

CALIFORNIA HORSE RACING BOARD

1010 Hurley Way, Suite 300
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**NOTICE OF EMERGENCY RULEMAKING ACTION
READOPTION OF EMERGENCY REGULATIONS TO DEAUTHORIZE CLENBUTEROL
IN POST-RACE TEST SAMPLES AND TO ESTABLISH REPORTING REQUIREMENTS FOR
CLENBUTEROL PRESCRIPTIONS AND ADMINISTRATIONS FOR QUARTER HORSES
(TITLE 4, SECTIONS 1844 & 1866.1)**

NOTICE DATE: APRIL 6, 2016

Pursuant to the requirements of Government Code Section 11346.1(a)(2), the California Horse Racing Board (CHRB) is providing notice of proposed emergency regulatory action. The CHRB proposes to readopt the emergency regulations amending Title 4 CCR 1844, Authorized Medication, and adopting Title 4 CCR 1866.1, Presence of Clenbuterol in Quarter Horses (the Emergency Regulations). This action is taken pursuant to Government Code Section 11346.1(h).

The Emergency Regulations deauthorize any detectable level of clenbuterol in a quarter horse's official urine test sample. The Emergency Regulations also require that any quarter horse that is prescribed or otherwise tests positive for clenbuterol in a blood, urine, or other official test sample be placed on the Veterinarian's List until clenbuterol is no longer detected in the horse's blood or urine by an official test sample. Finally, the Emergency Regulations require veterinarians to report all clenbuterol prescriptions for quarter horses using CHRB-24, Veterinarian Report (Revised 07/15), and trainers to report all clenbuterol administrations to quarter horses on form CHRB-60, Trainer Medication Report (Revised 07/15).

These Emergency Regulations became effective on July 31, 2015, and were readopted for 90 days on January 26, 2016. They will expire on April 26, 2016 unless the CHRB readopts the Emergency Regulations for an additional 90 days. This will allow the Emergency Regulations to remain in effect while the CHRB finalizes a separate rulemaking to certify and make permanent the Emergency Regulations. As discussed in the following section of this notice, the Notice of Proposed Action for this separate rulemaking was published in the California Regulatory Notice Register on December 11, 2015.

Government Code Section 11346.1(a)(2) requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law, the adopting agency provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the Office of Administrative Law, the Office of Administrative Law shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code Section 11349.6.

Concurrent Rulemaking Action to Certify and Make Permanent the Emergency Regulations

Pursuant to Government Code Section 11346.1(h), the CHRB initiated a separate rulemaking action to certify and make permanent the Emergency Regulations through a rulemaking in compliance with Government Code Section 11346.1(e) (the Certification Rulemaking). The Notice of Proposed Action for the Certification Rulemaking was published in the California Register on December 11, 2015, and the CHRB held a public hearing on the Certification Rulemaking on February 25, 2016, at which time it approved the proposed permanent regulations.

For convenience, the original Finding of Emergency Notice, posted on July 14, 2015, is reproduced below.

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**Finding of Emergency
(pursuant to Government Code section 11346.1(b)(2))**

Notice Date: July 14, 2015

The California Horse Racing Board (CHRB) finds that an emergency exists that requires the implementation of these emergency regulations for the immediate preservation of the public peace, health, safety, or general welfare, within the meaning of Government Code section 11346.1.

Government Code section 11346.1(a)(2) requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law, the adopting agency provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the Office of Administrative Law, the Office of Administrative Law shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6.

Facts Demonstrating the Existence of an Emergency & Need for Immediate Action

Since February 28, 2014, the CHRB has implemented and enforced the provisions of a memorandum (“the memorandum”) entitled “Instructions Pursuant to Rule 1855, Medication Procedures and Related Instructions.” In short, the memorandum described procedures for how and when quarter horses should be placed on the Veterinarian’s List when clenbuterol is prescribed to or detected in a horse, as well as the procedures for removing a horse from the list once it tests clear of clenbuterol.

On May 26, 2015, however, the Office of Administrative Law released 2015 OAL Determination NO. 6 (OAL MATTER NO. CTU2014-1110-01), which declared that the memorandum was an “underground regulation.” The CHRB has concluded that this determination has directly created an emergency situation for quarter horse racing in California.

Clenbuterol is a beta-2 agonist approved for use as a bronchodilator in horses. Beta-2 agonists also have an anabolic-type effect through their muscle partitioning side effects.¹ Clenbuterol is banned in human sport by the World Anti-doping Association² for this reason. The drug is also abused in horses because of its anabolic effects. Clenbuterol became a problem in horse racing—especially quarter horse racing—when the CHRB and other racing authorities in the United States restricted the use of anabolic steroids. Quarter horses often engage in sprint racing. Accordingly, the preferred body-type for racing quarter horses is a

¹ Nolen-Walston et al. AJVR 76:460-466 (2015).

