

Management (ICH)," June 2006 (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073511.pdf>), and FDA's guidances for industry entitled "PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance," September 2004 (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070305.pdf>), and "Quality Systems Approach to Pharmaceutical CGMP Regulations," September 2006 (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070337.pdf>). Quality-by-design and risk-based approaches are also described in "Q10 Pharmaceutical Quality Systems," April 2009 (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073517.pdf>).

The agency's Office of New Drug Quality Assessment in OPS, CDER, initiated a pilot program (70 FR 40719, July 14, 2005) to gain experience in assessing CMC sections of new drug applications (NDAs) that demonstrate an applicant's product knowledge and process understanding at the time of submission. This pilot was extremely useful in helping identify appropriate information to be shared regarding quality-by-design for small molecules. Although many of the principles of quality-by-design apply equally to small molecules and more complex pharmaceuticals, the ability to assess relevant attributes is a much greater challenge for complex pharmaceuticals.

Because the pilot program initiated in 2005 proved constructive, on July 2, 2008, FDA announced this pilot program to provide additional information to FDA for use in facilitating quality-by-design, risk-based approaches for complex molecules. Based on experience gained during the pilot program and prior knowledge, FDA will develop procedures to facilitate implementing a quality-by-design, risk-based approach for complex products. In addition, the experience gained by FDA under this pilot is expected to facilitate the development of guidance for industry. The pilot is open to original submissions and postapproval supplements to biologics license applications (BLAs) and NDAs reviewed by the Office of Biotechnology Products (OBP).

The July 2, 2008, notice provided deadlines related to the submission of certain information related to the pilot program. To ensure inclusive and

relevant results from the pilot program, this document extends the deadline for requests to participate in this pilot program for products regulated by OBP from September 30, 2009, to September 30, 2010. Because the deadline for requests to participate in the pilot is being extended, FDA is also extending the application submission deadlines. As explained in the July 2, 2008, notice, it is preferable for original applications to enter the pilot as INDs. FDA is extending the deadline for submission of INDs from March 31, 2010, to March 31, 2011. FDA is also extending the deadline for submission of postapproval supplements from March 31, 2010, to March 31, 2011. In addition, the pilot is being expanded from five to eight original applications for products reviewed by OBP (BLA or NDA) in Common Technical Document format, paper or electronic. See the July 2, 2008, notice for instructions on submitting requests to participate in the pilot program and additional information regarding the pilot program.

Dated: September 11, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-22378 Filed 9-16-09; 8:45 am]

BILLING CODE 4160-01-S

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Draft Program Comment for the National Telecommunications and Information Administration and the U.S. Department of Agriculture's Rural Utilities Service Regarding the Effects of Communication Facilities Construction or Modification Subject To Review by the Federal Communications Commission

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of Intent to Issue Program Comments for the National Telecommunications and Information Administration and the U.S. Department of Agriculture's Rural Utilities Service Regarding the Effects of Communication Facilities Construction or Modification Subject to Review by the Federal Communications Commission.

SUMMARY: The Advisory Council on Historic Preservation (ACHP) is considering issuing a Program Comment for the National Telecommunications and Information Administration and the U.S. Department of Agriculture's Rural Utilities Service that would relieve them of the need to conduct a separate Section 106 review regarding the effects

of communication facilities construction or modification that will be subject to such review by the Federal Communications Commission. The ACHP seeks public input on the proposed Program Comment.

DATES: Submit comments on or before October 8, 2009.

ADDRESSES: Address all comments concerning this proposed Program Comment to Blythe Semmer, Office of Federal Agency Programs, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., Suite 803, Washington, DC 20004. Fax (202) 606-8647. You may submit electronic comments to: bsemmer@achp.gov.

FOR FURTHER INFORMATION CONTACT: Blythe Semmer, (202) 606-8552, bsemmer@achp.gov; or Laura Dean, PhD, RUS Federal Preservation Officer, (202) 720-9634, laura.dean@wdc.usda.gov.

