

Rockville, MD 20852-1448, 301-435-5681.

*Regarding the ICH:* Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH steering committee includes representatives from each of the ICH sponsors and IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In November 2007, the ICH steering committee agreed that a draft guidance entitled "Q8(R1) Pharmaceutical Development Revision 1" should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

The draft guidance is an annex to the parent guidance ICH Q8. It provides further clarification of key concepts outlined in ICH Q8 and describes the principles of QbD. The annex is not intended to establish new standards or increase regulatory expectations. It is intended to show how concepts and tools (e.g., design space) outlined in ICH Q8 could be put into practice by the applicant for all dosage forms. Where a company chooses to apply QbD and quality risk management (see ICH "Q9 Quality Risk Management"), linked to an appropriate pharmaceutical quality system (see ICH "Q10 Pharmaceutical Quality Systems"), then opportunities arise to enhance science- and risk-based regulatory approaches.

The draft guidance outlines the elements that should be included in pharmaceutical development and additional elements when QbD principles are applied. It elaborates, by means of description and example, possible approaches to gaining a more systematic, enhanced understanding of the product and process under development. The draft guidance also provides recommendations on the placement of pharmaceutical development and other related information in module 3 of a regulatory submission in the common technical document format.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition

date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

##### III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: January 2, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8-213 Filed 1-9-08; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2007-29070]

#### Collection of Information Under Review by Office of Management and Budget: OMB Control Number 1625-0108

**AGENCY:** Coast Guard, DHS.

**ACTION:** Thirty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) requesting an extension of their approval for the following collection of information: 1625-0108, Standard Numbering System for Undocumented Vessels. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

**DATES:** Please submit comments on or before February 11, 2008.

**ADDRESSES:** To make sure your comments and related material do not enter the Coast Guard docket [USCG-2007-29070] or are received by OIRA more than once, please submit them by only one of the following means:

(1) *Electronic submission.* (a) To Coast Guard docket at <http://www.regulations.gov>. (b) To OIRA by e-mail to: [nlessar@omb.eop.gov](mailto:nlessar@omb.eop.gov).

(2) *Mail or hand delivery.* (a) To Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001. Hand deliver between the hours of 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329. (b) To OIRA, 725 17th Street, NW., Washington, DC 20503, to the attention of the Desk Officer for the Coast Guard.

(3) *Fax.* (a) To Docket Management Facility at 202-493-2251. (b) To OIRA at 202-395-6566. To ensure your comments are received in time, mark the fax to the attention of Mr. Nathan Lesser, Desk Officer for the Coast Guard.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://www.regulations.gov>.

A copy of the complete ICR is available through this docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from Commandant (CG-611), U.S. Coast Guard Headquarters, (Attn: Mr. Arthur Requina), 2100 2nd Street, SW., Washington, DC 20593-0001. The telephone number is 202-475-3523.

**FOR FURTHER INFORMATION CONTACT:** Mr. Arthur Requina, Office of Information Management, telephone 202-475-3523 or fax 202-475-3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202-366-9826, for questions on the docket.

**SUPPLEMENTARY INFORMATION:** The Coast Guard invites comments on whether this information collection request should be granted based on it being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the collection; (2) the accuracy of the estimated burden of the collection; (3) ways to enhance the quality, utility, and clarity of information subject to the collection; and (4) ways to minimize the burden of collection on respondents, including the use of automated collection techniques

or other forms of information technology.

Comments to the Coast Guard or OIRA must contain the OMB Control Number of the ICR. Comments to the Coast Guard must contain the docket number [USCG 2007-29070]. For your comments to OIRA to be considered, it is best if OIRA receives them on or before February 11, 2008.

*Public participation and request for comments:* We encourage you to respond to this request by submitting comments and related materials. We will post all comments received, without change, to <http://www.regulations.gov>. They will include any personal information you provide. We have an agreement with DOT to use their Docket Management Facility. Please see the paragraph on DOT's "Privacy Act Policy" below.

*Submitting comments:* If you submit a comment, please include the docket number [USCG-2007-29070], indicate the specific section of the document to which each comment applies, providing a reason for each comment. We recommend you include your name, mailing address, an e-mail address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the underlying requirements in view of them.

The Coast Guard and OIRA will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the underlying requirements in view of them.

*Viewing comments and documents:* Go to <http://www.regulations.gov> to view documents mentioned in this notice as being available in the docket. Click on "Search for Dockets," and enter the docket number (USCG-2007-29070) in the Docket ID box, and click enter. You may also visit the Docket Management Facility in room W12-140

on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*Privacy Act:* Anyone can search the electronic form of all comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Privacy Act Statement of DOT in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://DocketsInfo.dot.gov>.

#### Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard has published the 60-day notice (72 FR 51826, September 11, 2007) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments.