² Wada Prohibited List 2015 (<https://wada-main-prod.s3.amazonaws.com/resources/files/wada-2015-prohibited-list-en.pdf> Accessed June 16, 2015).

well-muscled horse, which is easily accomplished and enhanced with the use of anabolic steroids.

The FDA approved formulation for horses was specifically formulated to make Ventiplulmin, the FDA approved brand, unpalatable to humans. Unapproved clenbuterol can be readily obtained though, and in fact in some countries it is allowed in food for animals to promote muscle weight gain. The official CHRB laboratory, the Maddy lab at UC Davis School of Veterinary Medicine, has analyzed a number of non-FDA clenbuterol preparations from quarter horse racing in California and other southwest racing locations where quarter horse racing is prominent. Furthermore, at least one study has described numerous side-effects associated with clenbuterol administration, including a repartitioning effect and major alterations in cardiac and skeletal muscle function, as well as affects on bone, immune, endocrine, and reproductive systems.³

Los Alamitos Racecourse and the Pacific Coast Quarter Horse Racing Association (PCQHRA), the horsemen's group representing quarter horse owners and trainers in California, began expressing concern to the CHRB in 2010 about what they perceived as unfair racing at Los Alamitos. Public confidence is critical to horse racing, and the perception of unfair competition amongst owners and trainers due to the use of clenbuterol became a serious issue for the public and licensees.

The CHRB conducted testing at Los Alamitos for their 2010 signature end of season races, the \$2,000,000 Futurity and Champion of Champions. A total of 72 blood samples were obtained and tested. Of those samples, every sample (72 out of 72) contained detectable levels of clenbuterol in the horse's blood. Realistically, clenbuterol can be detected in blood for no more than 4-7 days after administration, indicating that all of the tested horses had recently been administered clenbuterol. At the request of Los Alamitos Racecourse and PCQHRA, the CHRB suspended authorization to clenbuterol by breed and track for one year at a time, pursuant to Rule 1844.1. The suspension was in place for 2011, and upon conducting a similar testing program, the CHRB found that no horses tested positive for clenbuterol this time around. In 2013, however, a number of trainers began to once again push the limits on clenbuterol use. In Fiscal Year 2013-14 there were 13 clenbuterol violations at Los Alamitos. While trainers are sanctioned when caught, the public is not protected in these instances. Those who wager on races where certain horses have been administered clenbuterol have no recourse. The people who bet on a winning horse that has been administered clenbuterol—which often includes the horse's owners and trainers—are rewarded, while those who bet on a losing horse not administered clenbuterol become victims of an unfair and illegal performance enhancing scheme.

In response to these instances of unlawful clenbuterol use, the CHRB implemented the abovementioned memorandum to enhance reporting requirements and suspend authorization for clenbuterol in quarter horses. Los Alamitos Racecourse, with PCQHRA support, established additional internal clenbuterol regulations as well. As a direct consequence, there have been no clenbuterol violations so far in Fiscal Year 2014-15 and no clenbuterol was found in OOCT at Los Alamitos for the \$2,000,000 Futurity and Champion of Champions.

Because of the Office of Administrative Law's recent determination, however, the memorandum has effectively become unenforceable by the CHRB without seriously risking adverse litigation and judgments in court. Accordingly, trainers and veterinarians can presently

³ Charles F. Kearns & Kenneth H. McKeever, *Clenbuterol and the horse revisited*, *The Veterinary Journal* 182 (2009) 384-391.

administer clenbuterol to quarter horses entered to race in California, which not only can harm the animal as described above, but also severely degrade the integrity of quarter horse racing in California.

Authority and Reference Citations (pursuant to Gov Code 11346.5(a)(2))

The CHRB, pursuant to the authority granted by Business and Professions Code sections 19440 and 19580, in order to implement, interpret and make specific Title 4 California Code of Regulations (CCR) sections 1844, 1855, and 1866, proposes to add CCR section 1866.1 and amend section 1844.

Informative Digest (pursuant to Gov Code 11346.5(a)(3))

Title 4 CCR 1844, Authorized Medication, presently provides that official urine test samples from a horse may contain clenbuterol in an amount that does not exceed 140 picograms per milliliter. The proposed emergency regulations would revise the amount to 0 picograms per milliliter in quarter horses, making detection of clenbuterol in an official urine test sample impermissible for that breed of horse.

