

sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20851, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal

Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Certification of Identity for Freedom of Information Act and Privacy Act Requests OMB Control Number 0910—NEW**

In compliance with 44 U.S.C. 3507, FDA will submit to the Office of Management and Budget a request to review and approve a new collection of information: Certification of Identity for Freedom of Information Act and Privacy Act Requests. This new form provides the FDA with data necessary to identify an individual requesting a particular record under the Freedom of Information Act (FOIA) and the Privacy

Act. The form is available at the following FDA FOIA page at: <http://www.fda.gov/RegulatoryInformation/FOI/default.htm>, although if an individual requests one, we will send it by mail or email. The FOIA grants the public a right to access Federal records not normally prepared for public distribution. The Privacy Act grants a right of access to members of the public who seek access to one’s own records that are maintained in an Agency’s system of records (*i.e.* the records are retrieved by that individual’s name or other personal identifier). The statutes overlap, and individuals who request their own records are processed under both statutes. The Agency may need to confirm that the individual making the FOIA or Privacy Act request is indeed the same person named in the Agency records.

Members of the public who wish to access particular records will be asked for certain information: Name, citizenship status, social security number, address, date of birth, place of birth, signature, and date of signature.

FDA estimates the burden of this collection of information as follows:

As stated in table 1, the estimates are based on the following: The number of FOIA and Privacy Act requests received by FDA each year that require a certification of identity in order for FDA to process the request. Of the 10,000 requests received per year, only a small number require a certification of identity. In some cases, the requesters provide their own certification of identity. Therefore, we have estimated the number of affected individuals at 60 per year.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3975 .....	60	1	60	.17 (10 minutes) .....	10

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 28, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–18463 Filed 8–3–16; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Announcement of Requirements and Registration for the “MRC Serves” Video Challenge**

**AGENCY:** Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The Medical Reserve Corps (MRC) Program housed under the Office of the Assistant Secretary for

Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), announces the launch of the “MRC Serves” Video Challenge. The MRC is a national network of volunteers, organized locally to improve the health and safety of their communities. MRC volunteers have medical, public health, other backgrounds and have responded to natural disasters, public health and other emergencies, while also supporting community health activities. The MRC Program is looking for

innovative and cost effective ways to promote these activities and demonstrate how MRC units and their volunteers make their communities healthier, prepared, and more resilient. Today there are nearly 200,000 volunteers, in almost 1,000 MRC units nationwide, who give their skills and time year around to support their communities and serve as ambassadors for the MRC to their friends, families, neighbors, and co-workers. The MRC Program would like to engage MRC volunteers to also be national ambassadors by creating short promotional videos that will be used by the MRC Program to highlight how serving as MRC volunteers makes communities healthier, more prepared, and more resilient.

**DATES:** Challenge begins on August 1, 2016, and ends on September 2, 2016 at 11 p.m. EDT. ASPR staff will judge eligible submissions and select semifinalists September 6–7, 2016. Judging of semifinalist videos will take place from September 8–26, 2016. The winners will be notified and announced no later than September 30, 2016. Timeline changes will be announced on <https://mrc.hhs.gov> as well as on the MRC Program's listservs and social media.

**ADDRESSES:** Contestants must be a member of a local Medical Reserve Corps unit. Videos must be submitted between August 1, 2016 and September 2, 2016. Contestants may be individuals or groups. A contestant can submit a video for each question for up to three total videos. Make sure to only answer one question per video. To register for the Challenge, each contestant will need to create a free account at <http://www.challenge.gov>. Groups must submit an entry through a single designated individual or entity within the group. Contestants must follow submission rules found at <https://www.challenge.gov/challenge/mrc-serves>.

**FOR FURTHER INFORMATION CONTACT:** Please submit an inquiry via [MRCContact@hhs.gov](mailto:MRCContact@hhs.gov).

**SUPPLEMENTARY INFORMATION:** MRC units consist of volunteers from all walks of life. We want to highlight the reasons that MRC volunteers join and continue to volunteer with the question, why I volunteer with the MRC? By answering the questions—How does MRC make my community healthier? and How does MRC make my community more prepared and resilient?—the goal is to highlight specific examples of how MRC units and their volunteers are making a difference. Contestants are encouraged

to be creative when addressing these questions and sharing their story. The video can include other visuals such as footage or pictures of a MRC activity or event (see Contest Guidelines section for restrictions). Contestants are encouraged to wear MRC gear such as shirts and hats. Videos can also be submitted as a group with fellow MRC volunteers.

