office 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Food Safety (HFS–300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *For questions relating to the guidance as it applies to human food:* Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2166.

For questions relating to the guidance as it applies to animal food: Jeanette Murphy, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6246.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Guidance for Industry.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). This guidance 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. This guidance is not subject to Executive Order 12866.

In the **Federal Register** of May 16, 2016 (81 FR 30219), we made available a draft guidance for industry entitled ''Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)'' and gave interested parties an opportunity to submit comments by November 14, 2016, for us to consider before beginning work on the final version of the guidance. We received a couple of comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include: (1) Clarification regarding recordkeeping and FDA review of records, (2) clarification regarding how a facility can meet the definition of a ''very small business,'' (3) addition of new examples of calculations, and (4) explanation of a simpler method for determining whether a facility's 3-year average of food sales and food market value is below the inflation adjusted threshold for a ''very small business.'' In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated May 16, 2016.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 21 CFR 117.201 and 507.7 have been approved under 0910–0854.

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 117 have been approved under OMB control number 0910–0751. The collections of information in part 507 have been approved under OMB control number 0910–0789.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA 2016: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Instructions for Submitting Your Attestation. Accessible at: *https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm.*
2. FDA 2017: Form FDA 3942a. Accessible at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsAlphabetically/default.htm.*
3. FDA 2017: Form FDA 3942b. Accessible at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsAlphabetically/default.htm.*

Dated: September 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20109 Filed 9–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0761]

Drawbridge Operation Regulation; James River, Isle of Wight and Newport News, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the US 17/US 258/SR 32/James River Bridge, which carries US 17, US 258, and SR 32, across the James River, mile 5.0, between Isle of Wight and Newport News, VA. The deviation is necessary to facilitate bridge maintenance. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: The deviation is effective from 7 a.m. on September 26, 2018, through 12:01 a.m. on September 28, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0761 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Michael Thorogood, Bridge Administration Branch Fifth District, Coast Guard; telephone 757–398–6557, email *Michael.R.Thorogood@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Virginia Department of Transportation, owner and operator of the U.S. 17/U.S. 258/SR 32/James River Bridge which carries U.S. 17, U.S. 258, SR 32, across the James River, mile 5.0, between Isle of Wight and Newport News, VA, has requested a temporary deviation from the current operating schedule to facilitate replacement of a rotary cam limit switch in the span drive system of the vertical lift span of the drawbridge. The bridge has a vertical clearance of 60 feet above mean high water in the closed position and 145 feet above mean high water in the open position.

The current operating schedule is set out in 33 CFR 117.5. Under this temporary deviation, the bridge will be in the closed-to-navigation position from 7 a.m. on September 26, 2018, through 12:01 a.m. on September 28, 2018.

The James River is used by a variety of vessels including deep draft ocean-going vessels, U.S. government and public vessels, small commercial vessels, tug and barge traffic, and recreational vessels. The Coast Guard has carefully coordinated the restrictions with waterway users in publishing this temporary deviation.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will not be able to open for emergencies and there is no immediate alternative route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterway through our Local Notice and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 11, 2018.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2018–20067 Filed 9–14–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2017–0542; FRL–9983–75—Region 4]

Air Plan Approval; Tennessee: Knox County NSR Reform

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing approval of several Tennessee State Implementation Plan (SIP) revisions submitted by the Tennessee Department of Environment & Conservation (TDEC), on behalf of Knox County's Air Quality Management Division, through letters dated March 7, 2017, and April 17, 2017. The SIP revisions modify the Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) regulations in the Knox County portion of the Tennessee SIP to address changes to the federal new source review (NSR) regulations in recent years for the implementation of the national ambient air quality standards (NAAQS). Additionally, the SIP revisions include updates to Knox County's minor source permitting regulations. This action is being approved pursuant to the Clean Air Act (CAA or Act).

DATES: This rule will be effective October 17, 2018.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2017–0542. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Andres Febres of the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8966. Mr. Febres can also be reached via electronic mail at *febres-martinez.andres@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What action is EPA taking?

EPA is finalizing approval of changes to the Knox County portion of the Tennessee SIP regarding PSD and NNSR permitting, as well as updates to minor NSR, submitted by TDEC on behalf of Knox County's Air Quality Management Division.

On March 7, 2017, Tennessee submitted two SIP revisions updating Knox County's Air Quality Management Regulations, Section 41.0 entitled ''Regulations for the Review of New Sources,'' and Section 45.0 entitled ''Prevention of Significant Deterioration.'' [1] On April 17, 2017, Tennessee submitted two additional SIP revisions, including additional changes to Section 41, and updates to Section 25.0 entitled ''Permits.'' [2] These SIP revisions are meant to address changes to the federal NSR regulations, as

[1] EPA notes that the Agency may not have received the submittal on this date, which is the date of the State submittal's cover letter.

[2] EPA notes that the Agency may not have received the submittal on this date, which is the date of the State submittal's cover letter.