Title 4 CCR 1866, Veterinarian's List, provides that the official veterinarian shall maintain a Veterinarian's List of those horses determined to be unfit to compete in a race due to veterinary treatment, physical distress, injury, lameness, unsoundness or infirmity. The proposed emergency regulations would make the prescription of clenbuterol to a quarter horse a "veterinary treatment" under 1866, and further require any quarter horse who tests positive for clenbuterol in a blood, urine, or other official test sample to be placed on the Veterinarian's List until the presence of clenbuterol is no longer detected by an official test sample.

The proposed emergency regulations do not differ substantially from an existing comparable federal regulation or statute.

The CHRB finds that the broad objective of the regulation is to protect quarter horses from the unregulated and potentially harmful administration of clenbuterol, as well as to protect the wagering public from unfair advantages gained by trainers and owners who illegitimately enhance the performance of their horses using clenbuterol. The anticipated benefits of these regulations are that quarter horses receiving clenbuterol will not be permitted to race in California, protecting both the horse from potential injury and the public from negative perceptions of horse racing.

The proposed emergency regulations are not inconsistent or incompatible with existing state regulations.

Statutory Requirements Specific to Agency (pursuant to Gov Code 11346.5(a)(4))

There are no other matters as are prescribed by statute applicable to the specific state agency or to any specific regulation or class of regulations.

Local Mandate Determination (pursuant to Gov Code 11346.5(a)(5))

These proposed regulations impose no mandates on local agencies or school districts, or mandates which require reimbursement of costs or savings pursuant to Government Code sections 17500 – 17630.

Fiscal Impact Statements of Cost or Savings for the Following (pursuant to Gov Code 11346.5(a)(6))

- Cost to any local agency or school district that is required to be reimbursed: None
- Cost or savings to any state agency: None
- Cost or savings in federal funding to the state: None
- Other nondiscretionary cost or savings imposed on local agencies: None

CALIFORNIA HORSE RACING BOARD
TITLE 4. CALIFORNIA CODE OF REGULATIONS
ARTICLE 15. VETERINARY PRACTICES
PROPOSED ADDITION OF
RULE 1866.1. PRESENCE OF CLENBUTEROL IN QUARTER HORSES

1866.1. Presence of Clenbuterol in Quarter Horses

(a) A quarter horse prescribed clenbuterol will be placed on the Veterinarian's List for veterinary treatment until an official test sample shows that there is no clenbuterol in the blood or urine of the horse after a workout to demonstrate its physical fitness, pursuant to Rule 1866. Quarter horses on the Veterinarian's List for clenbuterol administration will not be allowed to start in a race until the horse is removed from the Veterinarian's List.

1) Veterinarians prescribing clenbuterol within the inclosure shall include the diagnosis justifying the prescription of clenbuterol, the dosage, and the most recent date of administration on the label. Clenbuterol shall only be prescribed to an individual quarter horse for a specific diagnosis to last for a defined period of time to ensure compliance with Rule 1864, Labeling of Medication. The quarter horse's name, diagnosis, dosage and most recent date of clenbuterol administration must be reported to the Official Veterinarian on form CHRB-24 (Rev. 7/15) (Veterinarian Report), which is hereby incorporated by reference.

(2) Administration of clenbuterol to a quarter horse must be reported by the trainer of the horse to the Official Veterinarian on form CHRB-60 (Rev. 7/15) (Trainer Medication Report), which is here by incorporated by reference.

(b) A quarter horse that, pursuant to Rules 1858 or 1859, tests positive for clenbuterol in either a blood, urine, or other official test sample will be placed on the Veterinarian's List until an investigation has been conducted to determine the circumstances of the presence of clenbuterol in the official test sample, and until an official test sample shows that there is no clenbuterol in the blood or urine of the horse after a workout to demonstrate its physical fitness, pursuant to Rule 1866.

(1) A "positive" test result is one in which the presence of clenbuterol is detected in an official test sample at an amount greater than 0.00%.

(c) A quarter horse shall not be removed from the Veterinarian's List and allowed to start in a race until an official test sample shows that there is no clenbuterol in the blood or urine of the horse after a workout to demonstrate its physical fitness pursuant to Rule 1866.

Authority: Sections 19440, 19562, and 19580
 Business and Professions Code

Reference: Sections 19440, 19562, and 19580
 Business and Professions Code

TRAINER MEDICATION REPORT

HORSE: _____

DATE OF RACE: _____ RACE NO.: _____

MEDICATION: _____

DATE TREATED: _____ TIME: A.M.
P.M.

TRAINER: _____
(SIGNATURE)

(PLEASE PRINT NAME)

COMMENTS: _____