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Issued in College Park, Georgia, on November 25, 1998.

Nancy B. Shelton,

Acting Manager, Air Traffic Division Southern Region.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91 and 121

General Operating and Flight Rules

CFR Correction

In Title 14 of the Code of Federal Regulations, parts 60 to 139, revised as of Jan. 1, 1998, make the following corrections:

1. On page 173, left column, the date in Sec. 9 of the effective date note for SFAR No. 50-2 is corrected to read "January 31, 1999".

2. On page 261, in Appendix G to part 91, right column, under *Section 2. Aircraft Approval*, in paragraphs (c) (2)(i), (ii), (3)(i) and (ii) the symbol "#" is corrected to read "±".

3. On page 452, § 121.402, paragraph (a), add the word "flight" between the words "provide" and "training" in the sixth line.

4. On page 520, § 121.713, paragraph (b)(2), "§ 119.35" is corrected to read "§ 119.36".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 141

Pilot Schools

CFR Correction

In Title 14 of the Code of Federal Regulations, parts 140 to 199, revised as of Jan. 1, 1998, page 22, Appendix A to part 141, paragraph 4(a) is corrected by removing the words "as provided in section No. 5 of this appendix" beginning in the third line, and moving them to line 6 after the word "training".

BILLING CODE 1505-01-D

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 140

Requests for Exemptive, No-Action and Interpretative Letters

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") is adopting Rule 140.99, which establishes procedures for the filing of requests for the issuance of exemptive, no-action and interpretative letters from the Commission's staff. The Commission believes that implementation of these procedures will significantly assist the Commission, its staff and requesters by assuring a focused presentation of the guidance sought, the issues raised thereby, and the relevant legal authorities.

DATES: Effective January 11, 1999.

FOR FURTHER INFORMATION CONTACT:

David M. Battan, Chief Counsel, Christopher W. Cummings, Special Counsel, or Helene D. Schroeder, Attorney-Advisor, Division of Trading and Markets, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC 20581. Telephone: (202) 418-5450.

SUPPLEMENTARY INFORMATION:

I. Requests for Exemptive, No-Action and Interpretative Letters

In the course of administering the Commodity Exchange Act ("Act")¹ and the rules, regulations and orders promulgated thereunder by the Commission,² Commission staff receives written requests for advice on, or interpretation of, particular provisions of the Act or Commission rules and the application of those provisions to proposed transactions or activities. Where appropriate, Commission staff provides the relief, advice or guidance sought through the issuance of exemptive, no-action or interpretative letters ("Letters"), respectively.³

On January 22, 1998, the Commission published for comment Proposed Rule 140.99 (the "Proposal")⁴ to establish procedures for requesting Letters. As stated in the Proposal, although a

procedural rule such as Rule 140.99 is not required to be published for comment, the Commission decided to seek comment in the belief that input from interested persons would assist it in fashioning a final rule.⁵ The comment period on the Proposal originally was due to expire on March 22, 1998. To maximize public participation in this rulemaking process, the Commission extended the comment period for an additional thirty days,⁶ and the comment period closed on April 22, 1998. The input received was very helpful, and a number of changes were made to the Proposal following consideration of the comments.⁷

While the commenters generally were supportive of the Commission's intention to establish uniform procedures for persons requesting Letters, they expressed various concerns of which the most significant are discussed below. Before addressing the comments received and the final rules the Commission is issuing hereby, the Commission wishes to emphasize that under the new rules Commission staff will continue to be receptive to informal inquiries and to engage in discussions with industry participants, counsel, members of the public, and others, by telephone, in face-to-face meetings or otherwise, regarding the application of the provisions of the Act and the Commission's rules, with the caveat that any advice given in the context of those discussions does not bind the Commission or its staff.⁸ The Commission's goal in adopting new Rule 140.99 is to ensure that, where an issue has been framed and defined sufficiently that a request for a Letter is appropriate, proper procedures exist for submitting that request.

II. Section-By-Section Analysis

A. Definitions—Section 140.99(a)

The Proposal defined "exemptive letter," "no-action letter," and "interpretative letter" for purposes of Rule 140.99. Briefly stated, the Proposal defined: (1) an exemptive letter as involving a grant of exemptive relief by the staff of the Division of Trading and Markets or the Division of Economic

⁵ See 63 FR 3287.

⁶ *Requests for Exemptive, No-Action and Interpretative Letters*, 63 FR 14866 (March 27, 1998).

⁷ The Commission received eight comment letters in response to the Proposal: two from registered futures commission merchants; two from commodity industry associations; one from a securities industry association; two from bar associations; and one from a law firm.

⁸ See Rule 140.99(e), which provides that no response to a request for a Letter is effective unless it is in writing, signed by appropriate Commission staff and transmitted in final form to the requester.

