

amended by revising the ECCN heading to read as follows:

2B351 Toxic gas monitoring systems that operate on-line and dedicated detectors therefor, except those systems and detectors controlled by ECCN 1A004.c.

* * * * *

Dated: January 10, 2005.

Eileen Albanese,

Director, Office of Exporter Services.

[FR Doc. 05-719 Filed 1-12-05; 8:45 am]

BILLING CODE 3510-33-P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 171

RIN 3038-AC12

Rules Relating to Review of National Futures Association Decisions in Disciplinary, Membership Denial, Registration and Member Responsibility Actions

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission ("Commission" or "CFTC") hereby amends its rules relating to the scope of Commission review of National Futures Association ("NFA") decisions in disciplinary, membership denial, registration and member responsibility actions. First, the Commission makes a technical amendment to add the NFA's Hearing Committee to the list of committees covered by that section. This change conforms Rule 171.1(b)(4) to changes in NFA's committee structure since part 171 was first adopted in October 1990. Secondly, the Commission adds a new provision to exclude from Commission review any appeal concerning NFA suspension of a member for failing to pay settlement or arbitration award ("award suspension cases") unless there are extraordinary circumstances that would otherwise warrant Commission review.

DATES: Effective January 13, 2005.

FOR FURTHER INFORMATION CONTACT: Thuy Dinh or Gail Scott, Office of the General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone: (202) 418-5120.

SUPPLEMENTARY INFORMATION:

I. Scope of Commission Review

On June 15, 1990, the Commission published proposed rules establishing

standards and procedures for its review of decisions of registered futures associations such as NFA in disciplinary actions, membership denial actions, registration actions and member responsibility actions. 55 FR 24254. Under the proposed rules, two categories of decisions were excluded from Commission review: (a) Disciplinary decisions in which the aggrieved party failed to pursue his or her appeal rights to the NFA Appeals Committee and no extraordinary circumstances warranted Commission review; and (b) decisions in arbitration actions. See 171.1(b)(1) and 171.1(b)(2), respectively. Two comment letters were received in response to the request for public comment. Of particular interest to the Commission was a letter it received from the NFA.¹

In its letter, the NFA proposed that the Commission exclude any appeal arising from NFA suspension of an association member based solely on that member's failure to pay NFA dues or arbitration awards.² In its final rules published on October 9, 1990, the Commission agreed that the suspension for non-payment of dues should not generally be considered a disciplinary action subject to Commission review and accordingly amended the proposed rules by adding 171.1(b)(3) under "Matters excluded" in the publication of its final rules. See 55 FR 41061. However, the Commission specifically rejected NFA's request to exclude from Commission review the suspension of a member for failing to pay arbitration awards, stating:

The Commission is reluctant at this time * * * to exclude suspension of a member for failing to pay arbitration awards. When the Commission has excluded NFA arbitration decisions themselves from its review, one of the reasons it has done so is that these decisions can be reversed in the court system. In contrast, membership suspension raises somewhat different issues which generally go to the core of the Commission's

¹ August 31, 1990 NFA Letter ("NFA Letter").

² The NFA presumed that "actions in these areas would not be deemed disciplinary actions" within Commission review under Part 171. NFA Letter at 7. Section 10(g) of NFA's Code of Arbitration (Code) and Section 10(g) of NFA's Member Arbitration Rules (Member Rules) authorize NFA to summarily suspend an NFA member or associate if such member or associate fails to pay an NFA award or settlement reached in an NFA arbitration or mediation proceeding within 30 days. Members and associates receive a 30-day written notice before the suspension becomes effective, giving them a minimum of 60 days to satisfy the award or settlement. Once the suspension becomes effective, a member or associate can get it lifted at any time by paying the amount due. A member or associate can also file a motion to vacate the award. A timely motion to vacate an award stays the suspension while the motion is pending in a court of competent jurisdiction.

role in reviewing NFA actions affecting membership status. Pending additional experience on the issue the Commission has determined not to exclude such NFA action from its appellate jurisdiction.

Id. at 41064.

From 1990 to the present, the Commission has received a total of five appeals related to the suspension of a member for failing to pay an arbitration award. The Commission first considered this issue in 1991, shortly after Part 171 was adopted. In the initial case, the respondent asked the Commission to stay the suspension while he worked out a payment schedule. In rejecting the petition, the Commission stated, "NFA's ministerial imposition of a pre-determined sanction for a member's failure to perform an undisputed duty of membership [to pay an arbitration award] is not, without more, a proper subject for Commission review." *Machin v. NFA*, [1990-1992 Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶ 25,041 at 37,893 (CFTC Apr. 25, 1991).

