

LAW AND PUBLIC SAFETY

NEW JERSEY RACING COMMISSION

Harness Racing

Medication and Testing Procedures

Adopted Amendment: N.J.A.C. 13:71-23.8

Proposed: November 20, 2006 at 38 N.J.R. 4820(b)

Adopted: April 19, 2007 by the New Jersey Racing Commission,
Frank Zanzuccki, Executive Director

Filed: April 27, 2007 as R. 2007 d. 172, **with a substantive change**,
not requiring additional public notice and comment (N.J.A.C. 1:30-6.3)

Authority: N.J.S.A. 5:5-30

Effective Date: May 21, 2007

Expiration Date: June 17, 2010

Summary of Public Comments and Agency Responses:

COMMENT: The rule amendment was proposed by Dr. Jay Baldwin, a licensed veterinary practitioner who treats race horses in this State and is licensed to do so by the New Jersey Racing Commission. In his petition, Dr. Baldwin commented that the drug AMICAR[®] is an adjunct medication which provides more aggressive therapy to prevent exercise induced pulmonary hemorrhage (EIPH), or respiratory bleeding, in racehorses. Dr. Baldwin further commented that AMICAR[®] is superior to

Furosemide (LASIX®), which drug is presently permissible to treat respiratory bleeding in eligible New Jersey race horses. Dr. Baldwin included in his comments a summary of research from the Oregon State University, which he indicated shows that AMICAR® is effective in controlling bleeding in race horses. Dr. Baldwin further commented that most of the other Mid-Atlantic region racing states currently allow race-day use of AMICAR®.

RESPONSE: As further discussed below, the preliminary findings of a Kansas State University study, and the preliminary findings of a University of Pennsylvania, School of Veterinary Medicine, New Bolton Center study, appear to question the research of the Oregon State University study, as reported by Dr. Baldwin, that AMICAR® is effective in controlling bleeding in race horses.

Significantly, however, in addition to the findings of scientific studies concerning AMICAR®, Dr. Baldwin correctly notes that AMICAR® is presently being used on racehorses in all the Mid-Atlantic region racing jurisdictions (i.e. Pennsylvania, Delaware, Maryland, Virginia, West Virginia), with the exception of New Jersey and New York. That permitted usage, under actual race conditions, allows for some assessment of the impact of such administrations in a direct sense. As concerns other states which have allowed the use of AMICAR®, the Racing Commission

has no information that equine practicing veterinarians administering the drug have reported witnessing negative impacts to the animal. Further, we have no information from the Racing Commissions of those states which indicates that any negative impacts have been experienced. While both the Kansas State University and the New Bolton Center study appear to conclude that the administration of AMICAR[®] has no efficacy in the treatment of respiratory bleeding, many practicing veterinarians and licensed horsemen, who have direct experience with the actual administration of the drug on racehorses, support the use of AMICAR[®].

The Racing Commission believes, as more fully explained below (See “Summary of Agency Initiated Change”), that permitting the use of AMICAR[®] in New Jersey on a limited basis, to December 31, 2007, will afford more time for scientific studies in this area to be finalized and, significantly, will also allow for direct observation of AMICAR[®] administration in this State. The permitted use of AMICAR[®] in this State for this designated time period, under the watchful eyes of the Racing Commission, the Racing Commission veterinary staff, and the New Jersey licensed veterinary practitioners, will afford opportunity for the Racing Commission and such veterinary professionals to directly observe the impact of AMICAR[®] administration on the eligible New Jersey horse race population.

In sum, the Racing Commission believes, in view of Dr. Baldwin's comments, as well as the other received comments and the various factors present, that its determination to adopt this rule with an agency initiated change limiting the effective date of paragraph 4 to the rule as proposed (that is, limiting AMICAR[®] administration to December 31, 2007), will not only allow time for additional scientific evidence to be developed, but among other things will beneficially allow for a direct assessment of AMICAR administration on the eligible New Jersey horse population.

COMMENT: Dr. Kenneth McKeever, Ph.D., filed comments in opposition to the proposed rule because, although the AMICAR[®] study at Kansas State University has not been formally completed, preliminary findings presented by Dr. McKeever indicate that: 1) AMICAR[®] has no efficacy in the treatment of EIPH; 2) its use demonstrates an ergolytic effect in racing horses (decreasing performance); and 3) the drug is potentially dangerous to the well-being of the horse's normal blood clotting mechanisms.