The challenge is authorized by Public Law 111–358, the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science Reauthorization Act of 2010 (COMPETES Act).

**Eligible Entities:** This video contest is open to MRC volunteers and MRC units. Contestants may be individuals, public or private entities that are MRC units, or groups. An individual, whether participating individually or in a group, must be a citizen or permanent resident of the U.S. If the contestant is less than 18 at the time of entry, the entrant must have a completed Parental/Guardian Consent Form. In the case of a private entity, the entity must be incorporated in and maintain a primary place of business in the U.S. Federal entities are not eligible; federal employees acting within the scope of their employment are not eligible. ASPR employees are not eligible. Federal grantees may not use federal funds to develop an application unless consistent with the purpose of their grant award and specifically requested to do so due to competition design and as announced in the **Federal Register**. Federal contractors may not use federal funds from a contract to develop applications or to fund efforts in support of a challenge submission. The contest is subject to all applicable federal laws and regulations. Participation constitutes contestant's full and unconditional agreement to these official rules, which are final and binding in all matters related to the contest. Eligibility for a prize award is contingent upon fulfilling all requirements set forth herein. An individual or entity shall not be deemed ineligible because the individual or entity used federal facilities or consulted with federal employees during a competition if the facilities and employees are made available to all individuals and entities participating on an equitable basis.

**Contest Guidelines:** Only complete entries that follow application instructions will be reviewed. ASPR reserves the right to disqualify participants in instances where misconduct is identified. We expect participants will treat each other and their communities with respect. We will not accept submissions that contain vulgar language, personal attacks, or

offensive terms that target individuals or groups. We will not accept submissions that promote services or products. Submissions that make unsupported claims will not be accepted. Other rules include:

- Contestants must be a member of a local Medical Reserve Corps unit;
- Contestants must submit their video by September 2, 2016, at 11 p.m. EDT;
- All videos must be submitted through the Challenge Web site at <https://www.challenge.gov/challenge/mrc-serves>;
- A video must be 60–90 seconds and must answer only one of these three questions:
  1. Why I/we volunteer with the MRC?;
  2. How does the MRC make my community healthier?;
  3. How does the MRC make my community more prepared and resilient?;
- The video should be an MPEG–4 video file with an aspect ratio of 16 x 9;
- The trademarked MRC logo or the words Medical Reserve Corps/MRC should be clearly visible and accurately displayed in the video; view the MRC Identity Guide for guidance on correct logo use at <https://mrc.hhs.gov/>;
- Contestants may submit their entry as an individual or part of a group;
- Submissions by groups should be submitted only once by one member of the group (one prize will be awarded for each winning entry);
- Contestants must upload their video to YouTube (<http://www.youtube.com>) and add the link to their video on the “Submit Solutions” form, along with a description and transcript of the video;
- Each video must contain closed captioning;
- Only use royalty free music and/or images. No copyrighted images, footage, or music;
- Do not promote any company, service, or product in the video;
- Do not include any personal identifiable information in the video such as unit badges;
- Helpful links and information:
  - YouTube: How to upload <https://support.google.com/youtube/answer/57407?hl=en&rd=1>.
  - YouTube: How to add closed captions <https://support.google.com/youtube/answer/57407?hl=en&rd=1>.
- If under 18, a contestant must have their adult parent or legal guardian complete the Parental/Guardian Consent Form at <http://www.phe.gov/Preparedness/planning/authority/nhss/Documents/parental-consent-form.pdf>. This form must be submitted with your entry.

- Contestants must have the necessary documented permissions for individuals heard and/or seen on the submitted video. Please have individuals who are identifiable in the video complete a release form.

- The documented permission of the adult parent or guardian of each person under the age of 18 seen or heard in the video is also required.

- Any individual contestant or group entry with a member on the Excluded Parties List ([https://www.sam.gov/sam/transcript/Public\\_-\\_Identifying\\_Excluded\\_Entities.pdf](https://www.sam.gov/sam/transcript/Public_-_Identifying_Excluded_Entities.pdf)) will not be eligible for prizes.

- The video must be an original creation. Contestants must not infringe upon any copyright or any other rights of any third party.

- By submitting a video to this contest, contestants grant a royalty-free license to ASPR to copy, distribute, modify, display and perform publicly and otherwise use, and authorize others to use, your video for any educational purpose throughout the world and in any media.