#### Information Collection Request

*Title:* Standard Numbering System (SNS) for Undocumented Vessels.

*OMB Control Number:* 1625-0108.

*Type of Request:* Extension of a currently approved collection.

*Affected Public:* Owners of all undocumented vessels propelled by machinery are required by Federal law to apply for a number from the issuing authority of the State in which they are to be principally operated. In addition, States may require other vessels, such as sailboats, canoes, and kayaks, to be numbered. Owners may include individuals or households, non-profit organizations, and small businesses (e.g., liveries offering recreational vessels for rental by the public) or other for-profit organizations.

*Abstract:* Paragraph (a) of 46 U.S.C. 12301 requires undocumented vessels equipped with propulsion machinery of any kind to be numbered in the State where they are principally operated. In 46 U.S.C. 12302(a), Congress authorized the Secretary to prescribe, by regulation, a SNS, directing approval of a State numbering system if it is consistent therewith. In DHS Delegation No. 0170.1 section 2 (92)(h), the Secretary has delegated his authority under 46 U.S.C. 12301 and 12302 to the Commandant of the Coast Guard. Regulations requiring the numbering of undocumented vessels are in 33 CFR part 173; those applicable to the States for approval of their systems are contained in 33 CFR part 174.

In order to have an approved state numbering system, a State must collect and report annually to the Coast Guard information on its numbered vessels (number, size, construction, etc.). We

need this information for the following reasons: (1) To provide Federal, State, and local law enforcement personnel information for enforcement of boating laws and for theft/fraud investigations; (2) To increase officers' safety by assisting boarding officers in determining how best to approach a vessel suspected of illegal activity; (3) To publish annual Boating Statistics reports required by 46 U.S.C. 6102(b); and (4) To determine proper allocation of Federal funds to assist States in carrying out the National Recreational Boating Safety Program established by 46 U.S.C. chapter 131.

**Burden Estimate:** The estimated burden has increased from 15,507 hours to 286,458 hours a year.

Dated: December 21, 2007.

**D.T. Glenn,**

*Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.*

[FR Doc. E8-212 Filed 1-9-08; 8:45 am]

**BILLING CODE 4910-15-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

#### Agency Information Collection Activities: Form I-601, Revision of a Currently Approved Information Collection; Comment Request

**ACTION:** 30-Day Notice of Information Collection Under Review: I-601, Application for Waiver of Grounds of Inadmissibility; OMB Control Number 1615-0029.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on July 31, 2007, at 72 FR 41771. The notice allowed for a 60-day public comment period. USCIS received two comments from the public on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 11, 2008. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this

notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at [rfs.regs@dhs.gov](mailto:rfs.regs@dhs.gov), and to the OMB USCIS Desk Officer via facsimile at 202-395-6974 or via e-mail at [kastrich@omb.eop.gov](mailto:kastrich@omb.eop.gov).

When submitting comments by e-mail please make sure to add OMB Control Number 1615-0029 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

#### Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved information collection.

(2) *Title of the Form/Collection:* Application for Waiver of Grounds of Inadmissibility.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-601. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* **Primary:** Individuals or Households. The information collected on this form is used by U.S. Citizenship and Immigration Services (USCIS) to determine whether the applicant is eligible for a waiver of excludability under section 212 of the Immigration and Nationality Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 15,500 responses at 1 1/2 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 23,250 annual burden hours.

If you have additional comments, suggestions, or need a copy of the information collection instrument, please visit the USCIS Web site at: <http://www.regulations.gov/fdmspublic/component/main>. We may also be contacted at: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, NW., 3rd floor, Suite 3008, Washington, DC 20529, telephone number 202-272-8377.

Dated: January 7, 2008.

**Richard Sloan,**

*Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.*

[FR Doc. E8-282 Filed 1-9-08; 8:45 am]

**BILLING CODE 4410-10-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-R1-ES-2007-N0005]

#### Proposed Safe Harbor Agreement for the Guam Rail on Cocos Island, Guam

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Receipt of application; notice of availability.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), have received applications for enhancement of survival permits pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA), from Cocos Island Resort and the Guam Department of Agriculture (Applicants). The permit applications include a proposed Safe Harbor Agreement (SHA) among the Applicants and the Service. Implementation of the proposed SHA provides for voluntary habitat restoration, maintenance, enhancement, or the creation of activities to enhance the habitat and recovery of the Guam rail (*Gallirallus owstonii*) ("Covered Species") on 83.1 acres of non-Federal lands on Cocos Island, Guam. The proposed duration of both the SHA and permits is 10 years.

The Service has made a preliminary determination that the proposed SHA and permit application are eligible for categorical exclusion under the National Environmental Policy Act of 1969 (NEPA). The basis for this determination