 133.32, are eligible for border enforcement by CBP in accordance with the provisions of § 133.42:

(1) Non-expired claims to copyright in U.S. works which are registered with the U.S. Copyright Office and recorded with CBP;

(2) Claims to copyright in non-U.S. works entitled to protection under 17 U.S.C. 104 which are recorded with CBP; and

(3) Claims to copyright in sound recordings and motion pictures or similar audio-visual works eligible for recordation under the provisions of § 133.32.

(b) *Persons eligible to record.* The owner of a copyright registered with the U.S. Copyright Office, including any person who has acquired copyright ownership through an exclusive license, assignment, or otherwise, who has registered that ownership interest with the U.S. Copyright Office, or their duly appointed representative may file an application to record that registered copyright. In addition, claimants to copyright in non-US works protected under 17 U.S.C. 104 and claimants to copyright in sound recordings and motion pictures or similar audio-visual works may also file an alternative application to record such claims in accordance with the provisions of § 133.32 of this subpart. The term “copyright owner,” with respect to any of the exclusive rights comprised in a copyright (*see* 17 U.S.C. 106), refers to the owner of a particular right protected under title 17.

(c) *Notice of recordation and other action.* Applicants will be notified of the approval or denial of an application filed in accordance with § 133.32 upon completion of review.

4. Section 133.32 is revised to read as follows:

§ 133.32 Procedure for recording protected copyrighted works.

(a) *Address.* Applications to record protected copyrighted works under this section must be submitted in writing, addressed to the Intellectual Property Rights Branch, Office of Regulations and

Rulings, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Washington, DC 20229.

(b) *Contents; format.* (1) All recordation applications must include the following information (an electronic copyright recordation template can be found at the CBP Web site (<http://www.cbp.gov>)):

(i) The name, complete business address, and citizenship of the copyright owner (or owners) or claimants to copyright for protected works (if a partnership, the citizenship of each partner; if an association or corporation, the state, country, or other political jurisdiction within which it was organized, incorporated, or created);

(ii) A complete description of the rights asserted which adequately identifies the work including, as appropriate, either: a sample of the article(s) containing the claimed protected work; a digital image of same; or a photograph of same reproduced on paper no larger than 8 1/2" x 11" in size (an application will be excepted from this requirement if the subject matter is a work such as a book, magazine, periodical, or similar copyrighted matter readily identifiable by title and author);

(iii) The foreign title of the work, if different from the U.S. title;

(iv) In the case of copyright in a sound recording, a statement setting forth the name(s) of the performing artist(s) and any other information identifying the content thereof appearing on the reproduction surface of the sound recording or its label or container; and

(v) The place(s) of manufacture of genuine copyrighted articles and the identity of the manufacturer(s).

(2) For claims to copyright in U.S. works which have been registered with the U.S. Copyright Office, recordation applications must also contain an additional certificate of registration issued by the U.S. Copyright Office. Where the name of the applicant differs from the name of the copyright owner identified in the registration certificate issued by the U.S. Copyright Office, the application must be accompanied by a certified copy of any assignment, exclusive license, or other document showing that the applicant has acquired an ownership interest in the copyright.

(3) For claims to copyright in non-U.S. works, including sound recordings and motion pictures or similar audio-visual works, entitled to protection under 17 U.S.C. 104, recordation applications must also contain a written affidavit (in English), appropriately sworn to by a duly authorized party, validating the existence, ownership, and nature of the rights claimed. Claims for

protection made under this provision are subject to independent verification by CBP, which maintains sole discretion as to whether to accept such claims for enforcement. CBP may require additional information where the written affidavit fails to provide sufficient clarity as to the nature or ownership of the work for which enforcement is being sought.

(4) For claims to copyright in U.S. sound recordings and motion pictures or similar audio-visual works pending registration with the U.S. Copyright Office, recordation applications must also contain a copy of a valid registration application with respect to the work and acceptable proof that such has been officially filed with the U.S. Copyright Office. Claims for protection made under this section are subject to independent verification by CBP, which maintains sole discretion as to whether to accept such claims for enforcement. CBP may require additional information where the copy of the registration application provided fails to provide sufficient clarity as to the nature or ownership of the work for which enforcement is being sought. The applicant must provide proof of registration with the U.S. Copyright Office no later than six months after the date of the application for recordation. Such proof will consist of an "additional certificate of registration" (see 17 U.S.C. 706) issued by the U.S. Copyright Office. In the event that the applicant fails to provide CBP with proof that a registration has been issued by the U.S. Copyright Office, CBP will cancel the related recordation. Where the name of the applicant for CBP recordation differs from the name of the copyright owner identified in the registration application filed with the U.S. Copyright Office, the application for recordation must be accompanied by a certified copy of any assignment, exclusive license, or other document showing that the party applying for recordation has acquired an ownership interest in the copyright.