¹ 7 U.S.C. 1 *et seq.* (1994).

² Commission regulations are found at 17 CFR Ch. I. *et seq.* (1998).

³ These types of letters are proposed to be defined in Rules 140.99(a)(1), (a)(2) and (a)(3), respectively, and each is discussed in Part II, below.

⁴ *Requests for Exemptive, No-Action and Interpretative Letters*, 63 FR 3285.

Analysis (each a "Division") pursuant to authority delegated to staff by the Commission; (2) a no-action letter as denoting the determination by staff of the Division of Trading and Markets or the Division of Economic Analysis not to recommend commencement of enforcement action if a proposed activity or transaction was conducted; and (3) an interpretative letter as conveying the advice or guidance of staff of the Division of Trading and Markets, the Division of Economic Analysis or the Office of the General Counsel concerning the application of provisions of the Act or Commission rules in the context of specific activities or transactions.

In response to the comments, the Commission has modified the definitions somewhat. "Exemptive letter" is now defined to make clear that only the person on whose behalf an exemptive letter is sought may rely upon it and that an exemptive letter binds the Commission and its staff with respect to the relief provided. "No-action letter" is now defined to clarify that only the person on whose behalf a no-action letter is sought may rely upon the Letter and that a no-action letter binds only the staff of the Division (or the Office of the General Counsel)⁹ that issues the Letter. Finally, interpretative letter has been redefined to clarify that an interpretative letter binds only the Division that issues it (or the Office of General Counsel, is issued thereby). The definition of interpretative letter also now expressly provides that an interpretative letter generally may be relied upon by persons in addition to the person on whose behalf the interpretative letter was sought.¹⁰

The Commission is not adopting the recommendation of some commenters that no-action letters be accorded precedential value such that third parties may rely upon them without requesting their own Letters. The Commission likewise is declining to expand the class of persons who may rely on an exemptive letter to include persons not exempted by name in the Letter. The Commission continues to believe that, where a situation not covered by a rule is encountered on a

repeated basis, the appropriate remedy is rulemaking. Letters generally address particular, fact-specific issues either not clearly addressed by relevant rules or otherwise requiring individualized review by Commission staff. It would not be appropriate to allow uninvolved third parties to rely on staff positions taken on the basis of different sets of facts. Of course, counsel may wish to consider Letters issued by Commission staff in advising their clients about particular courses of conduct. Moreover, if an industry participant or its counsel determines to seek its own Letter from Commission staff, prior Letters on similar issues are relevant and should be cited to staff.

Some comments indicated that the commenters did not understand that Rule 140.99 does not apply to requests for exemption submitted pursuant to Section 4(c) of the Act.¹¹ To make clear that exemption requests under Section 4(c) must be made directly to the Commission—and must comply with the requirements set forth in Section 4(c)—paragraph (i)(B) of Rule 140.99 provides that the rule "shall not affect the requirements of, or otherwise be applicable to" requests for exemption pursuant to Section 4(c) of the Act.

B. General Requirements—Section 140.99(b)

Paragraph (b)(1) of the Proposal stated that the issuance of Letters is entirely within the staff's discretion and that the staff could deny or refuse to consider or respond to a request without explanation. While it was clearly not the intent of the Commission, commenters were concerned that this provision would allow staff to ignore requests. In response to these comments, the rule as adopted simply provides that issuance of Letters is within the Commission staff's discretion. While the Commission recognizes the importance of Letters to industry participants and their counsel, nothing in the Act or the Commission's rules requires Commission staff to issue Letters. Because the staff exercises its discretion to issue Letters within the constraints of its limited staffing and other resources, certain circumstances

may arise in which as prompt a reply to a request as counsel would like becomes difficult or impossible. Moreover, in some limited instances the issuance of a Letter may not be justified from a legal or regulatory standpoint, or it may not be an appropriate resolution from a policy standpoint.

Paragraph (b)(2), which sets forth the staff's right to reject or decline to respond to a request that does not comply with Rule 140.99, was adopted as proposed. In this connection, Commission staff will not issue a Letter in response to an oral request, and a Letter will not be issued in response to a tentative or "draft" request.

As proposed and as adopted, paragraph (b)(3) states that a request must relate to a proposed transaction or activity and that, absent extraordinary circumstances, Letters will not be issued based upon past transactions or activities. This stricture is consistent with longstanding Commission staff policy. Commenters expressed concern that persons who become aware that ongoing activities raise issues under the Act or Commission rules would have no recourse under this provision. The Commission disagrees. In the absence of extraordinary circumstances, a Letter issued with regard to ongoing activities will be prospective in terms of its coverage (and will not cover past activities or transactions).¹² Thus, a Letter will not ordinarily relieve the person for whose benefit it is issued from the consequences of non-compliance that pre-dates the Letter. Nevertheless, persons (or their counsel) who become aware that their activities are not in compliance with the Act or Commission rules are urged to contact the staff as soon as possible. Although the staff generally reserves the right to refer prior violations for enforcement action in appropriate situations, the good faith demonstrated by efforts to regularize non-complying activities on a "going forward" basis will be carefully considered.

