

Country	Entity	License requirement	License review policy	Federal Register citation
	d. 15 str. 2 ul. Novy Arbat, Moscow 119019, Russia. *	*	*	*
	Transservice LLC, a.k.a., the following three aliases: —Limited Liability Company Transservis; —Obschestvo S Ogranichennoi Otvetstvennostyu Transservis; and —OOO Transservis. 35 Prospekt Gubkina, Omsk, Omskaya Oblast 664035, Russia. *	For all items subject to the EAR. (See § 744.11 of the EAR)	Presumption of denial	80 FR [INSERT FR PAGE NUMBER]; 12/28/2015.
	*	*	*	*
SWITZERLAND	*	*	*	*
	LTS Holding Limited (f.k.a. IPP-International Petroleum Products Ltd.), Rue du Conseil-General 20, Geneva 1204, Switzerland. (See alternate address under United Kingdom). *	For all items subject to the EAR. (See § 744.11 of the EAR). *	Presumption of denial .....	80 FR [INSERT FR PAGE NUMBER]; 12/28/2015. *
	*	*	*	*
UNITED KINGDOM.	*	*	*	*
	Fentex Properties LTD., Tortola, British Virgin Islands. *	For all items subject to the EAR. (See § 744.11 of the EAR). *	Presumption of denial .....	80 FR [INSERT FR PAGE NUMBER]; 12/28/2015. *
	LTS Holding Limited (f.k.a. IPP-International Petroleum Products Ltd.), Tortola, British Virgin Islands. (See alternate address under Switzerland). *	For all items subject to the EAR. (See § 744.11 of the EAR). *	Presumption of denial .....	80 FR [INSERT FR PAGE NUMBER]; 12/28/2015. *

Dated: December 22, 2015.

**Eric L. Hirschhorn,**

*Under Secretary of Commerce for Industry and Security.*

[FR Doc. 2015-32607 Filed 12-24-15; 8:45 am]

**BILLING CODE 3510-33-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 606 and 610**

[Docket No. FDA-1999-N-0114 (formerly 1999N-2337)]

**RIN 0910-AB76**

**Hepatitis C Virus “Lookback” Requirements Based on Review of Historical Testing Records; Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the biologics regulations by removing the Hepatitis C Virus (HCV) “lookback” requirements regarding review of

historical testing records. FDA is taking this action because the HCV “lookback” regulations based on review of historical testing records expired on August 24, 2015, due to the sunset provision provided under the regulation.

**DATES:** This rule is December 28, 2015.

**FOR FURTHER INFORMATION CONTACT:** Gretchen Opper, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 24, 2007 (72 FR 48766), FDA published a final rule entitled “Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting Hepatitis C Virus Infection (‘Lookback’).” Under

§ 610.48 (21 CFR 610.48) of the final rule, FDA established HCV “lookback” requirements based on review of historical testing records. The requirements under § 610.48 were to remain in effect for 8 years after the date of publication of the final rule in the **Federal Register** (§ 610.48(e)). Section 610.48(e) specifically provides that the section expired on August 24, 2015; therefore, FDA is removing this regulation from Title 21 of the Code of Federal Regulations.

FDA is also making conforming changes to other biologics regulations where § 610.48 is referenced.

FDA is revising the biologics regulations as follows:

- Removing and reserving § 610.48.
- Revising § 606.100(b)(19) (21 CFR 606.100(b)(19)) by removing the reference to § 610.48.
- Revising § 606.160(b)(1)(viii) by removing the reference to § 610.48.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comments are unnecessary because the amendments to the regulations provide only technical changes to remove and update information and are nonsubstantive.

#### List of Subjects

##### 21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

##### 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 606 and 610 are amended as follows:

#### **PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS**

- 1. The authority citation for 21 CFR part 606 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

#### **§ 606.100 [Amended]**

- 2. Amend § 606.100(b)(19) introductory text by removing “§§ 610.46, 610.47, and 610.48” and adding in its place “§§ 610.46 and 610.47”.

#### **§ 606.160 [Amended]**

- 3. Amend § 606.160(b)(1)(viii) by removing “§§ 610.46, 610.47, and, 610.48” and adding in its place “§§ 610.46 and 610.47”.

#### **PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS**

- 4. The authority citation for 21 CFR part 610 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

#### **§ 610.48 [Removed and Reserved]**

- 5. Remove and reserve § 610.48.

Dated: December 21, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–32477 Filed 12–24–15; 8:45 am]

**BILLING CODE 4164–01–P**

#### **DEPARTMENT OF HOMELAND SECURITY**

##### **Coast Guard**

##### **33 CFR Part 165**

[Docket Number USCG–2015–1074]

RIN 1625–AA00

#### **Safety Zone; New Year’s Eve Firework Displays, Chicago River, Chicago, IL**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone that encompasses all waters of the Main Branch of the Chicago River between the Michigan Avenue Highway Bridge and the west entrance to the Chicago Harbor Lock. The safety zone is intended to restrict vessels from a portion of the Main Branch of the Chicago River from 11:30 p.m. on December 31, 2015 to 12:15 a.m. on January 1, 2016. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with multiple barge based firework displays for Chicago’s New Year’s Eve Celebration.

**DATES:** This rule will be effective from 11:30 p.m. on December 31, 2015 to 12:15 a.m. on January 1, 2016.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2015–1074 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email LT Lindsay Cook, Marine Safety Unit Chicago, U.S. Coast Guard; telephone (630) 986–2155, email [Lindsay.N.Cook@uscg.mil](mailto:Lindsay.N.Cook@uscg.mil).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Table of Abbreviations**

CFR Code of Federal Regulations  
DHS Department of Homeland Security  
E.O. Executive order  
FR Federal Register  
NPRM Notice of proposed rulemaking  
Pub. L. Public Law  
§ Section  
U.S.C. United States Code

##### **II. Background Information and Regulatory History**

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. The final details for this event were not known to the Coast Guard until there was insufficient time remaining before the event to publish a NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be impracticable because it would inhibit the Coast Guard’s ability to protect the public and vessels from the hazards associated with multiple barge based firework displays on the Main Branch of the Chicago River.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable.

##### **III. Legal Authority and Need for Rule**

The legal basis for the rule is the Coast Guard’s authority to establish safety zones: 33 U.S.C. 1231; 33 CFR 1.05–1, 160.5; Department of Homeland Security Delegation No. 0170.1.

December 31, 2015 and January 1, 2016 Chicago’s New Year’s Eve firework displays will take place from multiple barge based launch sites on the Main