

§ 320.30 [Amended]

■ 29. Section 320.30 is amended in paragraph (c)(1) by removing “and Biopharmaceutics (HFD-850), 5600 Fishers Lane, Rockville, MD 20857” and by adding in its place “, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002”.

PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 30. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa-25.

§ 600.2 [Amended]

■ 31. Section 600.2 is amended as follows:

a. In paragraph (b)(1) by removing “(HFD-330)” and by removing “5600 Fishers Lane, Rockville, MD 20857” and adding in its place “10903 New Hampshire Ave., Silver Spring, MD 20993-0002”;

b. In paragraph (b)(3) by removing “(HFD-42)” and by removing “5600 Fishers Lane, rm. 8B45, Rockville, MD 20857” and adding in its place “5901-B Ammendale Rd., Beltsville, MD 20705-1266”.

Dated: March 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-6795 Filed 3-25-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 558****New Animal Drugs for Use in Animal Feeds***CFR Correction*

In title 21 of the Code of Federal Regulations, part 558, revised as of April 1, 2008, on page 410, in § 558.58 (e)(1)(iii), the entry for Bambermycins 1 to 3, in the column under “Limitations” remove “057926” and in its place add “016592”; in the column under “Sponsors”, add “016592”.

[FR Doc. E9-6810 Filed 3-25-09; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 101**

[Docket Nos. TSA-2006-24191; USCG-2006-24196]

RIN 1652-AA41

Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Driver's License

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Department of Homeland Security (DHS) through the United States Coast Guard (Coast Guard) issues this final rule to amend one provision of its previously issued final rule. Specifically, the Coast Guard is amending its definition of secure area to take into account facilities in American Samoa, whose workers are not required to be authorized to work in the United States under U.S. immigration law when working in American Samoa.

DATES: This final rule is effective March 26, 2009.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of dockets TSA-2006-24191 and USCG-2006-24196, and are 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>, selecting the Advanced Docket Search option on the right side of the screen, inserting TSA-2006-24191 or USCG-2006-24196 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call LCDR Jonathan Maiorine, Coast Guard; telephone 1-877-687-2243. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:**I. Regulatory History**

On May 22, 2006, the Department of Homeland Security (DHS), through the

United States Coast Guard (Coast Guard) and the Transportation Security Administration (TSA), published a joint notice of proposed rulemaking entitled “Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Driver's License” in the **Federal Register** (71 FR 29396). This was followed by a 45-day comment period and four public meetings. The Coast Guard and TSA issued a joint final rule, under the same title, on January 25, 2007 (72 FR 3492) (hereinafter referred to as the original TWIC final rule). The preamble to that final rule contains a discussion of the provisions found in the original TWIC final rule, which became effective on March 26, 2007.

On September 28, 2007, the Coast Guard and TSA issued a joint final rule (72 FR 55043) that, among other things, revised the definition for “secure area” to account for facilities in the Commonwealth of the Northern Mariana Islands (the CNMI), as non-citizen workers at those facilities are not required to have authorization to work in the United States under U.S. immigration law before being allowed to work.

On May 7, 2008, the Coast Guard and TSA issued a joint final rule to realign the compliance date for implementation of the original TWIC final rule (see 73 FR 25562). The date by which mariners need to obtain a TWIC, and by which owners and operators of vessels and outer continental shelf facilities must implement access control procedures using TWIC, is April 15, 2009. Owners and operators of facilities that must comply with 33 CFR part 105 are subject to earlier, rolling compliance dates, as set forth in 33 CFR 105.115(e). The Coast Guard announced these rolling compliance dates via notices published in the **Federal Register**. The final compliance date for all COTP Zones is not later than April 15, 2009.

On September 30, 2008, the Coast Guard announced the compliance date for COTP Zone Honolulu would be February 12, 2009 (73 FR 56730). On February 12, 2009, the Coast Guard announced the extension of that compliance date, for the territory of American Samoa only, to April 14, 2009, due to the fact that a large percentage of the maritime workforce is not native to the island, and does not need to be authorized to work in the United States under U.S. immigration law before being allowed to work in American Samoa. In that notice, the Coast Guard stated that the extension was being granted in order to allow time

for the Coast Guard to consult with TSA, DHS, and the Department of State, to determine whether there is an equivalent visa category that these workers could use to qualify for a TWIC, or whether the TWIC requirement for facilities located in American Samoa should be reconsidered. This final rule is the result of those deliberations.

II. Background and Purpose

A complete discussion of the background and purpose of the original TWIC final rule may be found beginning at 72 FR 3494. This final rule is being issued in order to make an amendment to the original TWIC final rule that is necessary to address the fact that non-citizen workers on the island of American Samoa do not meet the immigration eligibility standards to obtain a TWIC, but make up approximately 87% of the maritime workers that would otherwise need a TWIC.

