**LAW AND PUBLIC SAFETY**

**NEW JERSEY RACING COMMISSION**

**Harness Racing**

**Medication and Testing Procedures**

**Proposed Amendment: N.J.A.C. 13:71-23.8**

Authorized By: New Jersey Racing Commission,
Frank Zanzuccki, Executive Director

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

Calendar Reference: See Summary below for explanation of exception to calendar requirement

Proposal Number: PRN 2008-97_____

Submit written comments by June 6, 2008 to:

Michael Vukcevich, Deputy Director
Department of Law and Public Safety
New Jersey Racing Commission
P.O. Box 088
Trenton, New Jersey 08625-0088

The agency proposal follows:

## Summary

N.J.A.C. 13:71-23, (Medication and Testing Procedures) sets forth the rules of the New Jersey Racing Commission concerning the administration of medication and foreign substances to standardbred race horses. On May 21, 2007, the Commission amended N.J.A.C. 13:71-23.8 to authorize the use of aminocaproic acid (AMICAR(R)) with Furosemide (LASIX(R)) as an adjunct bleeder medication for horses that have been placed on the Furosemide List. See 38 N.J.R. 4820(b), 39 N.J.R. 2135(a). At the time of the

adoption of this amendment to the rule, because of uncertainties concerning the efficacy of AMICAR(R) in the treatment of Exercise Induced Pulmonary Hemorrhage (EIPH), the Commission authorized the use of AMICAR(R) only until December 31, 2007.

To accomplish this limitation, the Racing Commission added subparagraph ii to paragraph (a)4 of rule N.J.A.C. 13:71-23.8. See 39 N.J.R. 2135(a). This subparagraph specifically provided that "[t]he administration of AMICAR(R), pursuant to this paragraph, is only approved through December 31, 2007." As a result of a subsequent amendment to N.J.A.C. 13:71-23.8, paragraph (a)4, which addressed the use of AMICAR(R), was moved to paragraph (a)6. See 39 N.J.R. 5365(a)(effective December 17, 2007). In adopting this sunset provision, the Racing Commission expressed concern over the lack of conclusive scientific data at that time which either established the efficacy of AMICAR(R) in treating EIPH or showed proof of harm to those horses to whom AMICAR(R) is administered. By authorizing the administration of AMICAR(R) until December 31, 2007, the Commission hoped for the development of valid, cognizable scientific evidence that would either support the medical use of AMICAR(R) or oppose it. However, to date, scientific data regarding the therapeutic value of AMICAR(R) or its harmful side effects have not yet materialized.

In proposing this current amendment to N.J.A.C. 13:71-23.8, which would allow for the continued use of AMICAR(R), the Commission anticipates that the industry's experience in using

AMICAR(R) in 2007 will generate meaningful and important public comment as to whether the use of AMICAR(R) in this jurisdiction has been positive or negative. The comment period would also allow interested parties to submit research studies from other jurisdictions that are published, or otherwise recognized as completed by the academic community. Following the 60-day comment period for this proposed amendment, the Commission will evaluate all available information and decide whether to reauthorize, through adoption, the use of AMICAR(R) pursuant to the terms and conditions set forth in the rule. As a result of this 60-day comment period, this notice is excepted from the rulemaking calendar requirements in accordance with N.J.A.C. 1:30-3.3(a)5.

The Commission looks forward to and welcomes further study and industry input into the efficacy of AMICAR(R). It is important to note that to date, the Commission has not received any information which establishes that the negative impact of allowing the use of AMICAR(R) outweighs the benefit to those horses to whom it is administered. As a result, the Commission has decided to propose, obtain comments and consider the continued use of AMICAR(R).

It is also important to note, however, that should the Commission obtain sufficient, valid evidence that the use of AMICAR(R) is harmful to the animal or it is otherwise contraindicated, it is the intent of the Commission to act expediently to propose the repeal of that portion of this rule that

authorizes the use of this drug. In doing so, provision will be made in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., to afford all interested parties an opportunity to submit data, comments or arguments regarding the discontinuance of AMICAR(R).

Finally, it is also important to note that by all appearances, the Commission's decision to allow the use of AMICAR(R) in 2007 was beneficial to the racing industry and horsemen who participate in New Jersey's "racing circuit" and neighboring states. Maryland, Pennsylvania, Delaware, West Virginia, Virginia, Kentucky and Ohio permit the administrative of AMICAR(R) to horses who race there. New Jersey's decision to allow the use of AMICAR(R) in this State means that horses who have a therapeutic need for this medication can move freely within these states to compete. Thus, because the use of AMICAR(R) is consistent with the racing practice in neighboring states, allowing its use in this State has had a positive impact on the racing industry in that regard.

**Social Impact**

It is anticipated that the proposed amendment will more likely have a positive social impact on horse racing in this state by ensuring that horses with a medical need for AMICAR(R) can receive it on race day. Of course as discussed above, further study regarding the therapeutic value of AMICAR(R) or its harmful side effects is necessary before its benefit can be conclusively

established. If the bulk of compiled data were to establish that AMICAR(R) harms horses or does not assist horses suffering from EIPH, permitting the race day administration this drug would clearly have a negative social impact. However, as set forth above, if such data were to materialize, it is the intention of the Commission to act expediently to repeal the use of AMICAR(R) in this State.

## Economic Impact

It is expected that the proposed amendment will have a positive economic impact for the New Jersey racetracks. The proposed amendment, if adopted, allows the New Jersey racetracks to continue to accommodate horsemen from other states that permit the use of AMICAR(R). Of course, an owner or trainer who decides to treat his or her horse with AMICAR(R) will be responsible for the cost of this veterinarian service.

## Federal Standards Statement

A Federal standards analysis is not required because the rules of racing are authorized by State statute, N.J.S.A. 5:5-22 et seq., and the proposed amendment is not subject to any Federal standards or requirements.

## Jobs Impact

The proposed amendment will not result in either the

generation or loss of jobs. Although the proposed amendment will impose additional job responsibilities on Racing Commission staff and the Commission's equine testing laboratory, the data from the 2007 administration of AMICAR(R) indicates that these additional job responsibilities can likely be handled by its existing staff without the need to hire additional personnel.

**Agriculture Industry Impact**

The proposed amendment will have no impact on the agriculture industry in the State.

**Regulatory Flexibility Analysis**

The proposed amendment does not impose any reporting or recordkeeping requirements on small businesses as defined by the Regulatory Flexibility Act, N.J.S.A. 52:14B-1 et seq. The proposed amendment to N.J.A.C. 13:70-14A.9 imposes minimal additional compliance responsibilities on racetrack veterinarians since the administration of AMICAR(R) takes place at the same time the horse is dosed with Furosemide. The only recordkeeping caused by the proposed amendment would require veterinarians to note the co-administration of AMICAR(R) on the currently-required Furosemide medication slips. Although some owners and trainers operate as small businesses, the proposed amendment does not impose any additional responsibility upon them. Costs related to the administration of AMICAR(R) are discussed above in the Economic

Impact.

**Smart Growth Impact**

The proposed amendment will have no impact on the achievement of smart growth or the implementation of the State Development and Redevelopment Plan.

Full text of the proposal follows (deletions indicated in brackets [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 - 5 (No change.)

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

i. (No change)

[ii. The administration of AMICAR(R) pursuant to this paragraph, is only approved through December

31, 2007.]

(b) - (k) (No change.)