

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647-5527) is provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2009-09-03 Turbomeca S.A.: Amendment 39-15889. Docket No. FAA-2007-28077; Directorate Identifier 2007-NE-20-AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective June 1, 2009.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Turbomeca S.A. Arriel 2B and 2B1 turboshaft engines. These engines are installed on, but not limited to, Eurocopter AS 350 B3 and EC 130 B4 helicopters.

Reason

(d) Several cases of Gas Generator Turbine (HP Turbine) blade rearward displacement

have been detected during borescope inspection or in repair centre following engine disassembly. Two of them resulted in blade rubs between the rear face of the fir-tree roots and the rear bearing support cover. High HP blade rearward displacement can potentially result in blade release due to fatigue of the blade, which would cause an uncommanded in-flight engine shutdown.

We are issuing this AD to prevent an uncommanded in-flight engine shutdown which could result in an emergency autorotation landing or, at worst, an accident.

Actions and Compliance

(e) Unless already done, do the following actions:

Initial Inspection

(1) Perform an initial HP turbine borescope inspection according to Turbomeca S.A. Mandatory Service Bulletin (MSB) No. 292 72 2825, dated April 5, 2007 as follows:

(i) For engines with fewer than 500 hours and 450 cycles since new or since the last HP turbine borescope inspection, inspect before reaching 600 hours or 500 cycles, whichever occurs first. Replace HP turbine modules with rearward turbine blade displacement greater than 0.5 mm.

(ii) For the remaining engines, inspect within the next 100 hours. Replace HP turbine modules with rearward turbine blade displacement greater than 0.5 mm.

Repetitive Inspections

(2) Perform repetitive HP turbine borescope inspections according to Turbomeca S.A. MSB No. 292 72 2825, dated April 5, 2007:

(i) Within 600 hours or 500 cycles from the previous inspection, whichever occurs first, if the rearward displacement of the turbine blades was less than 0.2 mm. Replace HP turbine modules with rearward turbine blade displacement greater than 0.5 mm.

(ii) Within 100 hours of the previous inspection if the rearward displacement of the turbine blades was between 0.2 mm and 0.5 mm. Replace HP turbine modules with rearward turbine blade displacement greater than 0.5 mm.

FAA AD Differences

(f) For clarification, we restructured the actions and compliance wording of this AD.

(g) We deleted the Turbomeca reporting requirement from the AD, since we determined that the reporting requirement was unnecessary.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Engine Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Related Information

(i) Refer to EASA Airworthiness Directive 2007-0109, dated April 19, 2007, and Turbomeca S.A. MSB No. 292 72 2825, dated April 5, 2007, for related information.

(j) Contact James Lawrence, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail: james.lawrence@faa.gov;

telephone (781) 238-7176; fax (781) 238-7199, for more information about this AD.

Material Incorporated by Reference

(k) You must use Turbomeca S.A. Mandatory Service Bulletin No. 292 72 2825, dated April 5, 2007, to do the actions required by this AD, unless the AD specifies otherwise.

(l) For service information identified in this AD, contact Turbomeca, 40220 Tarnos, France; telephone 33 05 59 74 40 00, fax 33 05 59 74 45 15.

(m) You may review copies at the FAA, New England Region, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Burlington, Massachusetts, on April 16, 2009.

Peter A. White,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E9-9333 Filed 4-24-09; 8:45 am]

BILLING CODE 4910-13-P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 38

RIN 3038-AC28

Conflicts of Interest in Self-Regulation and Self-Regulatory Organizations

AGENCY: Commodity Futures Trading Commission ("Commission").

ACTION: Final rule.

SUMMARY: The Commission hereby adopts its final definition of "public director" for the acceptable practices to Section 5(d)(15) ("Core Principle 15") of the Commodity Exchange Act ("CEA" or "Act").¹ In addition, the Commission is lifting the stay it had previously placed on these acceptable practices. All designated contract markets ("DCMs") must demonstrate full compliance with Core Principle 15, via the acceptable practices or otherwise, within one year of this document's publication in the **Federal Register**. The acceptable practices and their procedural history

¹ The Act is codified at 7 U.S.C. 1 *et seq.* (2000). The acceptable practices for the DCM core principles reside in Appendix B to Part 38 of the Commission's Regulations, 17 CFR Part 38, App. B. Core Principle 15 states: "CONFLICTS OF INTEREST—The board of trade shall establish and enforce rules to minimize conflicts of interest in the decision making process of the contract market and establish a process for resolving such conflicts of interest." CEA Section 5(d)(15). 7 U.S.C. 7(d)(15).

are summarized below, as is the final definition of public director.

DATES: *Effective date:* The stay is lifted on paragraph (b) of Core Principle 15 in Appendix B to 17 CFR Part 38 effective May 27, 2009. The amendments to the acceptable practices in appendix B to part 38 are effective May 27, 2009.

Compliance date: All DCMs must demonstrate full compliance with Core Principle 15 by April 27, 2010.

FOR FURTHER INFORMATION CONTACT: Rachel F. Berdansky, Deputy Director for Market Compliance, 202-418-5429, or Sebastian Pujol Schott, Special Counsel, 202-418-5641, Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

A. Summary of the Acceptable Practices

As noted above, the Commission hereby adopts its final definition of public director and lifts its stay on the acceptable practices for Core Principle 15.² These important acceptable practices consist of four interrelated provisions, including three operating provisions (sections (1), (3), and (4)) and one which provides necessary definitions (section (2)). The operating provisions pertain to DCM boards of directors, the insulation and oversight of self-regulatory functions through regulatory oversight committees ("ROCs"), and the composition of disciplinary panels. More specifically, section (1) requires that a DCM's board and any executive committee of the board be composed of at least 35% public directors. Section (3) requires that a DCM's regulatory programs fall under the authority of a board-level ROC consisting exclusively of public directors. Section (4) requires that a DCM's disciplinary panels include at least one public person. To fully implement the acceptable practices, DCMs must enact all three sections.