As proposed, paragraph (b)(4) states that a request must be made by the person seeking a Letter (or an authorized representative) and that Commission staff will not respond to requests made by or on behalf of unidentified persons. As adopted, the request is required to be made by or on behalf of the person on whose behalf a Letter is sought. Proposed paragraph

⁹ The Commission also has modified the definition of no-action letter to reflect that the Office of the General Counsel may issue no-action letters in certain circumstances. Similarly, the Commission has modified the definition of interpretative letter to reflect the practice of the Divisions of Trading and Markets and Economic Analysis of issuing interpretations of statutory provisions when related to regulatory matters under their review.

¹⁰ In the Proposal, the preamble, but not the text of the rule, stated that persons other than the recipient could rely on an interpretative letter.

¹¹ 7 U.S.C. 6(c) (1994). See footnote 5 of the Proposal (63 FR 3285, n.5), in which the Commission stated that the proposed rule would govern requests submitted to and processed by Commission staff and would not apply to those circumstances under which requests must be submitted to and processed by the Commission itself (e.g., requests pursuant to Section 4(c) of the Act and any other instance in which exemptive authority has not been delegated to the Staff). The Commission went on to state that paragraphs (b), (c), (f) and (h) nevertheless provide some helpful guidance for persons making requests not within the scope of Rule 140.99.

¹² One commenter pointed out that Section 4(c) of the Act expressly provides for retroactive relief and asserted that Rule 140.99(b)(3) is inconsistent with Section 4(c) in this respect. As noted earlier, the provisions of Rule 140.99 do not apply to requests for exemptions under Section 4(c). See also 63 FR 3285, n.5.

(b)(5)(i) would have required the request to set forth as completely as possible "the particular facts and circumstances giving rise to the request. As adopted, this paragraph now requires the request to set forth as completely as possible "all material facts and circumstances giving rise to the request." Proposed paragraph (b)(5)(ii) stated that Commission staff would not respond to a request based upon a hypothetical situation. In proposing this paragraph, the Commission did not intend to discourage requesters from presenting reasonably realistic alternatives.¹³ To make this clear, the rule as adopted has been modified to permit the request to include one or more alternative structures or fact situations, provided that the request complies with Rule 140.99 with respect to each alternative structure or fact situation.

C. Information Requirements—Section 140.99(c)

Paragraph 140.99(c)(1) as proposed and as adopted sets forth the required identifying information concerning the person on whose behalf a request is made and, where applicable, concerning the authorized representative if the requester is not making the request on his or her own behalf. Paragraph (c)(2) as proposed and as adopted requires that the requester indicate in the upper right-hand corner of the request the provision(s) of the Act and/or Commission rules to which the request relates.

Proposed paragraph (c)(3)(i) would have required a person with knowledge of the facts to certify that the representations in the request are accurate and complete. Commission staff too often has found, after modest scrutiny of representations made in support of a request for a Letter, that those representations were substantially inaccurate. Moreover, during recent market volatility events, it appears that the actual facts in certain instances proved to be substantially different from those the registrant had previously represented in their filings and other communications with the Commission. The Commission hopes that the certification requirement will encourage requesters to use proper care in making factual representations relating to their requests, thus saving time and resources (of staff and of requesters) that otherwise would be expended making and responding to successive requests for additional or corrected information. Upon consideration of the comments,

however, the Commission has modified the proposed text to make clear that the certification applies only to material statements of fact that are set forth in the request. While requesters have a responsibility accurately to analyze the legal issues surrounding their request, the certification requirement in paragraph (c)(3)(i) is limited to factual representations.¹⁴

Proposed paragraph (c)(3)(ii) would have required an undertaking by the person making the certification required by paragraph (c)(3)(i) that the person for whose benefit the request is made will promptly supplement the request in writing at such time as a material representation relating to the request ceases to be accurate and complete. Comments indicated uncertainty as to who would be bound by the undertaking and whether the obligation to update information material to a request would continue after issuance of a Letter. The Commission has modified paragraph (c)(3)(ii) to clarify that the undertaking must be made by the person on whose behalf the Letter is sought, or that person's authorized representative, and that it requires only that the person who made the undertaking will ensure that someone informs Commission staff of changed circumstances (without specifying who should actually submit any supplement). The Commission has modified paragraph (c)(3)(ii) to clarify that the duty to update pursuant to the undertaking required by paragraph (c)(3)(ii) applies only from the time of the submission of the request until the issuance of the Letter.