(c) CBP reserves the right to cancel any recordation which it determines has been obtained in any manner contrary to law.

(d) *Fee.* Applications to record protected copyrighted works with CBP must be accompanied by a fee of \$190 in the form of a check or money order made payable to the Bureau of Customs and Border Protection for each claim to copyright to be recorded. In order to reduce processing costs for business and government, CBP may enter into alternative fee arrangements with persons, companies, agents, or associations. Such alternative fee

structures will be subject to review on a periodic basis to ensure fairness, equity, and administrative efficiency. Fees in any such alternative structure will reflect costs for services provided in processing the applications for recordation, including data input, tracking of amounts paid, review for sufficiency, interface with field officers (principally, maintenance of intranet and internet databases for field and trade use), record maintenance, and any correspondence and associated administrative costs regarding filing, issue resolution, and recordation. Any recordation under such an alternative arrangement will remain in effect for twenty years or until the copyright ownership expires. Any lump sum fee arrangement will be valid only for renewable annual periods. No such alternative arrangement will become effective until published in the **Federal Register** by DHS/CBP, with Treasury concurrence. The difference in the per recordation rate under the alternative arrangement and the standard single recordation fee should not exceed the difference in processing costs. If the difference in the per recordation rate under the alternative arrangement and the standard single recordation fee exceeds the difference in processing costs, the alternative arrangement fees in the following year will be adjusted to compensate for that difference.

§ 133.33 [Removed]

5. Section 133.33 is removed and reserved.

6. The heading to subpart E is revised to read as follows:

Subpart E—Enforcement of the Prohibition on Importation of Infringing Copies or Phonorecords

7. Section 133.42 is revised to read as follows:

§ 133.42 Piratical articles; Unlawful copies or phonorecords of protected copyrighted works.

(a) *Definition.* "Piratical articles" are those which are unlawfully made (without the authorization of the copyright owner) copies or phonorecords of protected copyrighted works. "Protected copyrighted works" for these purposes refers to works falling into any of the following categories:

(1) U.S. works registered with the U.S. Copyright Office and duly recorded with CBP pursuant to § 133.32;

(2) Non-U.S. works that are protected under 17 U.S.C. 104 (including sound recordings and motion pictures or similar audio-visual works) and where relevant ownership information is recorded with CPB pursuant to § 133.32;

(3) U.S. sound recordings and motion pictures or similar audio-visual works which have been duly recorded with CBP pursuant to § 133.32.

(b) *Detention.*

(1) *Detention of suspected piratical articles (other than sound recordings and motion pictures or similar audio-visual works) that are recorded with CBP.* Imported articles appearing to be piratical copies of protected copyrighted works, other than sound recordings and motion pictures or similar audio-visual works, for which a claim to copyright has previously been recorded with CBP pursuant to § 133.32, may be detained for a period not to exceed 30 days, if CBP has reasonable suspicion to believe that they constitute piratical copies. Upon determination by the IPR Branch, CBP Office of Regulations & Rulings, that such detained articles constitute piratical copies, CBP will seize them and institute forfeiture proceedings in accordance with part 162 of this chapter. Articles that are not determined by the IPR Branch within 30 days to be piratical copies will be released.

(2) *Detention of suspected piratical sound recordings and motion pictures or similar audio-visual works.* Imported articles consisting of sound recordings and motion pictures or similar audio-visual works may be detained for a period not to exceed 30 days if CBP has reasonable suspicion to believe that they constitute piratical copies. Where the genuine works or sound recordings are not recorded with CBP at the time of detention of suspected piratical copies, recordation must take place no later than 30 days after the date on which the suspect articles were detained. Upon determination by CBP that such detained articles constitute piratical copies, CBP will seize them and institute forfeiture proceedings in accordance with part 162 of this chapter, provided that the copyright has been recorded with CBP pursuant to § 133.32. Articles not recorded with CBP within 30 days or articles which are not determined by CBP to be piratical copies will be released.