- By submitting a video to this contest, contestants agree that the MRC and ASPR may make your video available to the public from their Web sites (<https://mrc.hhs.gov> and <http://www.phe.gov>) and to distribute it to organizations interested in showing it for educational purposes. That includes, but is not limited to, internet sites, conferences and events, and television and other media outlets.

- Contestants must agree that if your video is selected as a winner that you are willing to submit a digital file of the video for the above mentioned purposes.

- Contestants must agree to follow applicable local, state, and federal laws, regulations, and policies.

- ASPR reserves the right, in its sole discretion, to cancel, suspend, or otherwise modify the challenge, or not award prizes if no entries are deemed worthy.

- Contestants must comply with these terms and conditions of these rules.

**Submission Topic:** All video submissions should answer one of three questions: "Why I/we volunteer with the MRC?", "How does the MRC make my community healthier?", "How does the MRC make my community more prepared and resilient?".

**Judges and Winner Selection:** Submissions will be judged by a panel of MRC and other ASPR staff, qualified by training and experience, to evaluate submissions on the identified criteria and select the semifinalists. Judges will rate the semi-finalists based upon the judging criteria. Judges will be fair and

impartial, may not have a personal or financial interest in, or be an employee, officer, director, or agent of, any entity that is a registered participant in the competition, and may not have a familial or financial relationship with an individual who is a registered contestant. ASPR staff will select the final winners by calculating the final scores.

**Judging Criteria:** Submissions will be scored by the challenge reviewers using the following criteria:

- Clear and consistent message/Overall impact (35 percent): Is the story clear, educational, inspiring, and persuasive? Does it motivate others to serve as MRC volunteers? Is it clear how the MRC impacts their community?

- Creativity and originality (25 percent): How creatively does the video answer the challenge question? How original is the idea?

- Production quality (25 percent): Does the video effectively use lighting, sound, and editing to tell the story? Is the dialogue clear and easy to understand? Do visual effects (if any) contribute to the message or detract from it?

- MRC Identity (15 percent): Does the video do a good job of promoting the MRC brand by showing the trademarked logo or names Medical Reserve Corps and MRC?

**Winners and Recognition:** There will be one winner selected for each category for a total of up to three winners. If you are selected as a winner, you will need to submit your digital video file to the MRC Program. The winners will be announced no later than September 30, 2016, on the MRC Program's listservs, Web site, and social media channels. Winning videos will be recognized on the MRC Program's Web site and social media and may also be posted to the ASPR Web site and social media. Winners will be invited to attend the 2017 Preparedness Summit where they will be recognized by MRC Program leadership and have their travel, lodging, and expenses covered. For group submissions that win, an invitation will be extended to one representative from the group who will be eligible to receive travel, lodging, and costs to attend the 2017 Preparedness Summit.

**Publicity:** Except where prohibited, participation in the challenge constitutes the winner's consent to use the winner's name, likeness, photograph, voice, opinions, and/or hometown and state information by ASPR and the MRC Program in any media without further payment or consideration.

**Intellectual Property:** By submitting an entry to the challenge, each contestant/submitter warrants that he or she is the sole author and owner of any copyrightable works that the entry comprises (or has obtained sufficient rights in any copyrightable works owned by third parties to satisfy its obligations set forth herein), that the works are wholly original with the contestant/submitter, and that the entry does not infringe any copyright or any other rights of any third party of which contestant/submitter is aware.

To receive an award, contestant/submitter will not be required to transfer their intellectual property rights to ASPR or the MRC Program. Each contestant/submitter retains title to their entry, and expressly reserves all intellectual property rights (e.g., copyrights and rights to inventions and patents that cover them) in their entry. By participating in the challenge, each contestant/submitter grants to the federal government a nonexclusive, non-transferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the U.S. any invention throughout the world owned or controlled by the contestant/submitter that covers the entry, and grants to the U.S. government and others acting on behalf of the U.S. government, a royalty-free, irrevocable, non-exclusive worldwide license to use, reproduce, and display publicly all parts of the entry for the purposes of the challenge. This license includes, without limitation, posting or linking to the entry on the ASPR, MRC, and official Challenge Web sites. Contestants/submitters are free to discuss their entry and the ideas or technologies that it contains with other parties, encouraged to share ideas/technologies publicly, and free to contract with any third parties, as long as they do not sign any agreement or undertake any obligation that conflicts with the challenge rules set forth herein.