With respect to material changes of circumstances after issuance of a Letter, paragraph (c)(3)(ii) has been revised to make clear that the person on whose behalf the Letter is sought, or its authorized representative at the time, must notify Commission staff of the occurrence of such changes. The Commission notes that staff typically concludes Letters with a statement to the following effect:

"This letter is based upon the representations made to us. Any different, changed or omitted material facts or circumstances might render this letter void. You must notify us immediately in the event that the operations or activities of [the party on whose behalf the Letter was requested] change in any material respect from those as represented to us."

The comments addressing the next three paragraphs of the proposed rules overlapped significantly. Proposed paragraph (c)(4) would have required

the request to indicate the type of Letter sought, to state why a Letter is needed, to identify the relevant legal and factual issues surrounding the request and to discuss the bases for issuance of the Letter. Proposed paragraph (c)(5) would have required the request to reference all relevant statutory, decisional and administrative authorities (favorable and otherwise). Proposed paragraph (c)(6) would have required identification of prior Letters issued by Commission staff in circumstances similar to the request (and any conditions imposed in those Letters).¹⁵ Some commenters expressed concern that a requirement of comprehensive exposition and discussion of issues, bases and authorities would result in excessive labor and expense on the part of the staff as well as the requesters. Commenters also stated that not all persons seeking Letters can afford experienced counsel or can afford to research relevant law and precedent, and they expressed concern that not all past Letters may be readily accessible.¹⁶

The Commission notes that it does not intend to impose a requirement, express or implied, that requests be submitted by counsel. Individuals and firms are invited to prepare and submit requests directly, or to engage counsel for that purpose, at their own option. The Commission intends that the staff will take into account the level of legal sophistication of the person submitting a request (including whether that person is represented by counsel) in determining whether the requirements of paragraphs (c)(4) through (c)(6) have been met.

Likewise, in adopting Rule 140.99 the Commission does not intend to require excessively lengthy briefing of the relevant issues. However, the request is required to contain a full statement of the material facts, a concise and clear statement of the issues and a thorough examination of any law that would be applicable to those issues, with citations to the relevant authorities. Requesters

¹⁵ Letters are published from 1975 forward in the *Commodity Futures Law Reporter*, published by CCH Incorporated. Letters also are available from 1987 onward from the Westlaw research database of West Publishing Corporation and from 1989 onward from the Lexis database service of Mead Data Central, Inc.

¹⁶ The Commission adopted Rule 140.98 in December 1992 (effective January 25, 1993). That rule requires that all Letters be made available for inspection and copying (subject to confidentiality safeguards). Prior to the effectiveness of Rule 140.98, in the absence of any specific requirements, the decision whether to make a Letter available for publication was subject to the discretion and policies of the various Commission staff. For example, the Division of Trading and Markets generally made available for publication only those Letters that it considered significant.

¹³ Moreover, paragraph (c)(7), discussed below, permits requesters to ask for alternative modes of response.

¹⁴ Legal arguments must nevertheless be supported by the facts and warranted by law.

are not required to cite more than a representative selection of authorities on any issue to the extent that those authorities are cumulative.

While paragraph (c)(4) has adopted essentially as proposed, paragraph (c)(5) as adopted makes clear that it seeks reference to "applicable provisions" of the Act, Commission rules, and other authorities, and paragraph (c)(6) as adopted requires identification of prior Letters that are "publicly available."¹⁷

Moreover, the requirements of paragraphs (c)(5) and (c)(6) should not be understood to require exhaustive citation and analysis where, for example, an issue raised by the request has been the subject of several substantially similar Letters. Rule 140.99(c)(6) as adopted states that citation of a representative sample of prior Letters is sufficient where a comprehensive recitation of prior Letters on a given topic would be repetitious or would not assist Commission staff in considering the request. A requester should exercise good judgment in presenting the request in the context of both the legal and regulatory requirements and the authorities that speak to the merits of the request.

D. Filing Requirements—Section 140.99(d)

Proposed paragraph (d) called for requests to be written, signed and filed with the Director of the Division of Trading and Markets for routing to appropriate Commission staff. Several commenters asked the Commission to accept electronically filed requests, with one commenter including a proposed caveat that a separate manually signed request be required in the absence of an electronic signature mechanism. Other commenters urged that the Commission agree to accept draft requests and urged the Commission to make clear that it welcomes informal discussions and meetings in advance of (or even in the absence of) the submission of a formal request.