Sections (1), (3), and (4) of the acceptable practices are each dependent on the presence of one or more "public" persons, either public directors serving on the board, public directors serving on the ROC, or public members serving on disciplinary panels. Thus, the acceptable practices include an important fourth provision—section (2)—that defines "public director" and

also impacts disciplinary panel members. The definition of public director includes several subsections. The first and most important, subsection (2)(i), is an overarching materiality test which requires that a public director "have no material relationship with the contract market." The definition also includes a series of bright-line tests in subsections (2)(ii)(A)–(2)(ii)(D), with specific relationships defined as *per se* material. Finally, subsections (2)(iii), (2)(iv) and (2)(v) pertain to a one-year look back period, affiliate relationships, and disclosure requirement, respectively.³

Given the acceptable practices' long procedural history, outlined below, industry participants may benefit from a brief review of their underlying rationale, purpose, and importance. Above all, the Commission emphasizes its full commitment to Core Principle 15's acceptable practices in their entirety. As the Commission noted when it adopted them, the acceptable practices "recognize DCMs' unique public interest responsibilities as self-regulatory organizations ("SROs") in the U.S. futures industry."⁴ They remind all DCMs that they "bear special responsibility to regulate effectively, impartially, and with due consideration of the public interest."⁵ They also clearly enumerate certain conflicts of interest for which DCMs must be alert. To comply with Core Principle 15, all DCMs must be "particularly vigilant" for "conflicts between and among any of their self-regulatory responsibilities, their commercial interests, and the several interests of their management, members, owners, customers and market participants, other industry participants, and other constituencies."⁶

When the Commission adopted the acceptable practices on January 31, 2007, it noted new structural conflicts of interest in self-regulation as for-profit DCMs operate in a competitive, global environment. The Commission expressed concern with the presence of potentially conflicting demands—regulatory responsibility vs. commercial imperatives—within a single for-profit entity. It concluded that such conflicts, arising from new business models, new ownership structures, and increased competition, could be addressed

³ While not required under these acceptable practices, the Commission believes that DCMs benefit from endeavoring to recruit their public directors from a broad and culturally diverse pool of qualified candidates.

⁴ 72 FR 6936 at 6937 (February 14, 2007).

⁵ 17 CFR Part 38, App. B, Core Principle 15 (Acceptable Practices).

⁶ *Id.*

through "reforms within the DCMs themselves, including reforms of DCMs' governing bodies."⁷ The acceptable practices reflect both concrete measures that DCMs may implement and principles of modern self-regulation based on public representation and the insulation of regulatory functions. They embody the Commission's settled position that "additional public directors on governing bodies, greater independence at key levels of decision making, and careful insulation of regulatory functions and personnel from commercial pressures are important elements in ensuring vigorous, effective, and impartial self-regulation now and in the future."⁸

One principle embodied in the acceptable practices is the inclusion of public persons on DCM boards, executive committees, and disciplinary panels. Subsection (1)(i) of the acceptable practices requires that at least 35% of a DCM's directors be public directors, with an identical minimum ratio of public directors required for executive committees of the board or similarly empowered bodies under subsection (1)(ii). As the Commission explained when adopting the acceptable practices, it "strongly believes that DCMs are best able to meet their statutory obligations if their boards and executive committees include a sufficient number of public directors. * * * Such boards and committees will gain an independent perspective that is best provided by directors with no current industry ties or other relationships which may pose a conflict of interest."⁹ The principle of public representation is also present in section (4) of the acceptable practices, which requires at least one public person on all disciplinary panels.¹⁰

A second principle embodied in the acceptable practices is the ROC required under subsections (3)(i) and (3)(ii). ROCs are tasked with overseeing DCM regulatory programs, including monitoring those programs for sufficiency, effectiveness, and independence. Their responsibilities also include reviewing the size and allocation of DCMs' regulatory budgets and resources; reviewing the number, hiring, termination, and compensation of regulatory personnel; and supervising DCMs' chief regulatory officers, who should report directly to their ROCs. As described by the Commission, "properly

⁷ 72 FR at 6937.

⁸ *Id.*

⁹ 72 FR at 6947.

¹⁰ A public person is not required for cases limited to decorum, attire, or the timely submission of accurate records required for clearing or verifying each day's transactions.

² As explained in the procedural history below, the Commission stayed the entire acceptable practices for Core Principle 15 in November of 2007. See Section B ("Procedural History of the Acceptable Practices and the Definition of Public Director").

functioning ROCs should be robust oversight bodies * * *.”¹¹ They should also “represent the interests and needs of regulatory officers and staff; the resource needs of regulatory functions; and the independence of regulatory decisions.”¹² ROCs should consist exclusively of public directors. “[A]nything less invites into regulatory oversight operations precisely those directors whose industry affiliations lend themselves to conflicts of interest in decision making.”¹³

The three operating provisions described above—board composition, disciplinary panel composition, and ROC—are all dependent upon the definition of public director in section (2). Now, as that definition is finalized and the stay on the acceptable practices is lifted, all industry participants should be aware that the Commission’s highest goal for self-regulation remains unchanged: Self-regulation must be vigorous, effective, and impartial. DCMs, in particular, are reminded that although they are free to comply with Core Principle 15 by means other than the acceptable practices, they must address the specific conflicts of interest that the Commission has identified and adopt measures that are substantive and responsive.

B. Procedural History of the Acceptable Practices and the Definition of Public Director

On January 31, 2007, the Commission adopted its first acceptable practices for Core Principle 15, which requires all DCMs to minimize conflicts of interest in their decision making process. The acceptable practices focus on conflicts between DCMs’ regulatory responsibilities and their commercial interests, and they offer all DCMs a safe harbor by which they may demonstrate core principle compliance. The acceptable practices for Core Principle 15 contain four provisions, including three “operating” provisions and one provision which primarily defines public director. All four provisions were published in the **Federal Register** on February 14, 2007.¹⁴ Existing DCMs were given a two-year phase-in period to implement the acceptable practices or otherwise demonstrate full compliance with Core Principle 15.

On March 26, 2007, the Commission published the “2007 proposed amendments,” which made certain clarifications and other changes to the

definition of public director.¹⁵ The proposed amendments did not alter the acceptable practices in any other respect. In proposing the amendments, the Commission emphasized that they should not be read as a diminution of the public representation, conflict-of-interest mitigation, and self-regulatory insulation intended by the acceptable practices. To that end, all three operating provisions in the acceptable practices remained as originally adopted.

