

**DEPARTMENT OF JUSTICE****Drug Enforcement Administration****21 CFR Part 1308**

[DEA-236F]

**Schedules of Controlled Substances:  
Exempt Anabolic Steroid Products**

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Final rule; reinstatement of exemptions.

**SUMMARY:** The DEA is withdrawing the suspension of the interim rule published on June 13, 2003 and reinstating the order published on January 15, 2003 designating two pharmaceutical preparations as exempt anabolic steroid products under the Controlled Substances Act (CSA). The current action is being taken after reconsidering the application for exemption in light of the comments and objections filed and other relevant information. This action is part of the ongoing implementation of the Anabolic Steroids Control Act (ASCA) of 1990.

**EFFECTIVE DATE:** September 12, 2003.

**FOR FURTHER INFORMATION CONTACT:** Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

**SUPPLEMENTARY INFORMATION:****Background**

The ASCA of 1990 (Title XIX of Public Law 101-647) placed anabolic steroids into Schedule III of the CSA (21 U.S.C. 812). Section 1903 of the ASCA provides that the Attorney General may exempt products which contain anabolic steroids from all or any part of the CSA (21 U.S.C. 801 *et seq.*) if the products have no significant potential for abuse. The authority to exempt these products was delegated from the Attorney General to the Administrator of the Drug Enforcement Administration (28 CFR 0.1009b), who, in turn, redelegate this authority to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (28 CFR appendix to subpart R, Section 7, paragraph (g)). The procedure for implementing this section of the ASCA is found in § 1308.33 of Title 21 of the Code of Federal Regulations.

In conformance with § 1308.33 of Title 21 of the Code of Federal Regulations, an application was received from Syntho Pharmaceuticals,

Inc. to exempt two of their anabolic steroid products, Syntest H.S. and Syntest D.S. This application was forwarded to the Assistant Secretary for Health, Department of Health and Human Services (HHS) for her evaluation. Upon the recommendation of HHS and other relevant information, the DEA published an interim rule and request for comments (68 FR 1964, January 15, 2003) in which the Deputy Assistant Administrator ordered the products to be added to the list of exempt anabolic steroids.

DEA received two comments from interested persons that raised issues regarding findings of fact or conclusions of law upon which this order was based. As set forth in 21 CFR 1308.33(d), the Deputy Assistant Administrator immediately suspended the effectiveness of this order until she reconsidered the application in light of the comments and objections filed.

**Reinstatement of Order To Add  
Anabolic Steroid Products to the List of  
Products Exempted From Application  
of the CSA**

A preparation containing an anabolic steroid may be exempted from the requirements of the CSA if it has no significant potential for abuse. Accordingly, the DEA is responding only to those aspects of the comments received that raise the issue of abuse potential of Syntest H.S. and Syntest D.S. One commenter made reference to the abuse of anabolic steroids, in general. Although the abuse of anabolic steroids is of great concern to the DEA, no information was presented to alter the initial findings that the products do not possess a significant potential for abuse. The second commenter alleged that Syntho Pharmaceutical, Inc. distributed the products as exempt preparations prior to the exemptions being granted; however, there is no evidence of any abuse or significant potential for abuse of the products as a result of this activity by the company. Thus, after a thorough review and investigation of the two comments DEA received, and all other relevant information, the DEA found no indication that there is a significant potential for abuse of either Syntest H.S. or Syntest D.S. Therefore, in compliance with 21 CFR 1308.33(d), the Deputy Assistant Administrator reinstates her original order to add the products to the list of exempt anabolic steroids.

Dated: September 8, 2003.

**Laura M. Nagel,**

*Deputy Assistant Administrator, Office of  
Diversion Control.*

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**DEPARTMENT OF HOMELAND  
SECURITY****Coast Guard****33 CFR Part 165**

[CGD13-03-022]

RIN 1625-AA00

**Security and Safety Zone; Protection  
of Large Passenger Vessels, Portland,  
OR**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** In order to maintain an increased maritime security posture, the Coast Guard is establishing regulations for the security and safety of large passenger vessels in the navigable waters of the Portland, OR Captain of the Port zone. This security and safety zone, when enforced by the Captain of the Port Portland, will provide for the regulation of vessel traffic in the vicinity of large passenger vessels in the navigable waters of the United States.