(3) *Detention of articles suspected of constituting violations of the Digital Millennium Copyright Act (17 U.S.C. 1201(b)(1)).* Imported articles appearing to constitute violations of 17 U.S.C. 1201(b)(1) may be detained for a period not to exceed 30 days if CBP reasonably believes that such articles are primarily designed or produced for the purpose of circumventing protection afforded by a technological measure that effectively protects a right of a copyright owner; have only limited commercially significant purpose or use other than to circumvent such protection; or are

marketed by the importer or trafficker, or another acting in concert with the importer or trafficker, for use in circumventing such protection. Upon determination by the IPR Branch, CBP Office of Regulations & Rulings, that such detained articles constitute violations of 17 U.S.C. 1201(b)(1) CBP will seize them and institute forfeiture proceedings in accordance with part 162 of this chapter. Articles that are not determined by the IPR Branch to constitute violations of 17 U.S.C. 1201(b)(1) will be released.

(c) *Seizure and forfeiture.* Articles which have been seized and forfeited to the U.S. Government will be disposed of in accordance with § 133.52 of this part, subject to the importer's right to petition for relief from the seizure and forfeiture under the provisions of part 171 of this chapter.

(1) *Seizure of copies of articles (other than sound recordings and motion pictures or similar audio-visual works).*

(i) Imported articles which, at the time of presentment to CBP, clearly constitute piratical copies of protected copyrighted works other than sound recordings and audio-visual works, for which a claim to copyright has previously been recorded with CBP pursuant to § 133.32 are subject to immediate seizure. After seizure, piratical goods are subject to forfeiture proceedings in accordance with part 162 of this chapter. CBP will notify the importer of the seizure in accordance with part 162 of this chapter.

(ii) Imported articles detained pursuant to § 133.42(b)(1) that are determined by CBP to constitute piratical copies are subject to seizure. After seizure, piratical goods are subject to forfeiture proceedings in accordance with part 162 of this chapter. CBP will notify the importer of the seizure in accordance with part 162 of this chapter.

(2) *Seizure of sound recordings and motion pictures or similar audio-visual works.* (i) Imported articles which, at the time of presentment to CBP, clearly constitute piratical copies or phonorecords of protected copyrighted works, for which a claim to copyright has previously been recorded with CBP pursuant to § 133.32 are subject to immediate seizure. After seizure, piratical goods are subject to forfeiture proceedings in accordance with part 162 of this chapter. CBP will notify the importer of the seizure in accordance with part 162 of this chapter.

(ii) Imported articles which have been detained pursuant to § 133.42(b)(2), for which a claim to copyright has been recorded with CBP within 30 days after the date on which the suspect articles

were detained, that are determined by CBP to constitute piratical copies are subject to seizure. After seizure, piratical goods are subject to forfeiture proceedings in accordance with part 162 of this chapter. CBP will notify the importer of the seizure in accordance with part 162 of this chapter.

(iii) Recordings of live musical performances determined by CBP to be in violation of 18 U.S.C. 2319A will be subject to seizure regardless of the recordation of any right with CBP. After seizure, piratical goods are subject to forfeiture proceedings in accordance with part 162 of this chapter. CBP will notify the importer of the seizure in accordance with part 162 of this chapter.

(3) *Seizure of articles determined by CBP to constitute violations of the Digital Millennium Copyright Act (17 U.S.C. 1201(b)(1)).* Imported articles determined by the IPR Branch, CBP Office of Regulations & Rulings to constitute violations of 17 U.S.C. 1201(b)(1) are subject to seizure regardless of the recordation of any right with CBP. After seizure, such goods are subject to forfeiture proceedings in accordance with part 162 of this chapter. CBP will notify the importer of the seizure in accordance with part 162 of this chapter.

(d) *Disclosure.* When merchandise is seized under this section, CBP will disclose to the owner of the protected copyrighted work (in the case of copyright piracy) or the producer, or duly authorized agent thereof, of circumvented copyright protection systems (in seizures effected for DMCA violations), the following information, if available, within 30 days, excluding weekends and holidays, of the date of the notice of seizure:

- (1) The date of importation;
- (2) The port of entry;
- (3) A description of the merchandise;
- (4) The quantity involved;
- (5) The name and address of the manufacturer;
- (6) The country of origin of the merchandise, if known;
- (7) The name and address of the exporter;
- (8) The name and address of the importer; and
- (9) Information from available shipping documents (such as manifests, air waybills, and bills of lading), including mode or method of shipping (such as airline carrier and flight number) and the intended final destination of the merchandise.

(e) *Samples available to the copyright owner.* At any time following detention or seizure of the merchandise, CBP may provide a sample of the suspect

merchandise to the owner of the protected work for examination, testing, or any other use in pursuit of a related private civil remedy for copyright infringement. To obtain a sample under this section, the owner of the protected work must furnish to CBP a bond in the form and amount specified by the port director at the port of importation, conditioned to hold the U.S., its officers and employees, and the importer or owner of the imported article harmless from any loss or damage resulting from the furnishing of a sample by CBP to the copyright owner. This requirement may be waived at the discretion of the port director where the value of the sample is less than \$50.00. CBP may demand the return of the sample at any time. The owner of the protected work must return the sample to CBP upon demand or at the conclusion of the examination, testing, or other use in pursuit of a related private civil remedy for copyright infringement. In the event that the sample is damaged, destroyed, or lost while in the possession of the owner of the protected work, the owner of the protected work must, in lieu of return of the sample, certify to CBP that: "The sample described as [insert description] provided by CBP pursuant to § 133.42(e) of the CBP Regulations was (damaged/destroyed/lost) during examination, testing, or other use."

(f) *Parallel Imports.* Copies or phonorecords made lawfully and imported into the U.S. without the consent of the owner of the protected copyrighted work, are not subject to detention, seizure, or forfeiture by CBP.

§ 133.43 [Removed]

8. Section 133.43 is removed and reserved.

§ 133.44 [Removed]

9. Section 133.44 is removed and reserved.

10. Section 133.46 is revised to read as follows:

§ 133.46 Demand for redelivery of released articles.

If CBP determines that articles which have been released from CBP custody are subject to the prohibitions or restrictions of this subpart, the appropriate field officer will promptly make demand for redelivery of the articles pursuant to § 141.113 of this chapter, under the terms of the bond on CBP Form 301, containing the bond conditions set forth in § 113.62 of this chapter. If the articles are not redelivered to CBP custody, a claim for liquidated damages may be made in accordance with § 141.113(h) of this chapter.

Dated: September 30, 2004.

Robert C. Bonner,

Commissioner of Customs and Border Protection.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 361

[Docket No. 2004N-0432]

Radioactive Drugs for Certain Research Uses; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the use of certain radioactive drugs for research purposes without an investigational new drug application (IND) under the conditions set forth in FDA regulations (typically, use of radioactive drugs to determine drug disposition in the body). We are seeking public input on the potential need to modify the conditions under which these radioactive drugs are studied in light of the scientific and technological developments since we adopted the regulations in 1975.

DATES: The public meeting will be held on November 16, 2004, from 8 a.m. to 4 p.m. Submit electronic requests to speak plus a presentation abstract by October 19, 2004, to Maria R. Walsh. Submit final presentations and requests for special accommodations (due to disability) by November 2, 2004, to Maria R. Walsh. Submit written or electronic comments by January 16, 2005, to Division of Dockets Management.

ADDRESSES: The public meeting will be held at the CDER Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD 20857.

You may submit comments, identified by Docket No. 2004N-0432, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2004N-0432 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts, or go to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Transcripts of the public meeting will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at <http://www.fda.gov/ohrms/dockets>.

FOR FURTHER INFORMATION CONTACT: Maria R. Walsh, Center for Drug Evaluation and Research (HFD-103), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3139, FAX 301-480-3761, e-mail: walsh@cdcr.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing a public meeting to discuss research on radioactive drugs that is conducted under § 361.1 (21 CFR 361.1). We added this section to FDA regulations in 1975 (40 FR 31298 at 31308, July 25, 1975). Under § 361.1, certain radioactive drugs (drugs that exhibit spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons) are considered generally recognized as safe and effective under specified conditions of use when administered to human research subjects for certain basic research uses. These uses include studies intended to obtain basic information regarding the metabolism (including pharmacokinetics,