As adopted, paragraph (d) differs from the Proposal only insofar as it permits submission of requests to the Director of the Division of Trading and Markets by electronic mail (as well as by post), provided a "hard copy" is submitted shortly after an electronic mail submission in order to permit authentication. As stated above, in adopting Rule 140.99 the Commission does not intend to discourage informal

discussions, whether by telephone, by face-to-face meeting or otherwise. As further stated above, however, Commission staff will *not* issue a Letter in response to an oral request, and a Letter will *not* be issued in response to a tentative or "draft" request.

E. Form of Staff Response—Section 140.99(e)

Proposed paragraph (e) stated that the grant of any request for a Letter is not effective unless the response has been signed and transmitted in final form to the requester and that inaction on the part of Commission staff does not constitute approval of the request. The paragraph further permitted the staff to respond by endorsing the request or by another abbreviated written form of response. Several commenters encouraged the Commission to allow abbreviated responses to requests in appropriate cases, such as where the staff has no objection to the request and where no special conditions or additional precautions are warranted.

Paragraph (e) has been adopted essentially as proposed, with minor word changes.¹⁸ To the extent that requests are adequately developed, articulated and complete, the Commission intends to encourage the use by the staff of abbreviated responses to requests where possible.¹⁹

F. Withdrawal of Requests—Section 140.99(f)

As proposed, paragraph (f) would have permitted withdrawal of a request prior to issuance of a Letter only under specific circumstances: (1) where a written withdrawal request is submitted with a certification that the person seeking a Letter has determined not to proceed with the contemplated transaction or activity or that intervening events have rendered the request for a Letter moot; or (2) where confidential treatment has been sought under Rule 140.98 in connection with the request for a Letter and Commission staff has notified the requester that confidential treatment will be denied. Several commenters claimed that the proposed restrictions were unnecessary and were likely to cause more harm than benefit. They argued that withdrawal should always be permitted.

¹⁸ The reference to "responsible staff" was changed to "appropriate staff."

¹⁹ In response to commenters' concerns, the Commission confirms that, when a Letter is issued by abbreviated or endorsed response to the request, a redacted version of the request letter will be made available for publication together with the Commission staff response unless the requester has sought confidential treatment under Rule 140.98(b) and confidential treatment has been granted for the period specified in that rule.

Some were concerned that the proposed restrictions would severely discourage requests for Letters because a person seeking a Letter who changed his or her mind could neither withdraw the request nor proceed with the proposed transaction or activity while the request was pending. Other commenters suggested that the provision could effectively block lawful activity, either where the response to a request is delayed or where a requester and Commission staff disagree concerning a change in facts or whether an issue has become moot.

Upon consideration of the comments, the Commission has determined to modify the proposed language of paragraph (f). As adopted, paragraph (f) now permits withdrawal of a request for a Letter by filing with Commission staff a signed written request for withdrawal that states whether the person on whose behalf the Letter was requested will proceed with the transaction or activity described in the request for a Letter. This change is designed to allow withdrawal of requests for Letters in appropriate circumstances beyond those enumerated in the Proposal. Paragraph (f) as adopted also now provides for the withdrawal from representation of the authorized representative of the person on whose behalf a Letter has been sought. The only requirement in such as event is that Commission staff be notified promptly of the change in representation. The requirement in the Proposal that requests for withdrawal of a Letter be accompanied by a certification has been eliminated in the final rule.

G. Failure To Pursue a Request—Section 140.99(g)

Paragraph (g) as proposed and as adopted provides that, where a requester fails to respond within 30 days to a Commission staff request for additional information or analysis, the staff generally will issue a denial of the request for a Letter unless an extension of time has been granted. Two commenters suggested that the 30-day period should be tolled as soon as a requester timely asks for an extension of time or that the rule should provide for an automatic 30-day extension if timely requested. Because the Commission believes that it is within the discretion of the staff to grant extensions of time in appropriate circumstances, it has modified paragraph (g) to make clear that any extensions of time are within the staff's discretion.

¹⁷ If a letter is not generally available publicly (i.e., it has not been published by a third-party service), it need not be cited *unless* the requester was the recipient of that prior Letter.

H. Confidential Treatment—Section 140.99(h)

Paragraph (h) as proposed and as adopted requires that, where confidential treatment is sought for a request, a separate request for such treatment must be submitted in accordance with Rule 140.98 or Rule 145.9, as applicable.

I. Applicability to Other Sections—Section 140.99(i)

As proposed and as adopted, paragraph (i) states that Rule 140.99 does not affect the requirements of, or otherwise apply to, notice filings submitted where relief is claimed under Rules 4.5, 4.7(a), 4.7(b), 4.12(b), 4.13(b) and 4.14(a)(8). As noted above, several commenters expressed perceived inconsistencies or conflicts between the provisions of proposed Rule 140.99 and the provisions for requesting exemption under Section 4(c) of the Act. In order to dispel such confusion, paragraph (i) as adopted also expressly excludes from Rule 140.99 requests made pursuant to Section 4(c).