RESPONSE: Although Dr. McKeever presented scientifically relevant information on the use of AMICAR[®], the Commission notes that the Kansas State University study is not a published peer-reviewed study at this time. Further, although the Dr. McKeever reports that the Kansas State University study evidences that AMICAR[®] administration may have a negative impact on the health of a horse and horse performance, the New

Bolton Center study (also not a published peer-reviewed study at this time), which was completed after the submission of Dr. McKeever's comments, does not reportedly find such as part of its conclusions. As concerns the other Mid-Atlantic region states which have allowed the use of AMICAR[®], as was noted above, the Racing Commission has no information evidencing that the administration of AMICAR[®] has a negative health impact to the animal. While both the Kansas State University and the New Bolton Center study appear to conclude that the administration of AMICAR[®] has no efficacy in the treatment of EIPH, many practicing veterinarians and horsemen support the use of AMICAR[®].

COMMENT: Barbara Sachau opposes the new rule because it concerns the legal administration of medication to race horses. Ms. Sachau indicates that there is no research study available on the use of AMICAR[®] to treat exercised induced pulmonary hemorrhage. Ms. Sachau believes the proposal does not benefit the health of the animal but benefits the owners as it permits them to make money by racing horses which display respiratory bleeding.

RESPONSE: Although Ms. Sachau opposes the rule, the Racing Commission believes that the adoption of this rule, with an agency initiated change to the proposal limiting the use of AMICAR[®] in this State until December 31, 2007, will be beneficial for the reasons set forth in the

other comment responses and as described below (See “Summary of Agency Initiated Change”).

COMMENT: The New Jersey Thoroughbred Horsemen’s Association, Inc. (“NJTHA”) commented that it supports the proposed rule for the reasons that the permissible administration of AMICAR® in New Jersey would: assist in increasing field size, that is, the number of horses eligible to and participating in races; encourage other horsemen to ship race horses into New Jersey; stop New Jersey horsemen from shipping to neighboring states; and bring a level playing field to New Jersey as compared to surrounding states.

RESPONSE: The Racing Commission believes that its adoption of the rule, with the described agency initiated change, addresses the valid concerns as expressed by the NJTHA. The Racing Commission recognizes that its determination to limit the ability to administer AMICAR® to eligible New Jersey race horses, as a result of its determination to limit the applicability of paragraph 4 to the rule to December 31, 2007, will only temporarily address the NJTHA’s concerns. However, in view of other received comments and for the reasons elaborated upon below (See “Summary of Agency Initiated Change”), the Racing Commission believes that the imposition of this limitation is prudent, warranted, and will allow for the development of additional scientific and practical evidence

concerning AMICAR®. In the event the Racing Commission determines, through the rulemaking process, to propose that this rule be further amended to permit the administration of AMICAR® beyond December 31, 2007, the additional evidence that will arise during this AMICAR® use period will likely be most pertinent.

COMMENT: The Racing Commission received a petition, signed by various horsemen, in favor of the rule as proposed. This petition was signed by approximately 71 persons, most of whom appear to be affiliated with harness racing. The petition reads as follows: “WE THE UNDERSIGNED NJRC Licensees respectfully request that race-day use of AMICAR® be allowed in NJ, for the health benefit of our horses...”

RESPONSE: As noted above, the question of whether AMICAR® is effective in aiding respiratory bleeding race horses appears inconclusive. The Racing Commission believes, in view of all factors present, including this and the other received comments, that the adoption of this rule with the described agency initiated change will allow time for additional scientific evidence to be developed or finalized. The Racing Commission further believes this will permit opportunity for a direct assessment of AMICAR® administration on the New Jersey horse population, and allow additional time to consult with other competing racing jurisdictions concerning their use or discontinuance of AMICAR® in 2008.

Summary of Agency Initiated Change:

The Racing Commission, at its public meeting of April 19, 2007, determined to adopt the rule proposal with a substantive change. For the reasons described herein, the Racing Commission determined to adopt paragraph 4 to the rule, but only until December 31, 2007. This change is set forth through the addition of subparagraph ii to paragraph 4 to the rule as proposed. As a result of this agency initiated change to the rule as proposed, and unless this rule is further amended through additional and independent rule making authorizing the administration of AMICAR® beyond such date, the administration of AMICAR® is only authorized as a result of the instant adoption until December 31, 2007.

Pursuant to its review of this matter, and in arriving at its determination to adopt this rule with the noted change, the Racing Commission balanced various factors relating to the use of AMICAR® in New Jersey racehorses. The Racing Commission considered that various racing jurisdictions (Maryland, Pennsylvania, Delaware, West Virginia, Virginia, Kentucky, Ohio), some of which are considered to form a “racing circuit” with New Jersey, have permitted and presently permit the administration of AMICAR®. The discrepancy concerning AMICAR®, between New Jersey and such other states, results in a competitive disadvantage to the New Jersey racing industry and its participants.