**DATES:** This rule is effective September 12, 2003.

**ADDRESSES:** Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD13-03-022] and are available for inspection or copying at Marine Safety Office Portland between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LT(jg) Tad Drozdowski, c/o Captain of the Port Portland, 6767 N. Basin Ave., Portland, OR 97217 at 503-240-9370.

**SUPPLEMENTARY INFORMATION:****Regulatory Information**

On July 28, 2003, we published a notice of proposed rulemaking (NPRM) entitled "Security and Safety Zone; Protection of Large Passenger Vessels, Portland, OR" in the **Federal Register** (68 FR 44256). We received no comments during the comment period. No public hearing was requested, and none was held.

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.** The security and safety zone in this regulation has been carefully designed to minimally impact the public while providing a reasonable level of protection for large passenger vessels. Similar protection is currently being provided by a temporary final rule (TFR), but that temporary section, 33 CFR T13-006, will expire September 12, 2003 (68 FR 23390, May 2, 2003). Continuous protection from the threats posed by hostile entities is necessary for the protection of large passenger vessels in the COTP Portland, OR zone. For these reasons, it would be impracticable, unnecessary, and contrary to the public interest to wait 30 days to enforce the regulation after publication in the **Federal Register**.

### Background and Purpose

Hostile entities continue to operate with the intent to harm U.S. National Security. The President has continued the national emergencies he declared following the September 11, 2001 terrorist attacks (67 FR 58317 (Sept. 13, 2002) (continuing national emergency with respect to terrorist attacks)), 67 FR 59447 (Sept. 20, 2002) (continuing national emergency with respect to persons who commit, threaten to commit or support terrorism)). The President also has found pursuant to law, including the Act of June 15, 1917, as amended August 9, 1950, by the Magnuson Act (50 U.S.C. 191 et seq.), that the security of the United States is and continues to be endangered following the attacks (E.O. 13,273, 67 FR 56215 (Sept. 3, 2002) (security endangered by disturbances in international relations of U.S. and such disturbances continue to endanger such relations)).

The ongoing hostilities in Afghanistan and Iraq have made it prudent for U.S. ports and waterways to be on a higher state of alert because the al Qaeda organization and other similar organizations have declared an ongoing intention to conduct armed attacks on U.S. interests worldwide.

Upon the expiration of the temporary security zone under 33 CFR 165.T13-006, through this final rule the Coast Guard will continue to assist large passenger vessels by establishing a permanent security and safety zone that when enforced by the Captain of the Port will exclude persons and vessels from the immediate vicinity of all large passenger vessels. Entry into this zone will be prohibited unless authorized by the Captain of the Port or his designee. The Captain of the Port may be assisted by other federal, state, or local agencies.

### Discussion of Comments and Changes

The Coast Guard received no comments in response to the NPRM proposing this final rule. In our NPRM, however, we did address a comment received in response to the TFR when we drafted our proposed final rule (68 FR 44257, July 28, 2003). We have not made any changes from the proposed rule to the final rule.

### Regulatory Evaluation

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. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). Although this rule will restrict access to the regulated area, the effect of this rule will not be significant because: (i) Individual large passenger vessel security and safety zones are limited in size; (ii) the official on-scene patrol or large passenger vessel master may authorize access to the large passenger vessel security and safety zone; (iii) the large passenger vessel security and safety zone for any given transiting large passenger vessel will effect a given geographical location for a limited time; (iv) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

### 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.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to operate near or anchor in the vicinity of large passenger vessels in the navigable waters of the United States.

This rule will not have a significant economic impact on a substantial number of small entities for the

following reasons: (i) Individual large passenger vessel security and safety zones are limited in size; (ii) the official on-scene patrol or large passenger vessel master may authorize access to the large passenger vessel security and safety zone; (iii) the large passenger vessel security and safety zone for any given transiting large passenger vessel will effect a given geographical location for a limited time; and (iv) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule will have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule will economically affect it.

### Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact one of the points of contact listed under **FOR INFORMATION CONTACT**.

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).

### 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).

### 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.

#### 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.

#### 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.

#### 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.

#### 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.

#### Indian Tribal Governments

The Coast Guard recognizes the rights of Native American Tribes under the Stevens Treaties. Moreover, the Coast Guard is committed to working with Tribal Governments to implement local policies to mitigate tribal concerns. Given the flexibility of this rule to accommodate the special needs of mariners in the vicinity of large passenger vessels and the Coast Guard's commitment to working with the Tribes, we have determined that passenger vessel security and fishing rights protection need not be incompatible and therefore have determined that 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.