III. Related Matters

A. Regulatory Flexibility Act—Final Regulatory Flexibility Analysis

1. Introduction

The Regulatory Flexibility Act ("RFA")²⁰ requires each federal agency that proposes and adopts rules to consider the impact of those rules on small entities²¹ that are subject to the agency's regulations. Pursuant to the provisions of the RFA, a federal agency is required to prepare an initial regulatory flexibility analysis to accompany any proposed rule that requires a general Notice of Proposed Rulemaking.²² A similar regulatory flexibility analysis must accompany the promulgation of the final rule.²³ An agency is not required to prepare a regulatory flexibility analysis if the agency publishes in the **Federal Register** a certification that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities."²⁴

In the preamble accompanying the Proposal, the Chairperson certified that Rule 140.99 would not have a significant economic impact on a substantial number of small entities.²⁵ In support of this certification, the Commission stated that Rule 140.99 would remove a burden on all persons by whom (or on whose behalf) Letters are sought, regardless of size, by providing greater certainty to requesters as to the procedures to follow in seeking relief and advice. In proposed Rule 140.99, the Commission also stated that the rule would provide Commission staff with the flexibility to accommodate requesters who lacked the financial resources to prepare a conforming request by accepting for consideration non-conforming requests, by providing guidance to the requester, or by other means. Because this certification was made, the Commission was not required to prepare an initial regulatory flexibility analysis.

While none of the commenters directly addressed the RFA, five of the comment letters raised issues within the scope of the RFA. Accordingly, the Commission has prepared this regulatory flexibility analysis to address these comments.

2. Analysis

(a) *Small Entities That May Be Subject to the Rule.* Requests for Letters may be submitted by any person, including those persons who are subject to or potentially subject to the Commission's oversight. Some of these persons may be considered to be small entities within the meaning of the RFA. In this regard, the Commission has established a definition of "small entities" to be used in evaluating the impact of its Rules on such small entities in accordance with the RFA.²⁶ In accordance with this definition, registered futures commission merchants, commodity pool operators ("CPOs"), leverage transaction merchants, large traders, and contract markets have been determined not to be small entities under the RFA.²⁷ Agricultural trade option merchants similarly have been found not to be small entities under the RFA.²⁸ With respect to persons registered as commodity trading advisors,²⁹

introducing brokers³⁰ and floor brokers,³¹ the Commission has stated that it would evaluate within the context of a particular rule proposal whether all or some of such registrants would be considered to be small entities, and, if so, the economic impact on them of the particular rule. Floor traders³² and CPOs exempt from registration³³ also may be considered small entities under the RFA.

In fiscal year 1997, the Office of Chief Counsel of the Division of Trading and Markets³⁴ received 303 inquiries from registrants, persons exempt from registration, unregistered persons and members of the general public. Written responses were issued or other dispositions were made with respect to 277 of these inquiries.³⁵ Many, but not all, of the responses took the form of Letters within the meaning of Rule 140.99. More than 55%, or 158, of these responses were provided to persons that are not small entities. The remaining responses were provided to persons that could, in the context of Rule 140.99, be classified as small entities as recognized by the Commission.

Rule 140.99 requires all requesters, including both small and large entities, to follow uniform procedures when requesting Letters. Based upon past experience, it is expected, though not required, that most requests will be prepared by the legal counsel of the person on whose behalf a Letter is sought.³⁶ In this regard, the type of skills required to submit a request for a Letter will not change under Rule 140.99. No other compliance or

Pool Operators and Commodity Trading Advisors for Delivery of Disclosure Documents and Other Materials, 62 FR 39104, 39114 (July 22, 1997); and *Exemption for Commodity Pool Operators with Respect to Offerings to Qualified Eligible Participants; Exemption for Commodity Trading Advisors with Respect to Qualified Eligible Clients*, 57 FR 34853, 34860 (Aug. 7, 1992).

³⁰ See e.g., *Financial Reporting Requirements for Futures Commission Merchants and Introducing Brokers*, 53 FR 4606, 4610 (Feb. 17, 1988).

³¹ 47 FR at 18620. See also *Adverse Registration Actions and Other Registration Matters*, 57 FR 23136, 23142 (June 2, 1992).

³² See e.g., *Registration of Floor Traders; Mandatory Ethics Training for Registrants; Suspension of Registrants Charged with Felonies*, 58 FR 19575, 19588 (April 15, 1993).

