

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, redelegated 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**