SUPPLEMENTARY INFORMATION: Section 106 of the National Historic Preservation Act requires federal agencies to consider the effects of their undertakings on historic properties and to provide the Advisory Council on Historic Preservation (ACHP) a reasonable opportunity to comment with regard to such undertakings. The ACHP has issued the regulations that set forth the process through which Federal agencies comply with these duties. Those regulations are codified under 36 CFR part 800 (Section 106 regulations).

Under Section 800.14(e) of those regulations, agencies can request the ACHP to provide a "Program Comment" on a particular category of undertakings in lieu of conducting individual reviews of each individual undertaking under such category, as set forth in 36 CFR 800.4 through 800.7.

The ACHP is now considering issuing a Program Comment to the National Telecommunications and Information Administration (NTIA) and the U.S. Department of Agriculture's Rural Utilities Service (RUS) that would relieve them of the need to conduct a separate Section 106 review regarding the effects of communication facilities construction or modification that will be subject to such review by the Federal Communications Commission (FCC).

I. Background

On February 17, 2009, President Obama signed the American Recovery and Reinvestment Act of 2009 (Recovery Act) into law. The Recovery Act provides the NTIA and the RUS with \$7.2 billion to expand access to broadband services in the United States. In implementing this responsibility, NTIA, through its Broadband

Technology Opportunities Program (BTOP), will award grants to expand public computer capacity, encourage sustainable adoption of broadband service and deploy broadband infrastructure to unserved and underserved areas. RUS, through its Broadband Initiatives Program (BIP), will use loan and grant combinations to support broadband deployment in rural communities.

Technological solutions available to speed the deployment of affordable broadband under those programs are diverse and include the construction and modification of communications towers and antennas. Some of those communication towers and antennas will be regulated by the FCC. For such proposals that are regulated by the FCC and assisted by RUS and/or NTIA, each agency would be individually responsible for compliance with Section 106.

The FCC, ACHP, and the National Conference of State Historic Preservation Officers (NCSHPO) have executed the Nationwide Programmatic Agreement for Review of Effects on Historic Properties For Certain Undertakings Approved by the FCC (FCC Nationwide PA) and the Nationwide Programmatic Agreement for the Collocation of Wireless Antennas (FCC Collocation PA) to govern how FCC meets its Section 106 responsibilities for certain undertakings, including communication towers and antennas. In implementing the terms of those programmatic agreements, FCC has established a procedure that is supported by innovative approaches that expedite review and facilitate the involvement of stakeholders, most notably Indian tribes, to ensure that effects to historic properties are taken into account.

Currently, it is not possible for RUS and NTIA to benefit from the implementation of those programmatic agreement solutions in meeting their individual Section 106 responsibilities, because the FCC Nationwide PA stipulates that it does not govern the Section 106 responsibilities of any federal agency other than the FCC. This means that FCC, RUS and NTIA must each conduct separate Section 106 reviews for the same proposed undertaking. Such an approach does not seem to be efficient, particularly within the context of the compressed schedules established by the Recovery Act. Accordingly, pursuant to 36 CFR 800.14(e), NTIA and RUS have requested the ACHP to issue a program comment that removes their requirement to comply with Section 106 with regard to the effects of

communications facilities construction or modification that has undergone, will undergo, or is exempt from, Section 106 review by the FCC under the cited FCC programmatic agreements.

Under the Recovery Act, all NTIA and RUS grants and loans must be awarded by September 30, 2010. Construction of proposals receiving awards must be complete within three years of the award. Recovery Act responsibilities of NTIA and RUS, therefore, will extend to 2013. In order to accommodate for currently unknown contingencies, RUS and NTIA have requested that the effective termination of the proposed program comment be extended to September 30, 2015.

RUS and NTIA have informed the ACHP that, prior to their formal request, they sought to share their intent to develop this program comment with the following historic preservation, tribal, and telecommunications industry organizations: National Trust for Historic Preservation, NCSHPO, American Cultural Resources Association, National Association of Tribal Historic Preservation Officers (NATHPO), United South and Eastern Tribes (USET), National Congress of American Indians, Affiliated Tribes of Northwest Indians, Office of Hawaiian Affairs (OHA), CTIA The Wireless Association, PCIA—The Wireless Infrastructure Association, and the Association of Public Safety Communications Officials. RUS and NTIA discussed this proposal with all of the listed parties except OHA, and reported that, in general, those organizations contacted were supportive, noting that this approach represented a common sense solution. In addition to those parties, NTIA and RUS have worked closely with the FCC throughout the development of the proposed program comment.