³³ See, e.g., *Commodity Pool Operators; Exclusion for Otherwise Regulated Persons From the Definition of the Term "Commodity Pool Operator"; Other Regulatory Requirements*, 50 FR 15868, 15881 (April 23, 1985).

³⁴ Historically, this Office has received and responded to the largest number of requests for Letters of any Office or Division of the Commission.

³⁵ Some of the responses were issued in fiscal year 1998.

³⁶ As the Commission noted above, "it does not intend to impose a requirement . . . that requests be submitted by counsel."

²⁰ 5 U.S.C. 601 *et seq.* (1994).

²¹ A small entity includes a "small business" as defined by an agency in consultation with the Office of Advocacy of the Small Business Administration. *Id.* at § 601(6).

²² The initial analysis must contain a description of the proposed rule's impact on small entities and any significant alternatives to the action "which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities." *Id.* at § 603.

²³ *Id.* at § 604.

²⁴ *Id.* at § 605(b).

²⁵ 63 FR 3287.

²⁶ *Policy Statement and Establishment of Definitions of "Small Entities" for purposes of the Regulatory Flexibility Act*, 47 FR 18618 (April 30, 1982).

²⁷ *Id.*

²⁸ *Trade Options on the Enumerated Agricultural Commodities*, 63 FR 18821 (April 16, 1998).

²⁹ 47 FR at 18620. See also *Interpretation Regarding Use of Electronic Media by Commodity*

reporting requirements are imposed by Rule 140.99.

(b) *Summary of the Issues Affecting Small Entities Raised by the Comments.* Commenters argued that Rule 140.99 essentially would require that requests be exhaustively researched and contain a lengthy recitation of all relevant legal and factual issues and all legal authority, including all prior Letters on a given topic. Commenters claimed that such requirements are unnecessary for routine or basic requests and would entail significant costs to persons on whose behalf Letters are sought, including small entities, which may lack the library or staffing resources to prepare a conforming request. They added that persons seeking Letters would be required to hire specialized legal counsel to prepare their requests. Some commenters further claimed that the requirements would discourage requests for Letters because relief could be denied simply because the request did not conform to the requirements of Rule 140.99.

Two commenters recommended that Rule 140.99 be modeled after comparable procedures adopted under Federal securities laws and regulations that provide that the writer should indicate why he thinks a problem exists, his own opinion in the matter and the basis for such opinion.³⁷ With respect to Rule 140.99's requirements that all prior Letters and all relevant legal authority be identified, some commenters recommended that the Commission clarify that requesters would be required to identify only relevant precedent or only those relevant authorities of which they are aware through the exercise of reasonable diligence.

Some of the commenters also expressed concerns about the availability of prior Letters, especially older ones, and the burden on persons seeking Letters, including small entities, arising from a requirement to locate and identify prior Letters. In this regard, the commenters pointed out that the Commission was not required to make its Letters available for public inspection and copying before 1993, the effective date of Rule 140.98.³⁸ They further claimed that Letters issued prior to 1987 are not available on any online database service and that it would be particularly onerous on all persons, including small entities, to conduct a manual search for such Letters. To address these concerns, one commenter recommended that the Rule be modified

to permit requesters to affirm the scope of any prior research or to note in their requests the practical limitations placed on the scope of their research. Another commenter suggested that the Commission commit to publish widely its prior Letters and to publish promptly all Letters issued in the future. The same commenter also recommended that the Commission post all of its Letters on its Internet web site.

(c) *Alternatives Proposed and Adopted.* The Commission has considered the concerns expressed by commenters and, as stated above, has clarified that requesters are not required to provide an excessively lengthy recitation of all relevant legal authority (including prior Letters) in support of a request for a Letter. It is sufficient that requests contain a full statement of the material facts, a concise and clear statement of the issues and a thorough examination of any law that would be applicable to those issues, with citations to the relevant authorities. Similarly, and as also stated above, the Commission has clarified that requesters are not required to cite more than a representative selection of authorities on any issue, to the extent that those authorities are cumulative.

To minimize the potential compliance burden on small entities, including those entities that are not represented by counsel, the Commission is reiterating that staff may accommodate persons who lack the financial resources to prepare a conforming request by accepting for consideration the non-conforming request as submitted, by providing guidance to the requesters, or by other means.

To address commenters' concerns about the lack of public availability of relevant authorities, including prior Letters, the Commission intends that the staff take this fact into account when reviewing requests, particularly those that are submitted by small entities. The Commission also has undertaken a review of the feasibility of making the full text of Letters available at the Commission's Internet web site as one commenter has suggested.³⁹

Other than these specific comments, commenters proposed no other alternatives short of abandonment of the Proposal. Given the goals sought to be achieved by Rule 140.99, including decreasing the burden on all persons seeking Letters, regardless of size, this alternative would not be feasible.