**Liability:** By participating in this challenge, each contestant/submitter agrees to assume any and all risks and waive claims against the federal government and its related entities (as defined in the America COMPETES Act), the challenge's expert advisors and judges, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this challenge, whether the injury, death, damage, or loss arises through negligence or otherwise. By participating in this challenge, each contestant/submitter agrees to indemnify the federal government

against third party claims for damages arising from or related to challenge activities.

**Insurance:** Based on the subject matter of the challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, or property damage, or loss potentially resulting from competition participation, contestants are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this challenge.

**Warranties:** By submitting an entry to the challenge, each contestant/submitter represents and warrants that all information provided in the entry and as a result of the challenge registration process is true and complete, that contestant/submitter has the right and authority to submit such entry on the contestant's/submitter's own behalf or on behalf of the persons and entities specified within the entry, and that the entry:

- Is your original work, or is submitted by permission with full and proper credit given within your entry;
- Does not contain confidential information or trade secrets (yours or anyone else's);
- Does not knowingly violate or infringe upon the patent rights, industrial design rights, copyrights, trademarks, rights in technical data, rights of privacy, publicity or other intellectual property or other rights of any person or entity;
- Does not contain malicious code, such as viruses, malware, timebombs, cancelbots, worms, Trojan horses, or other potentially harmful programs or other material or information.

**General Conditions:** ASPR reserves the right to cancel, suspend, and/or modify this challenge at any time. In the event the challenge is modified, contestants/submitters registered in the challenge will be notified by email and provided with a copy of the amended challenge rules and a listing of the changes that were made. Any contestant/submitter who continues to participate in the challenge following receipt of such a notice of amendment(s) will be deemed to have accepted any such amendment(s). If a contestant/submitter does not wish to continue to participate in the challenge pursuant to the Official Rules, as amended, such contestant/submitter may terminate participation in the challenge by not submitting additional entries or withdrawing their submission. ASPR reserves the right to not award prizes if no entries are deemed worthy. Only complete entries that follow application instructions will be reviewed and

eligible to win. ASPR reserves the right to disqualify any challenge participants in instances where misconduct is identified or other contest guidelines are not met.

Dated: July 28, 2016.

**Nicole Lurie,**

*Assistant Secretary for Preparedness and Response.*

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**BILLING CODE 4**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection [1651-0027]

#### Agency Information Collection Activities: Record of Vessel Foreign Repair or Equipment Purchase

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

**ACTION:** 60-Day notice and request for comments; extension of an existing collection of information.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Record of Vessel Foreign Repair or Equipment Purchase (CBP Form 226). CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

**DATES:** Written comments should be received on or before October 3, 2016 to be assured of consideration.

**ADDRESSES:** All submissions received must include the OMB Control Number 1651-0027 in the subject box, the agency name. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Email.* Submit comments to: [CBP\\_PRA@CBP.DHS.GOV](mailto:CBP_PRA@CBP.DHS.GOV), email should include OMB Control number in Subject.

(2) *Mail.* Submit written comments to CBP PRA Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 10th Floor, 90 K St NE., Washington, DC 20229-1177.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional PRA information should be directed to Paperwork Reduction Act Officer, U.S. Customs

and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229-1177, or via telephone (202) 325-0123. Please note contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs please contact the CBP National Customer Service Center at 877-227-5511, (TTY) 1-800-877-8339, or CBP Web site at <https://www.cbp.gov/>. For additional help: <https://help.cbp.gov/app/home/search/1>.

**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). 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 cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

*Title:* Record of Vessel Foreign Repair or Equipment Purchase.

*OMB Number:* 1651-0027.

*Form Number:* CBP Form 226.

*Abstract:* 19 U.S.C. 1466(a) provides for a 50 percent *ad valorem* duty assessed on a vessel master or owner for any repairs, purchases, or expenses incurred in a foreign country by a commercial vessel registered in the United States. CBP Form 226, Record of Vessel Foreign Repair or Equipment Purchase, is used by the master or owner of a vessel to declare and file entry on equipment, repairs, parts, or materials purchased for the vessel in a foreign country. This information enables CBP to assess duties on these foreign repairs, parts, or materials. CBP Form 226 is provided for by 19 CFR 4.7 and 4.14 and is accessible at: <https://www.cbp.gov/document/forms/form-226-record-vessel-foreign-repair-or-equipment-purchase>.