public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0922 for ''What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover 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.

Submit written requests for single copies of the SECG to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Jeanette Murphy, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20800, 240–402–6246.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 17, 2015 (80 FR 56170), we issued a final rule entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' (the final rule) in which we established requirements for facilities subject to food registration to implement current good manufacturing practices and establish and implement hazard analysis and risk-based preventive controls for food for animals. The final rule, which is codified at part 507 (21 CFR part 507), became effective November 16, 2015 (except for paragraph (2) of the definition of ''qualified auditor'' in § 507.3, and §§ 507.12(a)(1)(ii), 507.105(a)(2), 507.105(c), 507.110(d)(2)(ii), 507.130(d), 507.135(d), 507.175(c)(2), and 507.175(c)(13)) but has compliance dates staggered over several years after publication of the final rule.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28), we are making available the SECG to explain the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft 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 part 507 have been approved under 0910–0789.

III. Electronic Access

Persons with access to the Internet may obtain the SECG at *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm,* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: October 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26314 Filed 10–31–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2016–0936]

Safety Zone; Delaware River, Philadelphia, PA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce regulations for a safety zone for an annual fireworks event in the Captain of the Port Delaware Bay zone from 6 p.m. to 8 p.m. on November 19, 2016. Enforcement of this zone is necessary and intended to ensure safety of life on

the navigable waters immediately prior to, during, and immediately after this fireworks event. During the enforcement period, no vessel may transit this regulated area without approval from the Captain of the Port or a designated representative.

DATES: The regulations in 33 CFR 165.506 will be enforced from 6 p.m. to 8 p.m. on November 19, 2016, for the safety zone identified in row (a)(16) of Table to § 165.506.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email MST1 Thomas Simkins, Sector Delaware Bay Waterways Management Division, U.S. Coast Guard; telephone 215–271–4889, email *Tom.J.Simkins@uscg.mil.*

SUPPLEMENTARY INFORMATION:

From 6 p.m. to 8 p.m. on November 19, 2016, the Coast Guard will enforce regulations in 33 CFR 165.506 for the safety zone in the Delaware River in Philadelphia, PA listed in row (a)(16) in the table in that section. This action is being taken to provide for the safety of life on navigable waterways during the fireworks display.

Our regulations for recurring firework events in Captain of the Port Delaware Bay Zone, appear in § 165.506, Safety Zones; Fireworks Displays in the Fifth Coast Guard District, which specifies the location of the regulated area for this safety zone as all waters of Delaware River, adjacent to Penn's Landing, Philadelphia, PA, bounded from shoreline to shoreline, bounded on the south by a line running east to west from points along the shoreline at latitude 39°56′31.2″ N., longitude 075°08′28.1″ W.; thence to latitude 39°56′29″ .1 N., longitude 075°07′56.5″ W., and bounded on the north by the Benjamin Franklin Bridge.

As specified in § 165.506, during the enforcement period no vessel may transit this safety zone without approval from the Captain of the Port Delaware Bay. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

This notice of enforcement is issued under authority of 33 CFR 165.506 and 5 U.S.C. 552(a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advanced notification of this enforcement period via Broadcast Notice to Mariners (BNM).

If the Captain of the Port Delaware Bay determines that the regulated area need not be enforced for the full duration, a BNM to grant general permission to enter the safety zone may be used.

Dated: October 27, 2016.

Benjamin A. Cooper,

Captain, U.S. Coast Guard, Captain of the Port Delaware Bay.

[FR Doc. 2016–26342 Filed 10–31–16; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

U.S. Copyright Office

37 CFR Part 201

[Docket No. RM 2011–6]

Designation of Agent To Receive Notification of Claimed Infringement

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: Under the Digital Millennium Copyright Act (''DMCA''), the U.S. Copyright Office is required to maintain a ''current directory'' of agents that have been designated by online service providers to receive notifications of claimed infringement. Since the DMCA's enactment in 1998, online service providers have designated agents with the Copyright Office using the Office's or their own paper form, and the Office has made scanned copies these filings available to the public by posting them on the Office's Web site. Although the DMCA requires service providers to update their designations with the Office as information changes, an examination of the Office's current directory reveals that many have failed to do so, and that much of the information currently contained in the directory has become inaccurate and out of date. On September 28, 2011, the Office issued a notice of proposed rulemaking to update relevant regulations in anticipation of creating a new electronic system through which service providers would be able to more efficiently submit, and the public would be better able to search for, designated agent information. On May 25, 2016, with the electronic system in its final stages of development, the Office issued a notice of proposed rulemaking proposing significantly lower fees for designating agents through the forthcoming online system. As the next step in implementation, the Office today announces the adoption of a final rule to govern the designation and maintenance of DMCA agent information under the new electronic system and to establish the applicable fees.

DATES: Effective December 1, 2016.

FOR FURTHER INFORMATION CONTACT: Sarang V. Damle, General Counsel and Associate Register of Copyrights, by email at *sdam@loc.gov,* or Jason E. Sloan, Attorney-Advisor, by email at *jslo@loc.gov.* Each can be contacted by telephone by calling (202) 707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

In 1998, Congress enacted section 512 of title 17, United States Code, as part of the Digital Millennium Copyright Act (''DMCA'').[1] Among other things, section 512 provides safe harbors from copyright infringement liability for online service providers that are engaged in specified activities and that meet certain eligibility requirements.[2] A service provider seeking to avail itself of the safe harbor in section 512(c) (for storage of material at the direction of a user) is required to designate an agent to receive notifications of claimed copyright infringement by making contact information for the agent available to the public on its Web site, and by providing such information to the Copyright Office.[3] The safe harbors in subsections 512(b) (for system caching) and (d) (for information location tools) incorporate the notice provisions of section 512(c) and thus also require that notices of infringement be sent to ''the designated agent of a service provider'' [4]—that is, an agent that has been designated by the service provider as described above.[5]

The language of section 512(c)(2) makes clear that a service provider must maintain the same contact information required under section 512(c)(2)(A) and (B) both on its Web site and at the Copyright Office.[6] A service provider that fails to maintain current and accurate information, both on its Web site and with the Office, may not satisfy the statutory requirements necessary for

[1] Public Law 105–304, 112 Stat. 2860 (1998).

[2] 17 U.S.C. 512.

[3] *Id.* at 512(c)(2).

[4] *Id.* at 512(c)(3)(A).

[5] *See id.* at 512(b)(2)(E), (d)(3).

[6] 63 FR 59233, 59234 (Nov. 3, 1998) (''[A] service provider designates an agent by providing information required by Copyright Office regulations both on its publicly available Web site and in a filing with the Copyright Office.''); *see also BWP Media USA Inc.* v. *Hollywood Fan Sites LLC,* 115 F. Supp. 3d 397, 403 (S.D.N.Y. 2015) (''[T]he statutory scheme expressly requires two publicly available, parallel sources of a service provider's DMCA agent information (the service provider's Web site and the [Copyright Office] directory) in order for that provider to be shielded by the § 512(c) safe harbor.''); 4 Melville Nimmer & David Nimmer, Nimmer on Copyright 12B.04[B][3] (2015) (''Nimmer on Copyright'') (''In addition to providing the foregoing information to the Copyright Office, the service provider must provide the same information to the public.'').