Nevertheless, Indian Tribes that have questions concerning the provisions of this rule or options for compliance are encouraged to contact the point of contact listed under **FOR FURTHER INFORMATION CONTACT**.

#### 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.

#### Environment

The Coast Guard's review indicates this rule is categorically excluded from further environmental documentation under figure 2–1, paragraph 34 (g) of Commandant Instruction M16475.1D. The environmental analysis and Categorical Exclusion Determination has been prepared and will be available in the docket for inspection and copying where indicated under **ADDRESSES**. All standard environmental measures remain in effect.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

#### PART 165—REGULATED NAVIATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.1318 to read as follows:

#### § 165.1318 Security and Safety Zone Regulations, Large Passenger Vessel Protection, Portland, OR Captain of the Port Zone

(a) *Notice of enforcement or suspension of enforcement.* The large passenger vessel security and safety zone established by this section will be

enforced only upon notice by the Captain of the Port Portland. Captain of the Port Portland will cause notice of the enforcement of the large passenger vessel security and safety zone to be made by all appropriate means to effect the widest publicity among the affected segments of the public including publication in the **Federal Register** as practicable, in accordance with 33 CFR 165.7(a). Such means of notification may also include but are not limited to, Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port Portland will issue a Broadcast Notice to Mariners and Local Notice to Mariners notifying the public when enforcement of the large passenger vessel security and safety zone is suspended.

(b) *Definitions.* As used in this section—

*Federal Law Enforcement Officer* means any employee or agent of the United States government who has the authority to carry firearms and make warrantless arrests and whose duties involve the enforcement of criminal laws of the United States.

*Large Passenger Vessel* means any vessel over 100 feet in length (33 meters) carrying passengers for hire including, but not limited to, cruise ships, auto ferries, passenger ferries, and excursion vessels.

*Large passenger vessel security and safety zone* is a regulated area of water, established by this section, surrounding large passenger vessels for a 500 yard radius that is necessary to provide for the security and safety of these vessels.

*Navigable waters of the United States* means those waters defined as such in 33 CFR part 2.

*Navigation Rules* means the Navigation Rules, International-Inland.

*Official Patrol* means those persons designated by the Captain of the Port to monitor a large passenger vessel security and safety zone, permit entry into the zone, give legally enforceable orders to persons or vessels within the zone and take other actions authorized by the Captain of the Port. Persons authorized as Federal Law Enforcement Officers to enforce this section are designated as the Official Patrol.

*Oregon Law Enforcement Officer* means any Oregon Peace Officer as defined in Oregon Revised Statutes section 161.015.

*Public vessel* means vessels owned, chartered, or operated by the United States, or by a State or political subdivision thereof.

*Washington Law Enforcement Officer* means any General Authority Washington Peace Officer, Limited Authority Washington Peace Officer, or

Specially Commissioned Washington Peace Officer as defined in Revised Code of Washington section 10.93.020.

(c) *Security and safety zone.* There is established a large passenger vessel security and safety zone extending for a 500 yard radius around all large passenger vessels in the navigable waters of the United States, in Portland, OR at the Columbia River Bar "C" buoy and extending eastward on the Columbia River to Kennewick, WA and upriver through Lewiston, ID on the Snake River.

(d) *Compliance.* The large passenger vessel security and safety zone established by this section remains in effect around large passenger vessels at all times, whether the large passenger vessel is underway, anchored, or moored. Upon notice of enforcement by the Captain of the Port Portland, the Coast Guard will enforce the large passenger vessel security and safety zone in accordance with rules set out in this section. Upon notice of suspension of enforcement by the Captain of the Port Portland, all persons and vessels are authorized to enter, transit, and exit the large passenger vessel security and safety zone, consistent with the Navigation Rules.

(e) *Navigation Rules.* The Navigation Rules shall apply at all times within a large passenger vessel security and safety zone.

(f) *Restrictions based on distance from large passenger vessel.* When within a large passenger vessel security and safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course and shall proceed as directed by the on-scene official patrol or large passenger vessel master. No vessel or person is allowed within 100 yards of a large passenger vessel that is underway or at anchor, unless authorized by the on-scene official patrol or large passenger vessel master.