The Commission received six comment letters in response to the 2007 proposed amendments, but after careful consideration determined not to act upon them.¹⁶ Instead, on November 23, 2007, the Commission gave notice via the **Federal Register** that the acceptable practices for Core Principle 15 were stayed indefinitely and in their entirety.¹⁷ Likewise, the two-year compliance period for existing DCMs also was stayed. With the definition of public director in flux, the Commission concluded that a stay was an appropriate measure while it arrived at a final definition of public director.

Finally, on January 21, 2009, the Commission proposed and sought public comment on the “2009 amendments,” which also apply only to the definition of public director, and which are adopted herein.¹⁸ In publishing the 2009 amendments, the Commission asserted its continued commitment to “the fundamental philosophy underpinning the acceptable practices for Core Principle 15: that potential conflicts of interest in self-regulation by for-profit and publicly-traded DCMs * * * can be addressed successfully through appropriate measures embedded in DCMs’ governance structures.”¹⁹ The Commission also reaffirmed “its support for public representation on DCM boards of directors and disciplinary panels, including the 35% public board standard first enunciated in the acceptable practices,” and its “strong commitment to ROCs, consisting exclusively of public directors, to oversee all facets of DCMs’ self-regulatory programs and staff.”²⁰ The 2009 amendments and public comments thereon are summarized below. As stated previously, the Commission is

adopting the 2009 amendments in their entirety.

C. Summary of the 2009 Amendments

The 2009 amendments fall into four broad categories, all of which pertain to section (2) of the acceptable practices—the definition of public director. First, the Commission has amended subsection (2)(ii) to make its vocabulary more consistent with that in subsection (2)(i), but without altering its meaning. As originally adopted, the provision stated that “* * * a director shall not be considered public if [the bright-line tests are not met].” Now, subsection (2)(ii) reads “* * * a director shall be considered to have a ‘material relationship’ with the contract market if [the bright-line tests are not met].” Because the overarching material relationship test in subsection (2)(i) precludes a person with a material relationship from serving as a public director, the purpose and effect of the provision remains unchanged.

Second, the Commission has amended subsections (2)(ii)(A) and (2)(iv) to save a DCM’s public directors from bright-line tests that they would have failed if they also served as directors of the DCM’s affiliates. For this purpose, “affiliate” is now defined in subsection (2)(ii)(A) to include “parents or subsidiaries of the contract market or entities that share a common parent with the contract market” (“sister companies”). Previously, a DCM’s public directors could also serve as directors of its parent company, but not as directors of its subsidiary or sister companies. With this amendment, the latter two relationships no longer suffer automatic exclusion.

Third, the Commission has amended subsection (2)(ii)(B). As originally adopted, this subsection precluded DCM members, employees of members, and persons affiliated with members from service as public directors. “[A]ffiliated with a member” was defined as being an officer or director of a member, or having “any other relationship with the member such that his or her impartiality could be called into question in matters concerning the member.” Under that original text, subsection (2)(ii)(B) effectively inserted another material relationship determination in what was an otherwise bright-line test.

Now, the Commission has streamlined subsection (2)(ii)(B) in three ways. First, any material relationship determination made pursuant to section (2) takes place under the overarching material relationship test of subsection (2)(i), and not under the bright-line tests of subsection (2)(ii). Second, subsection

¹⁵ 72 FR 14051 (March 26, 2007). In addition to the clarifying amendments, the Commission also proposed to correct a technical drafting error.

¹⁶ The six comment letters are summarized in 74 FR 3475 (January 21, 2009).

¹⁷ 72 FR 65658 (November 23, 2007).

¹⁸ 74 FR 3475.

¹⁹ 74 FR at 3476–3477.

²⁰ *Id.* at 3477.

¹¹ 72 FR at 6950.

¹² *Id.* at 6950–6951.

¹³ *Id.* at 6951.

¹⁴ 72 FR 6936 (February 14, 2007).

(2)(ii)(B) sets forth the exact membership relationships that are automatically precluded. Finally, the subsection allows a DCM to conduct a material relationship analysis to determine whether employment by a member should preclude a specific individual from serving as a public director.

Finally, the Commission has amended subsection (2)(ii)(C) and its bright-line tests. Here again, the Commission has simplified the provision to ensure that the bright-line tests are clearly articulated. As originally adopted, subsection (2)(ii)(C) created a \$100,000 combined annual payments test for potential public directors and the firms with which they may be affiliated (“payment recipients”). A particular payment’s relevance to the \$100,000 bright-line test depends upon the source (“payment provider”) and nature of the payment. In this regard, the subsection did not specify which payments should count towards the \$100,000 annual cap—all payments or only those for certain types of services. In addition, the subsection also contained potential ambiguity with respect to the universe of potential payment providers and payment recipients.

The first amendment to subsection (2)(ii)(C) defines the nature of “payment,” specifying that it is payment for “legal, accounting, or consulting services.” The second amendment clarifies that the relevant payment recipients include the potential public director and any firm in which the director is an officer, partner, or director (“direct” and “indirect” compensation, respectively). The third amendment to subsection (2)(ii)(C) clarifies that the relevant payment providers include the DCM and any parent, sister, or subsidiary company of the DCM. Notably, the new payment providers provision no longer captures DCM members or persons or entities affiliated with members, although such relationships should still be scrutinized carefully under the overarching materiality test of subsection (2)(i). Finally, the Commission has amended subsection (2)(ii)(C) to take into account payments to a public director in excess of \$100,000 by sister and subsidiary companies of the DCM. This is consistent with the Commission’s intent, previously articulated, not to automatically prohibit overlapping public directors between DCMs and their affiliates.

D. The 2009 Amendments and the Material Relationship Test

As described above, the 2009 amendments touch only on the bright-

line tests for public director. The most important element of the definition—the overarching “material relationship” test in subsection (2)(i)—remains unchanged. As before, “[t]o qualify as a public director of a contract market, an individual must first be found, by the board of directors, on the record, to have no material relationship with the contract market.” And, as before, “[a] material relationship is one that reasonably could affect the independent judgment or decision making of the director.”

The practical consequence of the amended bright-line tests is that formerly disqualifying bright-line relationships must now be analyzed under the material relationship test recited above. However, DCMs should be aware that shifting the point of analysis in no way diminishes the importance of the relationships under review, nor does it mean that a formerly disqualifying relationship is now generally permissible. Instead, the amended bright-line tests make it incumbent upon DCMs to carefully evaluate the facts to determine whether a potential public director’s relationships could reasonably affect his or her independent judgment or decision making as a director of a DCM. The Commission will carefully review those determinations in evaluating DCMs’ compliance with Core Principle 15.

Finally, while reemphasizing the importance of the material relationship test in the definition of public director, the Commission also notes its continued commitment to specific bright-line tests for director-DCM relationships that are clearly material. Accordingly, the 2009 amendments to the bright-line tests retain most of the original tests’ substantive content. As with the original bright-lines, those adopted herein touch on a potential public director’s (A) Employment relationships with the contract market; (B) direct and indirect membership relationships with the contract market; (C) direct and indirect compensation relationships with the contract market; and (D) familial relationships with the contract market. The one-year look back period also remains intact, as does the requirement that a DCM disclose to the Commission those members of its board that are public directors and the basis for those determinations. Commission staff will also closely scrutinize the implementation of the material relationship and bright-line tests when conducting future reviews of DCM governance.

E. Public Comments on the 2009 Amendments

Before summarizing and responding to individual comment letters, the Commission wishes to address a recurring theme in the comments made by DCMs throughout the development of these bright-line tests for public director. DCMs have regularly argued that the tests will exclude otherwise desirable candidates from serving on their boards, or that it will be too difficult to determine with certainty whether an individual qualifies as a public director under the acceptable practices. The Commission has been responsive to DCMs’ concerns, even proposing alternative bright-line tests on two occasions after the acceptable practices were adopted. However, after these efforts, some DCMs continue to repeat this same criticism, including in their comments on the 2009 amendments.

The Commission is confident that the definition of public director adopted herein can be used effectively by all DCMs. Armed with this streamlined definition, DCMs should be able to implement the acceptable practices fully and easily. Moreover, if for some reason it is unclear whether a person qualifies as a public director, a solution is readily available: He or she is free to serve as a non-public director. Under the acceptable practices, almost two-thirds of a DCM’s board is filled at its discretion, subject to the fitness requirements of Core Principle 14. Thus, if a DCM believes that an individual adds exceptional value, it is free to install him or her as a non-public director. Furthermore, with respect to the 35% of directors who must be public under the acceptable practices, the difficulties alleged by DCMs might arise only if they attempt to seat directors who are too close to the DCM or to the futures industry, rather than authentically public persons.

The Commission has previously stated that “the most significant contribution made by public directors * * * is precisely their *outside, non-industry* perspective.”²¹ Directors who are truly unrelated to the futures industry and its participants should have little difficulty qualifying as public directors, and DCMs should have little difficulty in implementing the acceptable practices if they avoid public director candidates who are in the professional or personal orbit of the futures industry.

²¹ 72 FR at 6949.

1. Specific Comments Received and the Commission's Response

The Commission received five comment letters in response to the 2009 amendments, including comments from ICE Futures U.S., Inc. ("ICE Futures"), the Futures Industry Association ("FIA"), CBOE Futures Exchange, LLC ("CFE"), CME Group, Inc. ("CME Group"), and the Kansas City Board of Trade ("KCBT").²² Commission staff reviewed all five letters carefully. Most were generally supportive of the proposed amendments, while also suggesting further changes. The five letters and the Commission's responses thereto are summarized below.

a. CBOE Futures Exchange, LLC.

CFE's comment letter reiterates the exchange's belief that the acceptable practices will have a "positive impact" with respect to futures exchange governance and minimizing conflicts of interest, and that they "will serve to enhance the self-regulatory process."²³ The comment letter also summarizes the 2009 amendments and affirms the exchange's agreement with most of them. CFE states that it supports those amendments that "clarify (i) The types of payments that would disqualify a person from serving as a public director,²⁴ (ii) that a person who serves as a director of a futures exchange affiliate is not disqualified from serving as a public director of the futures exchange if the person otherwise qualifies to serve in that capacity, and (iii) that receipt of director compensation from a futures exchange affiliate does not disqualify the recipient from serving as a public director of the futures exchange if the person otherwise qualifies to serve in that capacity."²⁵

While generally supportive of the 2009 amendments, CFE's comment letter also raises certain concerns, both from the exchange's perspective and from the Commission's. First, CFE declares its opposition to an amendment in subsection (2)(ii)(B) removing employees of DCM member firms from automatic disqualification. In addition, the exchange offers certain interpretations with respect to the potential adverse impact of this amendment. Second, CFE states its support for the amendments to subsection (2)(ii)(C) (pertaining to a

bright-line test for payment for services rendered). Here again, CFE offers its own interpretation as to what the subsection now permits. The Commission believes that both of CFE's comments and interpretations merit further discussion. They are treated below, in order.

CFE disagrees "with the elimination by the CFTC's proposal of the previous disqualification of an employee of a member of a futures exchange from serving as a public director of that futures exchange."²⁶ This comment refers to amended subsection (2)(ii)(B), which no longer subjects a DCM member's employees to automatic disqualification from service as a public director (unless they are officers or directors). CFE observes, accurately, that "the CFTC has stated that one of the primary objectives of the Acceptable Practices is to insulate the regulatory functions of a futures exchange via public directors who are not conflicted by industry ties * * *."²⁷ The exchange argues that "permitting a member employee to serve as a futures exchange public director, and allowing the possibility that all 35% of the public directors of a futures exchange could be member employees, is inconsistent with that goal * * *."²⁸

The Commission agrees with CFE's overall sentiment, and although it stands by the amendments to subsection (2)(ii)(B), it is vital that no DCM misinterpret them. The Commission is concerned with any suggestion that the acceptable practices now allow a DCM's public directors to consist exclusively of members' employees. While the Commission is not prejudging any potential relationship that might be presented to it in the future, it is difficult to imagine that employees of member firms will routinely pass the material relationship test of subsection (2)(i).

DCMs are reminded that all director relationships, including employment, remain subject to the acceptable practices' overarching material relationship test. They should also be aware that the removal of a relationship from the bright-line tests does *not* mean that such relationship is now always permitted. Indeed, in the example offered by CFE, the Commission agrees that a board whose public directors are all employees of member firms is inconsistent with the intent of the acceptable practices. In that regard, the Commission emphasizes the language with which it proposed to amend

subsection (2)(ii)(B), stating "the amendments merely shift the point of analysis from the bright-lines of subsection (2)(ii) to the overarching material relationship test of subsection (2)(i)."²⁹ The Commission further affirmed—and this is of special importance with respect to member employees—that it "remains concerned about *any* relationship between potential public directors and DCM members that could 'affect the independent judgment or decision making of the director'" (emphasis added).³⁰ Accordingly, no DCM should interpret the removal of member employment from the bright-line tests as an invitation to seat a member's employee as a public director without careful consideration. Any finding that a member's employee qualifies as public will require full disclosure and explanation under subsection (2)(v) of the acceptable practices, which requires DCMs to disclose to the Commission the basis for any determination that a director qualifies as public.

CFE's second comment and interpretation relates to subsection (2)(ii)(C). There, the exchange asserts that the amendments "make clear that a public director of the National Futures Association ("NFA") is not disqualified as serving as a public director of CFE because NFA provides regulatory services to CFE * * *."³¹ CFE is correct that amended subsection (2)(ii)(C) now limits the bright-line definition of "payment" to payment for legal, accounting, or consulting services. Previously, the term was undefined and thus potentially broader in scope, to include payment for regulatory services to a regulatory service provider ("RSP") such as NFA.

The Commission cautions, however, that subsection (2)(ii)(C) is just one element in a multi-prong test for evaluating whether an individual is qualified to serve as a public director. While the clarification of subsection (2)(ii)(C) in this instance may leave RSP directors outside the scope of one bright-line test, such directors remain subject to other elements in the definition of public director. Most significant among these is the overarching material relationship test of subsection (2)(i). As with other potential relationships, the Commission will not prejudice what might be presented to it in the future. However, a DCM should move cautiously in any scenario where it outsources its regulatory functions to an RSP and seeks to install a director of

²² As explained below, CME Group is the parent company of four DCMs: the Chicago Board of Trade, the Chicago Mercantile Exchange, the Commodity Exchange, and the New York Mercantile Exchange.

²³ CFE comment letter ("CL") at 1.

²⁴ While ICE Futures and CME Group also support the amendments pertaining to payment for services rendered, CFE's support is offered in a very specific context, as explained below.

²⁵ CFE CL at 1.

²⁶ *Id.*

²⁷ CFE CL at 2.

²⁸ *Id.*

²⁹ 74 FR at 3478.

³⁰ *Id.*

³¹ CFE CL at 1.

its RSP as public director on its board, including its ROC. In this context, the DCM should recall that ROC members are charged with evaluating the quality of regulatory services provided to the DCM. Certain questions naturally arise under these circumstances. Would the RSP director be able to evaluate the RSP's performance objectively? Would he or she be able to impartially counsel the exchange to seek regulatory services elsewhere if the RSP, on whose board he/she also sits, was underperforming? Even if the RSP director was only being considered for service on the board, and not for the ROC, would his or her board actions with respect to the RSP be as objective as those of a public director with no RSP ties? Questions such as these must be addressed fully in any material relationship analysis.

b. The Futures Industry Association and the Kansas City Board of Trade.

The FIA's comment letter expresses its support for the 2009 amendments.³² Echoing the Commission's own sentiments, the FIA notes that "it is vitally important that DCMs include a significant number of Board Members that are recognized to be independent of the DCM and its members."³³ FIA also maintains that "no one could fairly contest the Commission's definition of a public director as someone with no material relationship with the DCM," and that "the Commission has proposed a workable and effective set of automatically disqualifying relationships" for potential public directors.³⁴ FIA's positive comments are balanced with the observation that it and others might "quibble" with the 35% standard for public directors on DCM boards, and that it might "recommend expanding the [bright-line tests] in some areas or restricting it in others."³⁵ Overall, however, FIA "urge[s] the Commission to adopt the [2009 amendments] quickly and to make its Acceptable Practices effective as soon as practicable."³⁶

KCBT's brief comment letter notes its "support for the revised public director definition published for comment in connection with the SRO governance core principle guidelines."³⁷ The exchange is "appreciative of the Commission narrowing the applicability of the \$100,000 in professional services payments to a public director (or the

firm such public director represents) by a DCM or its affiliates."³⁸

c. ICE Futures U.S., Inc.

ICE Futures' comment letter contains both supportive statements and suggestions for further modifications to the 2009 amendments. First, the exchange "commend[s] the decision to free a DCM's public directors from bright-line tests that would have been failed if the directors also served on the board of the DCM's affiliates."³⁹ This comment, which pertains to "interlocking directorships" under subsection (2)(iv), was echoed by CFE and CME Group.⁴⁰

The amendments to subsection (2)(iv) expand the universe of DCM affiliates on whose board public directors may serve.⁴¹ Previously, public directors could only serve on the board of a DCM's parent, but the 2009 amendments also permit interlocking directorships with a DCM's subsidiaries or entities sharing a common parent with the DCM. While ICE Futures and others find this amendment helpful, DCMs are reminded that as with all other public director relationships, the materiality test is still in place. In addition, interlocking public directorships are permitted only if the DCM director otherwise meets the definition of public director. DCMs should be particularly vigilant for circumstances where the interlocking directorship involves an entity that could come under the DCM's regulatory authority. An affiliate that trades or brokers in the DCM's markets, for example, could pose a conflict of interest.

In addition to the comments summarized above, ICE Futures also suggests further amendments to the bright-line tests for public director. The exchange's concerns center around subsection (2)(ii)(C), which, as amended, defines a bright-line test for potential public directors based on direct and indirect compensation in excess of \$100,000 for legal, accounting, and consulting services rendered. ICE Futures argues that, "[b]ecause this prohibition is so broad, and the dollar threshold so low, it needlessly sweeps into its net payments that would be considered *de minimis* by the firm being compensated and relationships that

might not automatically create a conflict of interest."⁴²

It should be noted that ICE Futures' comment seems limited to indirect compensation to a public director via the firm with which he or she is associated; the exchange's apparent preference is that indirect compensation not constitute part of the bright-line tests at all. It contends that "[t]he DCM should be entrusted to evaluate all the relevant facts and circumstances * * * and determine whether the independent judgment of a public director would be compromised by the indirect compensation arrangements."⁴³

If indirect compensation is not removed from the bright-line tests, then the exchange argues that the Commission should at least "significantly increase the dollar threshold for indirect compensation."⁴⁴ ICE Futures offers the listing standards of the New York Stock Exchange ("NYSE") as an "instructive" guide in establishing what it considers a more appropriate cut-off on payments for services rendered.⁴⁵

The Commission understands that the \$100,000 threshold in subsection (2)(ii)(C) is a significant bright-line test, and that others might have chosen to draw the line at a higher dollar value or as a percentage of revenues. However, it continues to believe that \$100,000 in combined annual payments is an appropriate cap in compensation for a public director or a firm on which he or she serves as an officer, director, or partner. The \$100,000 cap applies to payments from the DCM or any affiliate of the DCM for legal, accounting, or consulting services. As the Commission explained when it reduced the ratio of public directors required by the acceptable practices from 50% (as originally proposed) to 35% (as adopted), "the Commission believes that a strict definition of public director is especially necessary now that it will apply to 35% of a DCM's directors, rather than the 50% originally

⁴² ICE Futures CL at 2.

⁴³ ICE Futures CL at 3.

⁴⁴ *Id.*

⁴⁵ While the Commission understands the attraction of adopting a single payment cap based on the more widely used listing standards of the NYSE, it does not believe that the listing standards are an appropriate guide. The Commission continues to think that the listing standards serve a distinct purpose—the protection of shareholders through boards of directors that are sufficiently independent from management. In contrast, the acceptable practices for Core Principle 15, including the bright-line tests for public director, seek to protect self-regulation through DCM boards of directors and other bodies that include a sufficient number of truly public persons.

³⁸ *Id.*

³⁹ ICE Futures CL at 2.

⁴⁰ CME Group states, for example, "[t]he Commission has appropriately recognized that an individual may be a director of both a DCM and its parent, subsidiary, or entity that shares a common parent with the DCM, and not lose his or her status as a public director." CME CL at 3.

⁴¹ Subsection (2)(ii)(A) is also relevant, as it defines "affiliate" as used in subsection (2)(iv).

³² FIA CL at 1.

³³ *Id.*

³⁴ FIA CL at 1 and 2.

³⁵ *Id.*

³⁶ FIA CL at 2.

³⁷ KCBT CL at 1.

proposed.”⁴⁶ The Commission also reiterates its previous observation that a potential public director who fails one or more bright-line tests—the \$100,000 payment cap, for example—is free to serve as a non-public director if the DCM deems it important.

Finally, the Commission reminds DCMs that other relationships involving payment for services rendered—even those not specifically listed in subsection (2)(ii)(C)—should be scrutinized closely under the material relationship test. Such other relationships could include payments from other sources (e.g., a DCM member firm rather than the DCM itself); payments based on other relationships (e.g., employee rather than director or partner); and payments for lesser amounts (e.g., \$95,000 to a firm where the DCM director serves as partner and to which \$95,000 represents significant revenue). In short, DCMs must continue to consider the payment provider, the payment recipient, and the services provided when making materiality determinations under subsection (2)(ii)(C). DCMs also must disclose to the Commission which members of its board are public directors, and the basis for those determinations.⁴⁷ The Commission expects that all potentially material relationships will have been examined carefully.

d. CME Group Inc.

CME Group is the publicly-traded parent company of four DCMs: the Chicago Board of Trade (“CBOT”), the Chicago Mercantile Exchange (“CME”), the Commodity Exchange (“COMEX”), and the New York Mercantile Exchange (“NYMEX”). Its comment letter includes a brief history of the acceptable practices for Core Principle 15 and the amendments to the bright-line tests for public director. CME Group closes its comment letter by stating, “[i]n sum, we believe that the Commission has substantially improved its proposed definition of public director, in connection with the non-exclusive safe harbor acceptable practices for compliance with Core Principle 15.”⁴⁸

Like CFE and ICE Futures, CME Group approves of provisions in the 2009 amendments that allow for interlocking public directors across a DCM, its subsidiaries, and entities sharing a common parent with the DCM. CME Group also approves of provisions in the amendments that eliminate the bright-line test for employees of DCM

member firms.⁴⁹ Finally, CME Group supports amendments to subsection (2)(ii)(C) with respect to direct and indirect payments to directors for services rendered. All three amendments have already been discussed above in the context of CFE’s and ICE Futures’ comment letters. As the Commission noted there, potential public directors remain subject to the material relationship test of subsection (2)(i) in all three circumstances.

In addition to the supportive statements summarized above, CME Group also requests that the Commission “consider a further refinement [to the bright-line tests] with respect to immediate family members.”⁵⁰ Referring to subsection (2)(ii)(D), it argues “we do not believe that an individual should be considered to have a per se material relationship with a DCM merely because his immediate family member is a director or an officer of a member.”⁵¹ The Commission’s response is similar to that given ICE Futures’ request for a more relaxed bright-line test for indirect payments for services rendered. Because the final acceptable practices require that only 35% of a DCM’s directors be public, a strict definition of public director is appropriate. In this regard, the Commission believes that a close family bond certainly could affect the independent judgment or decision making of the director and should therefore be precluded automatically. The acceptable practices’ material relationship test is instructive: the Commission is concerned with relationships that “reasonably *could* affect” the director; proof of *certain* effect is not required.

CME Group’s comment letter also includes broader legal and policy arguments that the Commission has previously addressed at length. Nonetheless, they require a brief response here so that no DCM is confused as to what is required under Core Principle 15. DCMs should be aware that the acceptable practices are voluntary safe harbors which they may use to demonstrate compliance with Core Principle 15, and that they are free

to comply by other means. The Commission will fairly evaluate any alternatives presented to it. What DCMs are not free to do, however, is to substitute their interpretations of Core Principle 15 for the Commission’s.

CME Group argues that it “continues to believe that the board composition acceptable practices are not related to Core Principle 15 and conflict with the clear Congressional intent in the Commodity Futures Modernization Act of 2000 (“CFMA”) to impose no composition requirements on the boards of publicly owned futures exchanges.”⁵² CME Group’s beliefs notwithstanding, the Commission has interpreted its statutory authority and acted upon it. CME Group’s four regulated DCMs are required to comply with Core Principle 15, and all the core principles, as they are interpreted by the Commission.

To comply with Core Principle 15, DCMs must specifically address the conflicts of interest discussed at length during the development of these acceptable practices. The Commission has been clear in its requirements, and the preamble to the acceptable practices explains them as well. As stated in the acceptable practices, “[all DCMs] bear special responsibility to regulate effectively, impartially, and with due consideration of the public interest. * * * Under Core Principle 15, they are also required to minimize conflicts of interest in their decision-making process. To comply with this core principle, [DCMs] should be particularly vigilant for such conflicts between and among their self-regulatory responsibilities, their commercial interests, and the several interests of their management, members, owners, customers and market participants, and other constituencies.”

Within these boundaries, DCMs may demonstrate compliance with Core Principle 15 as they deem best. The Commission has repeatedly affirmed that the acceptable practices are not mandatory. What is mandatory, however, is that all DCMs mitigate conflicts of interest in their decision making process, *including the conflicts that the Commission has identified between their commercial interests and their regulatory responsibilities.*

Indeed, CME Group’s own comment letter expresses the potential conflict of interest between regulatory and commercial decision making. Referring to commercial interests, CME Group claims, “[w]e believe that each publicly traded DCM has an obligation to its shareholders to follow the listing rules

⁴⁶ 72 FR at 6949.

⁴⁷ Subsection (2)(v) of the acceptable practices.

⁴⁸ CME Group CL at 4.

⁴⁹ However, as explained previously, employees of DCM members, while no longer automatically disqualified from serving as public directors, are not automatically permitted to do so either. Instead, each one faces a robust and individualized material relationship analysis which must be disclosed to the Commission. In this regard, the Commission notes that blanket determinations by a DCM that particular categories of persons qualify as public directors without individual examination is insufficient to satisfy the acceptable practices for Core Principle 15.

⁵⁰ CME Group CL at 3.

⁵¹ *Id.*

⁵² CME Group CL at 2.

of the relevant securities exchange and to nominate for election as directors a mix of individuals based on their ability to create value for the corporation.”⁵³ While the Commission acknowledges all DCMs’ commercial interests, it also reminds them of their regulatory responsibilities.

In the case of CME Group, the Commission notes that its subsidiary DCMs—CBOT, CME, COMEX, and NYMEX—are not traded on national securities exchanges or subject to listing standards. While CME Group may be required to comply with certain listing rules and to maximize shareholder value, its regulated DCMs have additional statutory and regulatory obligations. Above all, regardless of their corporate structures, all DCMs must regulate effectively, impartially, and with due consideration of the national public interest as provided for in the Act.

The Commission is confident that regulatory and commercial interests can be reconciled in effective self-regulation. However, continued success depends on all DCMs recognizing the potential for conflicts; acknowledging the primacy of regulatory interests; and implementing effective solutions to protect self-regulatory functions, decisions, and personnel from improper commercial influence and considerations. As the Commission stated when it adopted the acceptable practices for Core Principle 15, and as it continues to believe now:

[I]t is crucial for all DCMs and their owners to understand that DCMs have two responsibilities: A responsibility to their ownership and a responsibility to the public interest as defined in the Act. Whereas the [listing standards] serve those with a direct fiduciary claim upon a company * * * the new acceptable practices serve the public, whose claim upon DCMs is entirely independent of ownership, membership, or any other DCM affiliation. In short, through the new acceptable practices for Core Principle 15, the Commission seeks to ensure adequate representation of a public voice that otherwise is not guaranteed any formal standing within a DCM, and which receives no effective representation under any regulatory regime other than the Commission’s.⁵⁴

II. Related Matters

A. Cost-Benefit Analysis

Section 15(a) of the Act requires the Commission to consider the costs and benefits of its actions before issuing a new regulation or order under the Act.⁵⁵ By its terms, Section 15(a) requires the

Commission to “consider the costs and benefits” of a subject rule or order, without requiring it to quantify the costs and benefits of its action or to determine whether the benefits of the action outweigh its costs. Section 15(a) requires that the costs and benefits of new regulations 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. In conducting its analysis, the Commission may, in its discretion, give greater weight to any one of the five enumerated areas of concerns and may 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 to accomplish any of the purposes of the CEA.⁵⁶

On February 14, 2007, the Commission published final acceptable practices for Core Principle 15 that included prophylactic measures designed to minimize conflicts of interest in DCMs’ decision making processes. The final rulemaking thoroughly considered the costs and benefits of the acceptable practices and responded to comments relating to the costs of adhering to their requirements.

The 2009 amendments to the definition of public director bring further clarity and finality to the acceptable practices for Core Principle 15. The Commission believes that the amendments are fully consistent with the design and purpose of the acceptable practices as originally conceived. Furthermore, through more consistent, streamlined, and precise articulations, the amendments will facilitate DCMs’ implementation of the acceptable practices and thereby advance important public interest considerations with respect to conflicts of interest in DCM self-regulation. In particular, the acceptable practices offer all DCMs a safe harbor for compliance with Core Principle 15, which requires them to “establish and enforce rules to minimize conflicts of interest in the decision making process of the contract market * * *.”⁵⁷ The acceptable practices’ safe harbor is based on the inclusion of public directors on their boards; the creation and empowerment

of ROCs consisting exclusively of public directors; and the presence of public persons on DCM disciplinary panels. Thus, each of these provisions depends heavily on a clear and settled definition of public director. The Commission believes that the 2009 amendments will not impose any additional costs upon DCMs. To the contrary, they may reduce the costs of compliance through improvements in the bright-line tests for public director, such that the tests truly operate as bright-lines and the definition of public director is well-settled.

After considering the above mentioned factors and issues, the Commission has determined to adopt these amendments to the acceptable practices for Core Principle 15. The Commission received no comments on its Section 15(a) analysis of the amendments and hereby adopts them as proposed.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* requires federal agencies, in promulgating rules, to consider the impact of those rules on small entities. The 2009 amendments affect DCMs, which the Commission has previously determined are not small entities for purposes of the Regulatory Flexibility Act.⁵⁸ Accordingly, the Acting Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that the 2009 amendments will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act of 1995

The 2009 amendments to the acceptable practices for Core Principle 15 will not impose any new recordkeeping or information collection requirements, or other collections of information that require approval of the Office of Management and Budget, under 44 U.S.C. 3501 *et seq.* Additionally, the Commission received no comments on the accuracy of the estimate of additional recordkeeping or information collection requirements. Accordingly, the Paperwork Reduction Act does not apply.

III. Text of Amendments

List of Subjects in 17 CFR Part 38

Commodity futures, Reporting and recordkeeping requirements.

In light of the foregoing, and pursuant to the authority in the Act, and in

⁵⁶ *E.g., Fishermen’s Dock Co-op., Inc. v. Brown*, 75 F.3d 164 (4th Cir. 1996); *Center for Auto Safety v. Peck*, 751 F.2d 1336 (D.C. Cir. 1985) (agency has discretion to weigh factors in undertaking cost benefit analyses).

⁵⁷ 7 U.S.C. 7(d)(15).

⁵⁸ See Policy Statement and Establishment of Definitions of “Small Entities” for Purposes of the Regulatory Flexibility Act, 47 FR 18618, 18619 (Apr. 30, 1982).

⁵³ CME Group CL at 2.

⁵⁴ 72 FR 6936, 6949.

⁵⁵ 7 U.S.C. 19(a).

particular, Sections 3, 5, 5c(a) and 8a(5) of the Act, the Commission hereby amends Part 38 of Title 17 of the Code of Federal Regulations as follows:

PART 38—DESIGNATED CONTRACT MARKETS

■ 1. The authority citation for part 38 continues to read as follows:

Authority: 7 U.S.C. 2, 5, 6, 6c, 7, 7a–2, and 12a, as amended by Appendix E of Public Law 106–554, 114 Stat. 2763A–365.

■ 2. The stay is lifted on paragraph (b) of Core Principle 15 in Appendix B to 17 CFR Part 38.

■ 3. In Appendix B to Part 38 revise paragraphs (b)(2)(ii) through (b)(2)(v) of Core Principle 15 to read as follows:

Appendix B to Part 38—Guidance on, and Acceptable Practices in, Compliance With Core Principles

* * * * *

Core Principle 15 of section 5(d) of the Act:
CONFLICTS OF INTEREST

* * * * *

(b) * * *

(2) * * *

(ii) In addition, a director shall be considered to have a “material relationship” with the contract market if any of the following circumstances exist:

(A) The director is an officer or employee of the contract market or an officer or employee of its affiliate. In this context, “affiliate” includes parents or subsidiaries of the contract market or entities that share a common parent with the contract market;

(B) The director is a member of the contract market, or an officer or director of a member. “Member” is defined according to Section 1a(24) of the Commodity Exchange Act and Commission Regulation 1.3(q);

(C) The director, or a firm with which the director is an officer, director, or partner, receives more than \$100,000 in combined annual payments from the contract market, or any affiliate of the contract market (as defined in Subsection (2)(ii)(A)), for legal, accounting, or consulting services. Compensation for services as a director of the contract market or as a director of an affiliate of the contract market does not count toward the \$100,000 payment limit, nor does deferred compensation for services prior to becoming a director, so long as such compensation is in no way contingent, conditioned, or revocable;

(D) Any of the relationships above apply to a member of the director’s “immediate family,” *i.e.*, spouse, parents, children and siblings.

(iii) All of the disqualifying circumstances described in Subsection (2)(ii) shall be subject to a one-year look back.

(iv) A contract market’s public directors may also serve as directors of the contract market’s affiliate (as defined in Subsection (2)(ii)(A)) if they otherwise meet the definition of public director in this Section (2).

(v) A contract market shall disclose to the Commission which members of its board are public directors, and the basis for those determinations.

* * * * *

Issued in Washington, DC, on April 21, 2009 by the Commission.

David A. Stawick,

Secretary to the Commission.

[FR Doc. E9–9508 Filed 4–24–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

[Docket No. FDA–2009–N–0665]

Intramammary Dosage Forms; Change of Sponsor

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 for an approved new animal drug application (NADA) from Merial Ltd. to Cross Vetpharm Group Ltd.

DATES: This rule is effective April 27, 2009.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: david.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 065–383 for Formula A–34 (procaine penicillin G) mastitis infusion tube to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.

Accordingly, the agency is amending the regulations in 21 CFR 526.1696a to reflect the transfer of ownership.

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 526

Animal drugs.

■ 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 526 is amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORMS

■ 1. The authority citation for 21 CFR part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 526.1696a [Amended]

■ 2. In paragraph (c) of § 526.1696a, remove “050604” and add in its place “061623”.

Dated: April 17, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–9527 Filed 4–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–0119]

RIN 1625–AA00

Safety Zone; Red Bull Air Races; San Diego Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the San Diego Bay in support of the Red Bull Air Races. The safety zone is necessary to provide for the safety of the crew, spectators, participants and other vessels and users of the waterway. Persons and vessels will be prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized to do so by the Captain of the Port or his designated representative.

DATES: This rule is effective from 10 a.m. on May 7, 2009 through 6 p.m. on May 10, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2009–0119 and are available Online by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG–2009–0119 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. They are also available for inspection or copying at two locations: the Docket Management Facility (M–30), U.S. Department of Transportation, West