There were no other appeals of this nature until 1997, when the Commission dismissed an appeal from an award suspension where the appeal was predicated on alleged procedural and substantive errors in the underlying arbitration. The Commission stated, "it would be inappropriate to consider either procedural or substantive errors in NFA's resolution of the issues raised in the arbitration." *Indelicato v. NFA*, [1996-1998 Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶ 27,130 at 45,287 (CFTC Aug. 7, 1997). Citing *Machin*, the Commission further noted, "the imposition of a suspension for failing to pay an arbitration award might be reviewable upon a showing that NFA acted arbitrarily in imposing the suspension. Here, however, as in *Machin*, petitioners have failed to establish such arbitrariness." *Id.*

The Commission's denials of review in three recent cases, from March 2003 to February 2004, have followed *Machin* and *Indelicato*, *i.e.*, declining to accept any appeal from this type of suspension unless it "involves something more than the ministerial application of a pre-determined sanction." See *Howell v. NFA*, [Current Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶ 29,702 at 55,993 (CFTC Feb. 27, 2004); *Mawhorr v. NFA*, [Current Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶ 29,633 at 55,717 (CFTC Nov. 28, 2003); *Bunyard v. NFA*, CRAA 03-01 (CFTC Mar. 5, 2003). In *Bunyard*, the Commission stated, "[only] an appeal raising a colorable claim that the NFA acted arbitrarily—or a similar claim that goes to the core of the Commission's role in ensuring the reliability of NFA's membership

process—would fall within our jurisdiction.” *Id.* at 2.

Against this backdrop, the NFA this year again proposed that the Commission exclude from its jurisdiction membership suspension cases based solely on the members’ failure to pay arbitration awards. *See* April 15, 2004 NFA Letter at 5. The NFA discussed the Commission’s disposition of these types of appeals during the last 14 years. Noting that the Commission had routinely rejected such appeals, the NFA proposed that the Part 171 Rules be amended to reflect the Commission’s actual practice, which is to limit review to cases presenting “extraordinary circumstances.” *Id.* at 4.

In its notice of proposed rulemaking, the Commission noted that it had reviewed its case history in this area and reached the following conclusions: (a) Such appeals are very infrequent; and (b) the few cases that have reached the Commission did not raise a colorable challenge to the fundamental fairness of the proceeding, and fell squarely into the “ministerial” category that would not warrant Commission review. Based on this experience, the Commission proposed to exclude these routine matters from appellate review. The Commission proposed to exercise its appellate jurisdiction in the extraordinary case where an appeal based on an award suspension involved “something more than a ministerial application of a predetermined sanction.” The proposed rule incorporated the Commission’s language used in *Machin* and *Indelicato*.

The notice for the proposed rule was published in the **Federal Register** on October 25, 2004, providing a thirty-day comment period. On November 17, 2004, Mr. Thomas Sexton, NFA Vice President and General Counsel, wrote to the Commission endorsing the proposed amendment. Reviewing NFA arbitration cases of the past 14 years, the letter noted the following statistics:

Since November 1, 1990, when Part 171 became effective, NFA has closed approximately 2750 arbitration cases. Approximately 450 of these cases have resulted in awards against Members and Associates. Approximately 1150 more of these cases settled since June 1, 1993, when we added unpaid settlements to the suspension rules. These 1600 cases generated only 61 suspensions, and only five of those have been appealed to the Commission. The Commission denied review in each of these five cases, ruling that the ministerial imposition of a predetermined sanction is not a proper subject for Commission review. Nonetheless, in each one of these cases the Commission and NFA—as well as the suspended Member or Associate—expended significant resources on the appeal.

Sexton Letter at 1.

The letter concluded that the Commission’s amendments will not eliminate existing rights, but “will clarify the current practice * * * and conserve resources * * * that * * * would otherwise [be] waste[d] on appeals that will not be accepted for review.” *Id.* at 2. The letter further acknowledged that the Commission amendments, in choosing to review only cases in which an NFA Member or Associate has a colorable claim that NFA acted arbitrarily or if other extraordinary circumstances exist, provide Members and Associates with an adequate remedy against unreasonable suspensions. *Id.* In essence, the letter reiterated the Commission’s objectives for instituting the amendments.

The Commissioner received no other comment from the public. The comment period ended on November 24, 2004.

II. Technical Amendment

Commission Rule 1.63 bars persons with certain disciplinary histories from serving on “a disciplinary committee” or in other leadership positions of any self-regulatory organization. Rule 171.1(b)(4) provides that NFA decisions made pursuant to Rule 1.63 are excluded from Commission review. As currently written, it forecloses appeals by an NFA member who is disqualified from service on NFA’s “Board of Directors, Business Conduct Committees or arbitration panels.” Since Rule 171.1(b)(4) was promulgated, NFA has established a Hearing Committee as part of its disciplinary function. The Commission is making a technical amendment to Rule 171.1(b)(4) to add the Hearing Committee to the list of committees covered by the rule.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (“RFA”), 5 U.S.C. 601 *et seq.*, requires agencies with rulemaking authority to consider the impact those rules will have on small businesses. With respect to persons seeking Commission reviews of NFA adjudicatory decisions, the amendments would impose no additional regulatory burden. Commission review of NFA disciplinary and membership denial actions has been carried out pursuant to 17 CFR Part 171 since 1990. These amendments do not present any significant changes and would in fact ease the regulatory burden to some extent by providing greater certainty and predictability concerning the standards and procedures governing such review.