(g) *Requesting authorization to operate within 100 yards of large passenger vessel.* To request authorization to operate within 100 yards of a large passenger vessel that is underway or at anchor, contact the on-scene official patrol or large passenger vessel master on VHF-FM channel 16 or 13.

(h) *Maneuver-restricted vessels.* When conditions permit, the on-scene official patrol or large passenger vessel master should:

(1) Permit vessels constrained by their navigational draft or restricted in their ability to maneuver to pass within 100 yards of a large passenger vessel in order to ensure a safe passage in accordance with the Navigation Rules; and

(2) Permit commercial vessels anchored in a designated anchorage area to remain at anchor within 100 yards of a passing large passenger vessel; and

(3) Permit vessels that must transit via a navigable channel or waterway to pass within 100 yards of an anchored large passenger vessel.

(i) *Stationary vessels.* When a large passenger vessel approaches within 100 yards of any vessel that is moored or anchored, the stationary vessel must stay moored or anchored while it remains within the large passenger vessel's security and safety zone unless it is either ordered by, or given permission by the Captain of the Port Portland, his designated representative or the on-scene official patrol to do otherwise.

(j) *Exemption.* Public vessels as defined in paragraph (b) of this section are exempt from complying with paragraphs (c), (d), (f), (g), (h), and (i), of this section.

(k) *Enforcement.* Any Coast Guard commissioned, warrant or petty officer may enforce the rules in this section. In the navigable waters of the United States to which this section applies, when immediate action is required and representatives of the Coast Guard are not present or not present in sufficient force to provide effective enforcement of this section in the vicinity of a large passenger vessel, any Federal Law Enforcement Officer, Oregon Law Enforcement Officer or Washington Law Enforcement Officer may enforce the rules contained in this section pursuant to 33 CFR 6.04-11. In addition, the Captain of the Port may be assisted by other federal, state or local agencies in enforcing this section.

(l) *Waiver.* The Captain of the Port Portland may waive any of the requirements of this section for any vessel or class of vessels upon finding that a vessel or class of vessels, operational conditions or other circumstances are such that application of this section is unnecessary or impractical for the purpose of port security, safety or environmental safety.

Dated: September 3, 2003.

**Paul D. Jewell,**

*Captain, U.S. Coast Guard, Captain of the Port, Portland.*

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**BILLING CODE 4910-15-P**

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

### 36 CFR Part 1280

RIN 3095-AB22

#### NARA Facilities; Hours of Operation for the Exhibition Halls

**AGENCY:** National Archives and Records Administration (NARA).

**ACTION:** Final rule.

**SUMMARY:** The National Archives and Records Administration is modifying the extended hours that the exhibition halls in the National Archives Building in Washington, DC, are open from April 1 through the Friday before Memorial Day. The exhibition halls will close at 7 p.m. instead of 9 p.m. during this period. We are limiting the extended hours during this period to be more cost-effective and because this is when attendance is the lightest. NARA's exhibition halls will still have the longest hours of any Washington museum on the National Mall. The change does not affect the research room hours stated in Part 1253 in any manner. This final rule affects the public.

**EFFECTIVE DATE:** October 14, 2003.

**FOR FURTHER INFORMATION CONTACT:** Kim Richardson at telephone number 301-837-2902, or fax number 301-837-0319.

**SUPPLEMENTARY INFORMATION:** The proposed rule was published in the June 17, 2003, **Federal Register** (68 FR 35829) for a 60-day comment period. NARA did not receive any comments.

This final rule is not a significant regulatory action for the purposes of Executive Order 12866 and has not been reviewed by the Office of Management and Budget. This rule is not a major rule as defined in 5 U.S.C. Chapter 8, Congressional Review of Agency Rulemaking. As required by the Regulatory Flexibility Act, I certify that this final rule will not have a significant impact on a substantial number of small entities. This regulation does not have any federalism implications.

#### List of Subjects in 36 CFR Part 1280

Federal buildings and facilities.

■ For the reasons set forth in the preamble, NARA amends part 1280 of title 36, Code of Federal Regulations, chapter XII, as follows:

#### PART 1280—PUBLIC USE OF NARA FACILITIES

■ 1. The authority citation for Part 1280 continues to read as follows:

**Authority:** 44 U.S.C. 2104(a).

■ 2. Revise § 1280.62 to read as follows: