

to the European Union, Japan, and the United States.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 18, 2010.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Mai Huynh, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8273, [mai.huynh@fda.hhs.gov](mailto:mai.huynh@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized

technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

##### **II. Draft Revised Guidance on Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients**

In April 2010, the VICH Steering Committee agreed that a draft revised guidance entitled "Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision) VICH GL18(R)" should be made available for public comment. The draft revised guidance is a revision of the 2001 final guidance on the same topic. The draft revised guidance revises the lower PDE (permissible daily exposure) for *N*-Methylpyrrolidone being kept in Class 2 (Table 2 of the draft revised guidance) and for Tetrahydrofuran being placed into Class 2 from Class 3 (Table 3 of the draft revised guidance). The draft revised guidance is a product of the Quality Expert Working Group of the VICH. Comments about this draft will be considered by FDA and the VICH Quality Expert Working Group.

##### **III. Paperwork Reduction Act of 1995**

This draft revised guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in sections II-VI of this document have been approved under OMB Control No. 0910-0032.

##### **IV. Significance of Guidance**

This draft guidance developed under the VICH process, includes mandatory language that does not describe a statutory or regulatory requirement, as permitted by good guidance practices regulation (21 CFR 10.115(i)(3)). Mandatory language that does not describe a statutory or regulatory requirement will be revised in the final guidance document.

The draft revised VICH guidance (GFI #100) is consistent with the agency's current thinking on this topic. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

##### **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### **VI. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: August 9, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

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## **DEPARTMENT OF HOMELAND SECURITY**

### **U.S. Customs and Border Protection**

#### **Agency Information Collection Activities: Importation Bond Structure**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** 60-Day Notice and request for comments; Extension and revision of an existing collection of information: 1651-0050.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the: Importation Bond Structure. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before October 18, 2010, to be assured of consideration.

**ADDRESSES:** Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 7th Floor, Washington, DC. 20229-1177.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street, NW., 7th Floor, Washington, DC 20229-1177, at 202-325-0265.

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

*Title:* Importation Bond Structure.  
*OMB Number:* 1651-0050.

*Form Numbers:* 301 and 5297.

*Abstract:* Bonds are used to assure that duties, taxes, charges, penalties, and reimbursable expenses owed to the Government are paid; to facilitate the movement of cargo and conveyances through CBP processing; and to provide legal recourse for the Government for noncompliance with laws and regulations. Any person who is required to post a bond to secure a customs transaction usually submits the bond on CBP Form 301, Customs Bond, to CBP.

CBP proposes to revise CBP Form 301 in order to accurately reflect the changes that have occurred with regard to CBP bonds. Specifically, the revised Form 301 will capture the new types of bonds which have been authorized by law and regulation, as well as better harmonize this form with current and future automation system requirements. Section II of the CBP Form 301 will be revised to specifically cover continuous activity code bonds for Importer Security Filing, Marine Terminal Operator, and Intellectual Property Rights Samples.

Bonds are usually executed by an agent of the surety. The surety company grants authority to the agent via CBP Form 5297, Corporate Surety Power of Attorney. Once this form is filed with CBP, the validity of the authority of the agent executing the bond and the name of the surety can be verified to the surety's grant. The trade community now has the ability to submit the information on CBP Form 5297 via the internet by using Automated Commercial Environment (ACE) portal technology. ACE surety portal account access allows sureties to add, revoke, and change their surety agent powers of attorney electronically. This ACE portal account access is available to any surety who applies for the functionality at <http://www.cbp.gov>.

Bonds are required pursuant to 19 U.S.C.1608, and 1623; 22 U.S.C. 463; 19 CFR Part 113.37 and 113.11. CBP Forms 301 and 5297 are accessible at <http://www.cbp.gov/xp/cgov/toolbox/forms/>.

*Current Actions:* This submission is being made to extend the expiration date with a change to the burden hours based on revised estimates by CBP.

*Type of Review:* Extension (with change)

*Affected Public:* Businesses.

#### **Form 301, Customs Bond**

*Estimated Number of Respondents:* 800,000.

*Total Number of Estimated Annual Responses:* 800,000.

*Estimated Time per Response:* 15 minutes.

*Estimated Total Annual Burden Hours:* 200,000.

#### **Form 5297, Corporate Surety Power of Attorney**

*Estimated Number of Respondents:* 500.

*Total Number of Estimated Annual Responses:* 500.

*Estimated time per Response:* 15 minutes.

*Estimated Total Annual Burden Hours:* 125.

Dated: August 11, 2010.

#### **Tracey Denning,**

*Agency Clearance Officer, U.S. Customs and Border Protection.*

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## **DEPARTMENT OF HOMELAND SECURITY**

### **Coast Guard**

[Docket No. USCG-2010-0783]

#### **Invocation of Sunken Military Craft Act**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice.

**SUMMARY:** The Coast Guard is announcing that a C-130 aircraft which crashed off the coast of California is a sunken military craft. It is therefore prohibited for any person to engage or attempt to engage the aircraft or its contents in any way that disturbs, removes, or injures the aircraft or its contents.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, contact LCDR Kevin Smith, Office of Aviation Forces, telephone 202-372-2211.

If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:** On the evening of October 29, 2009, the Coast Guard Air Station Sacramento C-130 aircraft CG 1705 collided with a Marine Corps AH-1W attack helicopter while conducting a search and rescue operation. All seven crewmembers aboard CG 1705 and both crewmembers of the Marine Corps helicopter were killed in the collision. CG 1705 was never recovered and currently rests in approximately 2450 ft of water near position: 32-58.0 N 118-10.10 W. This location now serves as the gravesite and final resting place for the U.S. Coast Guard personnel killed in the crash.

Both the Coast Guard and the Marine Corps undertook independent