RUS and NTIA also reported that several parties expressed concern that the proposed program comment would alter or modify the FCC Nationwide PA. That is not the intent of the proposed program comment and a statement to that effect has been included in the proposal itself.

RUS and NTIA anticipate that BTOP/EIP applications will not consist solely of tower construction and modification. Accordingly, they have clarified the applicability of the program comment for multi-component proposals.

NCSHPO was concerned about how this program comment would affect existing agreements. If, under the program comment, RUS and NTIA are not responsible for compliance with Section 106 for FCC regulated towers,

then the trigger for existing agreements has been removed.

USET explained to RUS and NTIA that it did not support expansion of the scope of the proposed program comment to all federal agencies. Accordingly, the proposal submitted to the ACHP applies to only NTIA and RUS. Finally, USET expressed concern that this process is being rushed and, as a consequence, tribes will not be allowed sufficient time to consult with agencies. However, the congressionally mandated Recovery Act schedules argue for an expedited process.

III. Text of the proposed Program Comment

The text of the proposed Program Comment is included below:

Program Comment for Streamlining Section 106 Review for Wireless Communication Facilities Construction and Modification Subject To Review Under the FCC Nationwide Programmatic Agreement and/or the Nationwide Programmatic Agreement for the Collocation of Wireless Antennas

I. Background: The Rural Utilities Service (RUS) and the National Telecommunications and Information Administration (NTIA) provide financial assistance to applicants for broadband deployment, which can involve the construction and placement of communications towers and antennas, and therefore RUS and NTIA must comply with Section 106 of the National Historic Preservation Act, 16 U.S.C. 470f, and its implementing regulations at 36 CFR part 800 (Section 106). Some of those communications towers and antennas are also regulated by the Federal Communications Commission (FCC), and therefore undergo, or are exempted from, Section 106 review under the Nationwide Programmatic Agreement for Review of Effects on Historic Properties for Certain Undertakings Approved by the FCC (FCC Nationwide PA) and the Nationwide Programmatic Agreement for the Collocation of Wireless Antennas (FCC Collocation PA). The FCC Nationwide PA was executed by the FCC, the Advisory Council on Historic Preservation (ACHP), and the National Conference of State Historic Preservation Officers (NCSHPO) on October 4, 2004. The FCC Collocation PA was executed by the FCC, ACHP, and NCSHPO on March 16, 2001. The undertakings addressed by the FCC Nationwide PA primarily include the construction and modification of communication towers. The undertakings addressed by the FCC

Collocation PA include the collocation of communications equipment on existing structures and towers.

This Program Comment is intended to streamline Section 106 review of the construction and modification of communication towers and antennas for which FCC and RUS or NTIA share Section 106 responsibility.

Nothing in this Program Comment alters or modifies the FCC Nationwide PA or the FCC Collocation PA, or imposes Section 106 responsibilities on the FCC for elements of an RUS or NTIA undertaking that are unrelated to a communications facility within the FCC's jurisdiction or are beyond the scope of the FCC Nationwide PA.

II. Establishment and Authority: This Program Comment was issued by the ACHP on (date to be determined) pursuant to 36 CFR 800.14(e).

III. Date of Effect: This Program Comment went into effect on (date to be determined).

IV. Use of this Program Comment to Comply with Section 106 for the Effects of Facilities Construction or Modification Reviewed under the FCC Nationwide PA and/or the FCC Collocation PA: RUS and NTIA will not need to comply with Section 106 with regard to the effects of communication facilities construction or modification that has either undergone or will undergo Section 106 review, or is exempt from Section 106 review, by the FCC under the FCC Nationwide PA and/or the FCC Collocation PA. For purposes of this program comment, review under the FCC Nationwide PA means the historic preservation review that is necessary to complete the FCC's Section 106 responsibility for an undertaking that is subject to the FCC Nationwide PA.