Accordingly, the Acting Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the amendments will not have a significant economic impact on a substantial number of small businesses.

B. Paperwork Reduction Act

The amendments to Part 171 rules do not impose a burden within the meaning and intent of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501, *et seq.*

C. Cost-Benefit Analysis

Section 15(a) of the Commodity Exchange Act, 7 U.S.C. 19(a), requires the Commission to consider the costs and benefits of its action before issuing a new regulation. The Commission understands that, by its terms, Section 15(a) does not require the Commission to quantify the costs and benefits of a new regulation or to determine whether the benefits of the proposed regulation outweigh its costs. Nor does it require that each proposed rule be analyzed in isolation when that rule is a component of a larger package of rules or rule revisions. Rather, section 15(a) simply requires the Commission to “consider the costs and benefits” of its action.

Section 15(a) further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. Accordingly, the Commission can, in its discretion, give greater weight to any one of the five enumerated areas of concern and can, in its discretion, determine that notwithstanding its costs, a particular rule is necessary or appropriate to protect the public interest or to effectuate any of the provisions, or accomplish any of the purposes, of the Commodity Exchange Act.

The amendments to Part 171 will not create any significant change in the Commission’s appellate process. In fact, the amendments should enhance the protection of market participants and the public by excluding from the Commission’s review matters that represent routine enforcement of a NFA pre-determined sanction, freeing both the Commission’s and NFA’s resources. In addition, since the amendments retain the Commission’s ability to consider appeals that present “extraordinary circumstances,” public interest considerations for fundamental fairness and the Commission’s supervisory authority regarding self-

regulated organizations will not be compromised.

After considering these factors, the Commission has determined to amend Part 171, as set forth below.

List of Subjects in 17 CFR Part 171

Administrative practice and procedure, Commodity exchanges, Commodity futures.

■ In consideration of the following, the Commission hereby amends chapter I of title 17 of the Code of Federal Regulations as follows:

PART 171—RULES RELATING TO REVIEW OF NATIONAL FUTURES ASSOCIATION DECISIONS IN DISCIPLINARY, MEMBERSHIP DENIAL, REGISTRATION AND MEMBER RESPONSIBILITY ACTIONS

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 7 U.S.C. 4a, 12a, and 21.

■ 2. Section 171.1(b) is amended in paragraph (b)(4) by adding “, Hearing Committee” between “Business Conduct Committees” and “or arbitration panels”; and replacing “.” with “;” at the end of (b)(4); and by adding new paragraph (b)(5):

§ 171.1 Scope of rules.

* * * * *

(b) * * *

(5) Suspension of a member or a person associated with a member based solely on that person’s failure to pay an arbitration award or a settlement agreement resulting from an arbitration action brought pursuant to section 17(b)(10) of the Act or rules and regulations of the National Futures Association, or a settlement agreement resulting from a mediation proceeding sponsored by the National Futures Association, unless there are extraordinary circumstances that involve something more than the ministerial application of a predetermined sanction, or raise a colorable claim that the National Futures Association has acted arbitrarily.

* * * * *

Issued in Washington, DC on the 10th day of January 2005, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 05–709 Filed 1–12–05; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor’s Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor’s address for Alstoe, Ltd.

DATES: This rule is effective January 13, 2005.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.gov*.

SUPPLEMENTARY INFORMATION: Alstoe, Ltd., Animal Health, Granary Chambers, 37–39 Burton St., Melton Mowbray, Leicestershire LE13 1AF, England has informed FDA of a change of address to Pera Innovation Park, Nottingham Rd., Melton Mowbray, Leicestershire, England LE13 0PB. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect the change.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for “Alstoe, Ltd.”; and in the table in paragraph (c)(2) by revising the entry for “062408” to read as follows.

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	* * * * *
Alstoe, Ltd., Animal Health, Pera Innovation Park, Nottingham Rd., Melton Mowbray, Leicestershire, England LE13 0PB	062408
* * * * *	* * * * *
(2) * * *	
Drug labeler code	Firm name and address
* * * * *	* * * * *
062408	Alstoe, Ltd., Animal Health, Pera Innovation Park, Nottingham Rd., Melton Mowbray, Leicestershire, England LE13 0PB
* * * * *	* * * * *

Dated: January 3, 2005.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 05–697 Filed 1–12–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Levamisole Powder for Oral Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of levamisole hydrochloride soluble powder to make a drench solution for oral administration to cattle and sheep which is effective against various internal parasites.

DATES: This rule is effective January 13, 2005.