

not result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year, FDA concluded that the proposed regulation is consistent with the principles of the Unfunded Mandates Reform Act without the need for further analysis.

B. Environmental Impact

The agency has determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. The Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. *American Journal of Epidemiology*, 103:399–407, 1976.
2. *Vox Sanguinis*, 47:7–18, 1984.
3. *Vox Sanguinis*, 47:28–40, 1984.
4. *Metabolism*, 14:1311–1323, 1965.
5. *Canadian Journal of Physiology and Pharmacology*, 45:29–38, 1967.
6. *Journal of Laboratory and Clinical Medicine*, 101:930–939, 1983.
7. *Neurology*, 28:940–944, 1978.
8. *Research in Experimental Medicine*, 189:347–354, 1989.
9. *Journal of Pharmacology and Experimental Therapeutics*, 191:10–16, 1974.
10. *American Journal of Gastroenterology*, 69:187–190, 1978.
11. *European Journal of Biochemistry*, 141:223–230, 1984.
12. *Proceedings of the Society for Experimental Biology and Medicine*, 167:36–39, 1981.
13. *American Journal of Physiology*, 261:H561–H567, 1991.
14. *Biomedica Biochimica Acta*, 45:S45–S50, 1986.
15. *Biochimica et Biophysica Acta*, 1093:125–134, 1991.
16. *Folia Medica*, 34:12–18, 1992.
17. *Pharmaceutical Research*, 8:1365–1371, 1991.
18. *Journal of Pharmaceutical Sciences*, 77:390–392, 1988.
19. *Pediatric Neurology*, 1:20–22, 1985.
20. *Pediatric Neurology*, 1:223–225, 1985.
21. *Thrombosis Research*, 4:479–484, 1974.
22. *Scandinavian Journal of Clinical and Laboratory Investigation*, 35:19–23, 1975.

23. *Metabolism*, 16:482–484, 1967.
24. *American Journal of Physiology*, 234:E162–E167, 1978.
25. *Journal of Physiology*, 356:479–489, 1984.
26. *Journal of Comparative Physiology*, B 166:305–309, 1996.
27. *American Journal of Physiology*, 217:715–719, 1969.
28. *Journal of Reproduction and Fertility*, 23:307–317, 1970.
29. *European Journal of Biochemistry*, 86:519–530, 1978.
30. *Archives of Biochemistry and Biophysics*, 309:254–260, 1994.
31. *American Journal of Physiology*, 231:880–887, 1976.
32. *Biochimica et Biophysica Acta*, 757:111–118, 1983.
33. *Comparative Biochemistry and Physiology*, B 91:339–344, 1988.
34. *Folia Medica*, 35:23–27, 1993.
35. *Experientia*, 34:232–233, 1978.
36. *European Journal of Biochemistry*, 97:389–394, 1979.
37. *Journal of Biological Chemistry*, 267:11208–11214, 1992.
38. *Journal of Pharmacology and Experimental Therapeutics*, 197:675–680, 1976.
39. *Hepatology*, 5:28–31, 1985.
40. *Journal of Biological Chemistry*, 267:14918–14927, 1992.
41. *Journal of Lipid Research*, 38:2548–2557, 1997.
42. *Vox Sanguinis*, 47:19–27, 1984.

List of Subjects in 21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 640 is amended as follows:

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

1. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

2. Section 640.81 is amended by revising the last sentence in paragraph (e) and by revising paragraph (f) to read as follows:

§ 640.81 Processing.

* * * * *

(e) *Heat treatment.* * * * Heat treatment shall be conducted so that the solution is heated continuously for not less than 10, or more than 11 hours, at an attained temperature of 60±0.5 °C.

(f) *Stabilizer.* Either 0.08±0.016 millimole sodium caprylate, or 0.08±0.016 millimole sodium acetyltryptophanate and 0.08±0.016

millimole sodium caprylate per gram of protein shall be present as a stabilizer(s). Calculations of the stabilizer concentration may employ the labeled value for the protein concentration of the product as referred to in § 640.84(d).

* * * * *

3. Section 640.102 is amended by revising the last sentence of paragraph (e) to read as follows:

§ 640.102 Manufacture of Immune Globulin (Human).

* * * * *

(e) * * * At no time during processing shall the product be exposed to temperatures above 45 °C, and after sterilization the product shall not be exposed to temperatures above 32 °C for more than 72 hours.

Dated: August 4, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–21897 Filed 8–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 6, 8, 10 and 11

[T.D. ATF–428]

RIN 1512–AC01

Delegation of Authority (99R–282P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury Decision; Final rule.

SUMMARY: This final rule places most ATF authorities contained in certain ATF regulations with the “appropriate ATF officer” and requires that persons file documents required by those regulations with the “appropriate ATF officer”. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director. Concurrently with this Treasury Decision, ATF Order 1130.7 is being published elsewhere in this issue of the **Federal Register**. Through this order, the Director has delegated most of the authorities in the affected regulations to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are filed.

EFFECTIVE DATE: August 28, 2000.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and

Firearms, 650 Massachusetts Avenue NW, Washington, DC 20226, (202–927–8220).

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Order 120–01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of the Federal Alcohol Administration (FAA) Act. The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under the FAA Act, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in parts 6, 8, 10 and 11 that were previously delegated and places those authorities with the “appropriate ATF officer.” Most of the authorities of the Director that were not previously delegated are also placed with the “appropriate ATF officer.” Along with this final rule, ATF is publishing ATF Order 1130.7, Delegation Order—Delegation of the Director’s Authorities in Parts 6, 8, 10 and 11, which delegates certain of these authorities to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in parts 6, 8, 10 and 11 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition, this final rule also amends parts 6, 8, 10 and 11 to provide that the submission of documents other

than ATF forms (such as letterhead applications, notices and reports) must be filed with the “appropriate ATF officer” identified in ATF Order 1130.7. These changes will facilitate the identification of the officer with whom forms and other required submissions are filed.

This final rule also makes various technical amendments to 27 CFR parts 6, 8, 10 and 11. New sections are added in each part to recognize the authority of the Director to delegate regulatory authorities and to identify ATF Order 1130.7 as the instrument reflecting such delegations.

ATF has begun to make similar changes in delegations to other parts of Title 27 of the Code of Federal Regulations through separate rulemakings. By amending the regulations part by part, rather than in one large rulemaking document and ATF Order, ATF minimizes the time expended in notifying interested parties of current delegations of authority.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming

changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b). Similarly it is unnecessary to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information

The principal author of this document is Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 6

Advertising, Alcohol and alcoholic beverages, Antitrust, Credit, Trade agreements and Trade practices.

27 CFR Part 8

Alcohol and alcoholic beverages, Antitrust, Trade agreements and Trade practices.

27 CFR Part 10

Alcohol and alcoholic beverages, Antitrust, Trade agreements and Trade practices.

27 CFR Part 11

Alcohol and alcoholic beverages, Antitrust, Trade agreements and Trade practices.

Authority and Issuance

Title 27, Code of Federal Regulations is amended to read as follows:

PART 6—TIED HOUSE

Paragraph 1. The authority citation for part 6 continues to read as follows:

Authority: 15 U.S.C. 49–50; 27 U.S.C. 202 and 205; 44 U.S.C. 3504(h).

Par. 2. Section 6.5 is redesignated as § 6.6.

Par. 3. A new section 6.5 is added and reads as follows:

§ 6.5 Delegations of the Director.

Most of the regulatory authorities of the Director contained in this part 6 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.7, Delegation Order—Delegation of the Director’s Authorities in 27 CFR Parts 6, 8, 10 and 11. ATF delegation orders, such as ATF Order 1130.7, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5190, or by accessing the ATF web site (<http://www.atf.treas.gov/>).

Par. 4. In newly designated § 6.6, paragraph (c) is amended by removing the words “Deputy Associate Director

(Regulatory Enforcement Programs)” each time it appears and adding in its place the words “appropriate ATF officer” and by revising paragraph (b) to read as follows:

§ 6.6 Administrative provisions.

* * * * *

(b) *Examination and subpoena.* Any appropriate ATF officer shall at all reasonable times have access to, for the purpose of examination, and the right to copy any documentary evidence of any person, partnership, or corporation being investigated or proceeded against. An appropriate ATF officer shall also have the power to require by subpoena the attendance and testimony of witnesses and the production of all such documentary evidence relating to any matter under investigation, upon a satisfactory showing the requested evidence may reasonably be expected to yield information relevant to any matter being investigated under the Act.

* * * * *

Par. 5–6. Section 6.11 is amended by removing the definitions of “ATF officer” and “Deputy Associate Director (Regulatory Enforcement Programs)” and by adding in alphabetically order a new definition of “appropriate ATF officer” to read as follows:

§ 6.11 Meaning of terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.7, Delegation Order—Delegation of the Director’s Authorities in 27 CFR Parts 6, 8, 10 and 11.

* * * * *

PART 8—EXCLUSIVE OUTLETS

Par. 7. The authority citation for part 8 continues to read as follows:

Authority: 15 U.S.C. 49–50; 27 U.S.C. 202 and 205; 44 U.S.C. 3504(h).

Par. 8. Section 8.5 is redesignated as § 8.6.

Par. 9. A new section 8.5 is added and reads as follows:

§ 8.5 Delegations of the Director.

Most of the regulatory authorities of the Director contained in this part 8 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.7, Delegation Order—Delegation of the Director’s Authorities in 27 CFR Parts 6, 8, 10 and 11. ATF delegation orders, such as ATF Order 1130.7, are available to any interested

person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5190, or by accessing the ATF web site (<http://www.atf.treas.gov/>).

Par. 10. Paragraph (c) of newly designated § 8.6 is amended by removing the words “Deputy Associate Director (Regulatory Enforcement Programs)” each place it appears and adding, in place thereof, the words “appropriate ATF officer” and revising paragraph (b) to read as follows:

§ 8.6 Administrative provisions.

* * * * *

(b) *Examination and subpoena.* Any appropriate ATF officer shall at all reasonable times have access to, for the purpose of examination, and the right to copy any documentary evidence of any person, partnership, or corporation being investigated or proceeded against. An appropriate ATF officer shall also have the power to require by subpoena the attendance and testimony of witnesses and the production of all such documentary evidence relating to any matter under investigation, upon a satisfactory showing the requested evidence may reasonably be expected to yield information relevant to any matter being investigated under the Act.

* * * * *

Par. 11.–12. Section 8.11 is amended by removing the definitions of “ATF officer” and “Deputy Associate Director (Regulatory Enforcement Programs)” and by adding in alphabetical order a new definition of “appropriate ATF officer” to read as follows:

§ 8.11 Meaning of terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.7, Delegation Order—Delegation of the Director’s Authorities in 27 CFR Parts 6, 8, 10 and 11.

* * * * *

PART 10—COMMERCIAL BRIBERY

Par. 13. The authority citation for part 10 continues to read as follows:

Authority: 15 U.S.C. 49–50; 27 U.S.C. 202 and 205; 44 U.S.C. 3504(h).

Par. 14. Section 10.5 is redesignated as § 10.6.

Par. 15. A new section 10.5 is added and reads as follows:

§ 10.5 Delegations of the Director.

Most of the regulatory authorities of the Director contained in this part 10 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.7, Delegation Order—Delegation of the Director’s Authorities in 27 CFR Parts 6, 8, 10 and 11. ATF delegation orders, such as ATF Order 1130.7, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5190, or by accessing the ATF web site (<http://www.atf.treas.gov/>).

Par. 16. Paragraph (c) of newly designated § 10.6 is amended by removing the words “Deputy Associate Director (Regulatory Enforcement Programs)” each time it appears and adding in its place the words “appropriate ATF officer,” and paragraph (b) is revised to read as follows:

§ 10.6 Administrative Provisions.

* * * * *

(b) *Examination and subpoena.* Any appropriate ATF officer shall at all reasonable times have access to, for the purpose of examination, and the right to copy any documentary evidence of any person, partnership, or corporation being investigated or proceeded against. An appropriate ATF officer shall also have the power to require by subpoena the attendance and testimony of witnesses and the production of all such documentary evidence relating to any matter under investigation, upon a satisfactory showing the requested evidence may reasonably be expected to yield information relevant to any matter being investigated under the Act.

* * * * *

Par. 17–18. Section 10.11 is amended by removing the definitions of “ATF officer” and “Deputy Associate Director (Regulatory Enforcement Programs)” and by adding in alphabetical order a new definition of “appropriate ATF officer” to read as follows:

§ 10.11 Meaning of terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.7, Delegation Order—Delegation of the Director’s Authorities in 27 CFR parts 6, 8, 10 and 11.

PART 11—CONSIGNMENT SALES

Par. 19. The authority citation for part 11 continues to read as follows:

Authority: 15 U.S.C. 49–50; 27 U.S.C. 202 and 205.

Par. 20. Section 11.5 is redesignated as § 11.6.

Par. 21. A new section 11.5 is added and reads as follows:

§ 11.5 Delegations of the Director.

Most of the regulatory authorities of the Director contained in this part 11 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.7, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 6, 8, 10 and 11. ATF delegation orders, such as ATF Order 1130.7, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5190, or by accessing the ATF web site (<http://www.atf.treas.gov/>).

Par. 22. Paragraph (b) of newly designated § 11.6 is revised to read as follows:

§ 11.6 Administrative provisions.

* * * * *

(b) *Examination and subpoena.* Any appropriate ATF officer shall at all reasonable times have access to, for the purpose of examination, and the right to copy any documentary evidence of any person, partnership, or corporation being investigated or proceeded against. An appropriate ATF officer shall also have the power to require by subpoena the attendance and testimony of witnesses and the production of all such documentary evidence relating to any matter under investigation, upon a satisfactory showing the requested evidence may reasonably be expected to yield information relevant to any matter being investigated under the Act.

* * * * *

Par. 23. Section 11.11 is amended by removing the definition of “ATF officer” and by adding in alphabetical order a new definition of “appropriate ATF officer” to read as follows:

§ 11.11 Meaning of terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.7, Delegation Order—Delegation of the Director's Authorities in 27 CFR parts 6, 8, 10 and 11.

* * * * *

Signed: May 18, 2000.

Bradley A. Buckles,
Director.

Approved: June 21, 2000.

John P. Simpson,
Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 00–21901 Filed 8–25–00; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 117**

[CGD08–00–020]

RIN 2115–AE47

Drawbridge Operating Regulation; Red River, LA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing the operating regulation for the State Route 107 vertical lift bridge across the Red River, mile 59.5, at Moncla, Louisiana. A new State Route 107 fixed bridge has opened and the vertical lift bridge has been removed from the waterway. The regulation governing the vertical lift bridge operation is no longer needed.

DATES: This regulation becomes effective on August 28, 2000.

ADDRESSES: Documents referred to in this notice are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, room 1313, 501 Magazine Street, New Orleans, Louisiana 70130–3396 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. Commander (ob) maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Mr. David Frank, Bridge Administration Branch, telephone number 504–589–2965.

SUPPLEMENTARY INFORMATION:**Background**

A new State Route 107 fixed bridge across the Red River, mile 59.9, at Moncla, Louisiana, was opened to traffic in March of 2000. The old State Route 107 vertical lift bridge across the Red River, mile 59.5, was removed. The elimination of this drawbridge necessitates the removal of the drawbridge operation regulation that pertained to this draw. This rule

removes the regulation for this bridge in § 117.491(a).

The Coast Guard has determined that good cause exists under the Administrative Procedure Act (5 U.S.C. 553) to forgo notice and comment for this rulemaking because removing the bridge makes the need for the regulation unnecessary. The Coast Guard has also determined that good cause exists for the rule to become effective upon publication in the **Federal Register** as the bridge was removed in July, 2000.

Regulatory Evaluation

This final rule is not a significant regulatory action under section 3(f) of Executive Order (E.O.) 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has not been reviewed by the Office of Management and Budget under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considers whether this final rule will have a significant economic impact on a substantial number of small entities. “Small entities” include (1) small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and (2) governmental jurisdictions with populations of less than 50,000.

This rule will have no impact on either vehicular or navigational traffic because the regulation being removed applies to a bridge that has been removed. Because it will have no impact, the Coast Guard certifies under 5 U.S.C. 605(b) that it will not have any economic impact on a substantial number of small entities.

Collection of Information

This final rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this final rule under Executive Order 13132 and have determined that this final rule does not have implications for federalism under that Order.