

Commonwealth of Puerto Rico  
Mental Health and Anti-Addiction Services  
Administration  
P.O. Box 21414  
San Juan, PR 00928-1414

*ASSMCA*

PUBLIC NOTICE

Proposed Amendments to Regulation No. 11 of the Secretary of Anti-Addiction  
Services of Controlled Substances (Regulation No. 4032 Approved October 6 1989)

In accordance with the powers and faculties that confers Law No. 67 of August 7 1993, as amended, Law No. 170 of August 12 1988, as amended, and Law No. 4 of June 23 1971, known as Law of Controlled Substances of Puerto Rico, as amended, the Administrator of the Mental Health and Anti-Addiction Services Administration proposes to amend regulation No. 11 of the Secretary of Anti-Addiction Services of Controlled Substances, Regulation No. 4032 approved October 6 1989, for which requests to the interested persons to present their comments to the proposed amendments to the afore mentioned Regulation.

The purpose of these amendments is to amend the afore mentioned Regulation to the effect of introducing changes in the classification of some substances in accordance with the standards established in Law No. 4 of June 23 1971, as amended. The amendments that are tried to adopt are the followings: **INCLUDE** in classification III the **anabolic steroids** and any compound material, mixture or preparation that contain any amount of anabolic steroids, including their salts, isomers and isomers salts, as long as the existence of such salts, isomers and isomer salts be possible within the specific chemical designation. The term does not include anabolic steroids expressly intended to be administered to cattle or other animal specie and whose use have been approved by the Secretary of the Department of Health and Human Services of the Federal Government. If any person prescribes, dispenses or distributes such steroids for human consumption, it shall be considered that that person have prescribed, dispensed or distributed an anabolic steroid of those included in this Order. (Declarative Order Number 19); **RECLASSIFY or TRANSFER** of Classification III to II, the substance designated with the name of **GLUTEMIDE**, whose commercial name is DORIEN (Declarative Order Number 20); **EXCLUDE** from Classification III the substances denominated compounds or preparations that contain the following anabolic steroids in the concentrations that are indicated: testosterone enanthate 90 mg-ml combined with Estradiol valerate 4 mg-ml; testosterone cypionate .50 mg-ml combined with Estradiol cypionate 2 mg-ml; conjugated estrogens 1.25 mg with methyltestosterone 10.0 mg; conjugated estrogens 0.625 mg with methyltestosterone 5.0 mg; esterified estrogens 1.25 combined with methyltestosterone 2.5 mg, esterified estrogens 0.625 mg combined with methyltestosterone 1.25 mg; propionate of testosterone 25 mg combined with estradiol Benzoate 2.5 mg; propionate of testosterone 10 parts combined with estradiol Benzoate (1) part; methyltestosterone 60 mg-1kg (fish food); (Declarative Order Number 21); **INCLUDE** in Classification IV the following substances: (a) Butorphanol, including its salts and optical isomers, said substance is known in the market or in commerce as "stadol," "torbugesic" and "torbutrol" (Declarative Order Number 22); the substance known as "Zolpidem" whose commercial name is AMBIEN (Declarative Order Number 23); (c) the SIBUTRAMINE, whose commercial name is MERIDIA, as well as its salts and isomers (Declarative Order Number 24); **INCLUDE** in Classification III the substance known as KETAMINE, whose commercial names are Kataral, Ketajet, Ketaset, and Vetalar, as well as its salts and isomers (Declarative Order Number 25); **RECLASSIFY or TRANSFER** of Classification II to III, the substance designated as **[(-)- $\Delta^9$ -(trans)-Tetrahydrocannabinol]**, better known as Dronabinol and whose commercial name is Marinol (Declarative Order Number 26); **INCLUDE** in Classification IV the ingredient Zapelon, including its salts, whose commercial name is SONATA (Declarative Order Number 27); **INCLUDE** in Classification IV the substance designated as Dichloralphenazone, as well as its salts, isomers, and isomer salts (Declarative Order Number 28); and **RECLASSIFY or TRANSFER** from Classification V to III the ingredient BUPRENORPHINE whose commercial name is Buprenex, Temgesic (Declarative Order Number 29).

The changes in the classification of the substances afore mentioned are realized in accordance with Declarative Orders 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, and 29 put on effect by the Administrator of the Mental Health and Anti-Addiction Services Administration and by the Secretary of Health of Puerto Rico on May 14 2003.

Copy of the proposed amendments afore mentioned will be available to the public during the next (30) days after this publication, at our electronic address: [www.gobierno.pr/gprportal/nuestrogobierno/reglamento](http://www.gobierno.pr/gprportal/nuestrogobierno/reglamento). In the same way copy of the proposed amendments will be available in the Office of the Legal Counsel of the Mental Health and Anti-Addiction Services Administration, located in the Sixth Floor of the MHAASA in # 414 Barbosa Avenue Hato Rey, Puerto Rico, from 8:AM to 4:30 PM from Monday through Friday.

Persons interested in submitting comments in writing or the holding of an oral hearing should do so within the term of (30) days counted after the publication of this notice, in order that such comments are considered for their final adoption. The comments as well as the request of an oral hearing could be mailed by regular mail to the following address: Mental Health and Anti-Addiction Services Administration, Office of the Legal Counsel, PO Box 21414 San Juan, Puerto Rico 00928-1414. Also, could be delivered personally in the Office of the Legal Counsel of the Mental Health and Anti-Addiction Services Administration, located in the Sixth Floor of the MHAASA in #414Barbosa Avenue, Hato Rey, Puerto Rico, from Monday trough Friday from 8:00 AM trough 4:30 PM. On the other hand, comments and / or recommendations could be addressed at our electronic mail: [legales@assmca.gobierno.pr](mailto:legales@assmca.gobierno.pr). Persons interested could also request in writing an oral hearing about the amendments whose adoption is being proposed.

Those persons interested in requesting an oral hearing about the proposed amendments should file their request in writing, stating the reasons that, under their judgment, made it necessary the granting of an oral hearing, to the afore stated addresses.

Any writing or document pertinent to this matter shall become part of the records if it is filed within the established term.

In San Juan, Puerto Rico, today March 29, 2005.



José L. Galarza Arbona, MD, MPH  
Administrator  
Mental Health and Anti-Addiction  
Services Administration

Approved for the CEE# 1071