As in the case of the CNMI, while American Samoa is part of the United States, it is not currently included in the definition of "United States" for purposes of the Immigration and Nationality Act (8 U.S.C. 110(a)(38)) (Title VII of the Consolidated Natural Resources Act of 2008, Pub. L. 110-229, will change this situation later this year with respect to the CNMI only by bringing the CNMI within U.S. immigration law). Therefore, the work authorization of aliens in American Samoa is a matter of territorial law only, and the U.S. immigration statuses relevant to TWIC eligibility determinations in U.S. jurisdictions subject to the Immigration and Nationality Act do not apply there.

III. Discussion of Change

On September 28, 2007, the Coast Guard and TSA issued a joint final rule (72 FR 55043) that, among other provisions, revised the definition for "secure area" to account for facilities in the CNMI, as workers at those facilities are not required to have authorization to work in the United States under U.S. immigration law before being allowed to work in the CNMI.

Similar to the CNMI joint final rule, this final rule amends the definition of "secure area" in 33 CFR 101.105, to state that facilities otherwise subject to 33 CFR part 105 located in the territory of American Samoa do not have secure areas for the purposes of the TWIC regulations. This action means that only the facility security officer and facility personnel whose primary employment responsibility is security will be required to obtain a TWIC, per 33 CFR 105.205 and 105.210, respectively.

Note that these facilities must continue to implement their previously approved facility security plans, which include provisions for maintaining access control. Vessels coming from American Samoa to any other port in the United States must continue to go through the same port state control screening required of a vessel coming from a foreign country. Additionally, workers provided unescorted access to facilities in American Samoa would not be eligible for unescorted access to any other part 105 facility outside of American Samoa, nor would they be eligible for unescorted access to any part 104 vessel, unless issued a TWIC.

The rule also takes the opportunity to correct a typographical error in the definition of "secure area" that resulted in an incorrect name of a U.S. territory, by changing "the Commonwealth of Northern Mariana Islands" to "the Commonwealth of the Northern Mariana Islands".

IV. Regulatory Requirements

The Coast Guard has not published a notice of proposed rulemaking (NPRM) for this final rule. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM, because providing opportunity for public comment would be contrary to the public interest. The amendment in this final rule eases a requirement, by removing it completely for an entire class of individuals. This serves the public interest by ensuring that after April 14, 2009, maritime businesses in the territory of American Samoa are able to continue operating without significantly impacting the security risk to the port area. Without this amendment, these businesses would be forced to escort the vast majority of their personnel in secure areas, because 87% of the maritime workforce who would require a TWIC (without this amendment) cannot qualify for one. This would be unduly disruptive to commerce in American Samoa and is therefore contrary to the public interest.

For the same reasons, and because this change is required before the April 14, 2009, TWIC compliance date, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

A. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. We expect the economic impact of this rule to be minimal; therefore a full economic evaluation is unnecessary.

This final rule effectively removes the TWIC requirement for the majority of workers at facilities located in the territory of American Samoa, thus lessening the costs of the regulatory action for the owners of these facilities, and removing it entirely for those workers who will no longer be required to purchase a TWIC.

B. Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

For the reasons stated above, we expect this final rule to reduce TWIC-related compliance costs, particularly with respect to the costs of providing escorted access to secure areas, for facilities located in American Samoa. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we want to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The

Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

D. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

E. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

H. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

J. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination

with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

L. Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 0023.1 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded under section 2.B.2, figure 2-1, paragraph (34)(c) of the Instruction. This rule involves regulations

concerning the training, qualifying, licensing, and disciplining of maritime personnel. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under

ADDRESSES.

List of Subjects in 33 CFR Part 101

Harbors, Maritime security, Reporting and recordkeeping requirements, Security measures, Vessels, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 101 as follows:

Title 33—Navigation and Navigable Waters

CHAPTER I—COAST GUARD

PART 101—MARITIME SECURITY: GENERAL

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 192; Executive Order 12656, 3 CFR 1988 Comp., p. 585; 33 CFR 1.05-1, 6.04-11, 6.14, 6.16, and 6.19; Department of Homeland Security Delegation No. 0170.1.

§ 101.105 [Amended]

■ 2. In § 101.105, in the definition for "secure area", remove the words "Commonwealth of Northern Mariana Islands" and add, in their place, the words "Commonwealth of the Northern Mariana Islands and American Samoa".

Dated: March 19, 2009.

Brian M. Salerno,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety, Security, and Stewardship.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG-2008-0069]

Drawbridge Operation Regulation; Gulf Intracoastal Waterway (Algiers Alternate Route), Belle Chasse, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the SR 23 bridge across the Gulf Intracoastal