Horsemen from those other states which permit AMICAR® are discouraged from bringing their horses to New Jersey, because those horses would be required to compete in this State without such an administration. Conversely, New Jersey horsemen are placed in a position where they must decide whether to transport their horses to these other jurisdictions and there allow them to be treated with AMICAR®, and in such case, whether to allow them to return to New Jersey where they must be taken off AMICAR® to be eligible to race. These factors translate to a decrease in the New Jersey race horse population.

Further, pursuant to the rulemaking process, the Racing Commission was presented with no evidence that the administration of AMICAR® in those jurisdictions permitting it has had any negative consequence to the animal, or to the conduct of racing. It appears that other states permitting the administration of AMICAR® have done so primarily based upon anecdotal information or veterinary opinion that it benefits racehorses by preventing or positively impacting respiratory bleeding in the animal, without impacting race performance. In its evaluation, the Racing Commission also considered the state of the available scientific evidence concerning AMICAR® administration. The Racing Commission, in view of ongoing research in this area of science, was interested in whether AMICAR® has been demonstrated to medically

assist racehorses that are respiratory bleeders, and whether such an administration impacts performance. The Racing Commission, in this regard, was awaiting the results of a most current study in this area, which was commissioned by the “National Racing Consortium” (i.e., the New Bolton Center study). Although that completed study has yet to be submitted for “peer review”, and has not been published in a scientific journal, the Racing Commission has been advised the study concludes that AMICAR® has no medical impact on respiratory bleeders and, in terms of the horses performance, has a benign or no effect.

In view of these findings of the New Bolton Center study, the Racing Commission has recently been informed that a number of the other Mid-Atlantic region jurisdictions, which permit the administration of AMICAR®, will continue to monitor the status of this science (and particularly the New Bolton Center study), as well as other pertinent factors regarding the administration of AMICAR®, to determine whether the administration of AMICAR® beyond 2007 should there be continue or be discontinued. The New Jersey Racing Commission will be meeting with these other jurisdictions, in the next few months, specifically to discuss this question of regional importance.

Accordingly, in considering this matter, the Racing Commission balanced the impact of the continued use of AMICAR® in competing

jurisdictions with the apparent fluid status of the scientific evidence surrounding AMICAR[®]. The Commission is of the view that, adopting the aspect of the rule allowing for the administration of AMICAR[®], until December 31, 2007 only, will have positive impacts. These positive impacts include, during this period, to place the New Jersey racing industry on a more equal competitive basis with those jurisdictions now permitting the use of AMICAR[®]. An additional significant benefit will be to allow the Racing Commission, and its regulated community, to view first-hand the impacts of AMICAR[®] administration upon New Jersey racehorses that qualify as respiratory bleeders for such an administration. It will also allow the Racing Commission to survey the other Mid-Atlantic racing jurisdictions to determine their position on AMICAR[®] usage during 2008. The Racing Commission further believes that the experience to be gained as a result of its action, in approving the administration of AMICAR[®] through the end of the year, will allow opportunity for meaningful first-hand rule proposal commentary to be submitted, should the Racing Commission determine to advertise a further amendment to this rule, proposing to authorize the administration of AMICAR[®] to New Jersey race horses beyond the current December 31, 2007 restriction.

Federal Standards Statement

A Federal standards analysis is not required because the rules of

racing are dictated by State statute, N.J.S.A. 5:5-22, et seq., and the adopted amendment is not subject to any Federal requirements or standards.

Full text of the adoption follows (additions to proposal indicated in boldface with asterisks *thus*):

13:71-23.8 Administering medication to respiratory bleeders;
standards for the administration of non steroidal anti-inflammatory drugs (NSAID) and anti ulcer medications;
environmental contaminants.

(a) The Board of Judges may permit the administration of medication to control respiratory bleeding under the following conditions:

1-3. (No change).

4. If a horse is approved to receive Furosemide, the use of aminocaproic acid (AMICAR[®] injectable only) as an adjunct bleeder medication may be co-administered by a licensed veterinarian only when the horse receives Furosemide. Dose: AMICAR[®] injectable 10 ml (2.5 gram) I.V. four hours pre-race.

i. Veterinarians must report that the horse was co-treated with AMICAR[®] on the Furosemide medication slip.

ii. The administration of AMICAR[®], pursuant to this paragraph, is only approved through December 31, 2007.

(b)-(k) (no change from proposal)