When an RUS or NTIA undertaking includes both communications facilities construction or modification covered by the FCC Nationwide PA or Collocation PA and components in addition to such communication facilities construction or modification, RUS and NTIA will comply with Section 106 in accordance with the process set forth at 36 CFR 5 800.3 through 800.7, or 36 CFR 800.8(c), or another applicable alternate procedure under 36 CFR 800.14, but will not have to consider the effects of the communication facilities construction or modification component of the undertaking on historic properties. Whenever RUS or NTIA uses this Program Comment for such undertakings, RUS or NTIA will apprise the relevant State Historic Preservation Officer (SHPO) or Tribal Historic Preservation Officer (THPO) of the use of this Program Comment for the

relevant communication facilities construction or modification component.

V. Amendment—The ACHP may amend this Program Comment after consulting with FCC, RUS, NTIA and other parties as appropriate, and publishing notice in the **Federal Register** to that effect.

VI. Sunset Clause—This Program Comment will terminate on September 30, 2015, unless it is amended to extend the period in which it is in effect.

VII. Termination—The ACHP may terminate this Program Comment by publication of a notice in the **Federal Register** thirty (30) days before the termination takes effect.

Authority: 36 CFR 800.14(e).

Dated: September 10, 2009.

John M. Fowler,

Executive Director.

[FR Doc. E9-22273 Filed 9-16-09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0744]

Certificate of Alternative Compliance for the Offshore Supply Vessel TYLER STEPHEN

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that a Certificate of Alternative Compliance was issued for the offshore supply vessel *Tyler Stephen* as required by 33 U.S.C. 1605(c) and 33 CFR 81.18.

DATES: The Certificate of Alternative Compliance was issued on July 29, 2009.

ADDRESSES: The docket for this notice is available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2009-0744 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call CWO2 David Mauldin, District Eight, Prevention Branch, U.S. Coast Guard, telephone 504-671-2153. If you have questions on viewing or submitting material to the docket, call Renee V.

Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The offshore supply vessel *Tyler Stephen* will be used for offshore supply operations. Full compliance with 72 COLREGS and the Inland Rules Act will hinder the vessel's ability to maneuver within close proximity of offshore platforms. Due to the design of the vessel, it would be difficult and impractical to build a supporting structure that would put the side lights within 5.4' from the greatest breadth of the Vessel, as required by Annex I, paragraph 3(b) of the 72 COLREGS and Annex I, Section 84.05(b), of the Inland Rules Act. Compliance with the rule would cause the lights on the offshore supply vessel *Tyler Stephen* to be in a location which will be highly susceptible to damage from offshore platforms. The offshore supply vessel *Tyler Stephen* cannot comply fully with lighting requirements as set out in international regulations without interfering with the special function of the vessel (33 U.S.C. 1605(c); 33 CFR 81.18).

Locating the side lights 6'-9⁵/₈" inboard from the greatest breadth of the vessel on the pilot house will provide a shelter location for the lights and allow maneuvering within close proximity to offshore platforms.

In addition, the horizontal distance between the forward and aft masthead lights may be 23'-1¹/₈". Placing the aft masthead light at the horizontal distance from the forward masthead light as required by Annex I, paragraph 3(a) of the 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act, would result in an aft masthead light location directly over the aft cargo deck, where it would interfere with loading and unloading operations.

The Certificate of Alternative Compliance allows for the placement of the side lights to deviate from requirements set forth in Annex I, paragraph 3(b) of 72 COLREGS, and Annex I, paragraph 84.05(b) of the Inland Rules Act. In addition the Certificate of Alternative Compliance allows for the horizontal separation of the forward and aft masthead lights to deviate from the requirements of Annex I, paragraph 3(a) of 72 COLREGS, and Annex I, Section 84.05(a) of the Inland Rules Act.

This notice is issued under authority of 33 U.S.C. 1605(c), and 33 CFR 81.18.