B. Paperwork Reduction Act

When publishing final rules, the Paperwork Reduction Act of 1989 ("PRA"), 44 U.S.C. 3501 *et seq.*, imposes certain requirements on federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the PRA. In compliance with the Act, this **Federal Register** release informs the public of: (1) The reasons the information is planned to be and/or has been collected; (2) the way such information is planned to be and/or has been used to further the proper performance of the functions of the agency; (3) an estimate, to the extent practicable, of the average burden of the collection (together with a request that the public direct to the agency any comments concerning the accuracy of this burden estimate and any suggestions for reducing this burden); (4) whether responses to the collection of information are voluntary, required to obtain or retain a benefit or mandatory; (5) the nature and extent of confidentiality to be provided, if any; and (6) the fact that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The Commission previously submitted Rule 140.99 in proposed form and its associated information collection requirements to the Office of Management and Budget. The Office of Management and Budget approved the collection of information associated with this rule on March 30, 1998, and assigned OMB control number 3038-0049 to the rule. The burden associated with this specific final rule is as follows:

Average burden hours per response: 7.

Number of Respondents: 215.

Frequency of response: On occasion.

Persons wishing to comment on the information required by this final rule should contact the Desk Officer, CFTC, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503 (202) 395-7340. Copies of the information collection submission to OMB are available from the CFTC Clearance Officer, 1155 21st Street, NW, Washington, DC 20581 (202) 418-5160.

List of Subjects in 17 CFR Part 140

Authority delegations (Government agencies), Organization and functions (Government agencies).

In consideration of the foregoing and pursuant to the authority contained in the Commodity Exchange Act and in particular section 8(a)(5) of the Act, as amended, 7 U.S.C. 12(a)(5), the

³⁷ Securities Act Release No. 5127, 36 FR 2600 (Jan. 25, 1971), and Securities Act Release No. 6269 (Dec. 5, 1980).

³⁸ See *supra* note 16.

³⁹ The Commission's web site (<http://www.cftc.gov>) currently contains a summary, but not the full text, of all Letters that were issued and made publicly available pursuant to Rule 140.98 commencing December 24, 1994.

Commission hereby proposes to amend Chapter I of title 17 of the Code of Federal Regulations as follows:

PART 140—ORGANIZATION, FUNCTIONS, AND PROCEDURES OF THE COMMISSION

1. The authority citation for part 140 continues to read as follows:

Authority: 7 U.S.C. 7a(j) and 12a.

2. Section 140.99 is added to read as follows:

§ 140.99 Requests for exemptive, no-action and interpretative letters.

(a) *Definitions.* For the purpose of this section:

(1) *Exemptive letter* means a written grant of relief issued by the staff of a Division of the Commission from the applicability of a specific provision of the Act or of a rule, regulation or order issued thereunder by the Commission. An exemptive letter may only be issued by staff of a Division when the Commission itself has exemptive authority and that authority has been delegated by the Commission to the Division in question. An exemptive letter binds the Commission and its staff with respect to the relief provided therein. Only the Beneficiary may rely upon the exemptive letter.

(2) *No-action letter* means a written statement issued by the staff of a Division of the Commission or of the Office of the General Counsel that it will not recommend enforcement action to the Commission for failure to comply with a specific provision of the Act or of a Commission rule, regulation or order if a proposed transaction is completed or a proposed activity is conducted by the Beneficiary. A no-action letter represents the position only of the Division that issued it, or the Office of the General Counsel if issued thereby. A no-action letter binds only the issuing Division or the Office of the General Counsel, as applicable, and not the Commission or other Commission staff. Only the Beneficiary may rely upon the no-action letter.

(3) *Interpretative letter* means written advice or guidance issued by the staff of a Division of the Commission or the Office of the General Counsel. An interpretative letter binds only the issuing Division or the Office of the General Counsel, as applicable, and does not bind the Commission or other Commission staff. An interpretative letter may be relied upon by persons in addition to the Beneficiary.

(4) *Letter* means an exemptive, no-action or interpretative letter.

(5) *Division* means the Division of Trading and Markets or the Division of Economic Analysis.

(b) *General Requirements.* (1) Issuance of a Letter is entirely within the discretion of Commission staff.

(2) Each request for a Letter must comply with the requirements of this section. Commission staff may reject or decline to respond to a request that does not comply with the requirements of this section.

(3) The request must relate to a proposed transaction or a proposed activity. Absent extraordinary circumstances, Commission staff will not issue a Letter based upon transactions or activities that have been completed or activities that have been conducted prior to the date upon which the request is filed with the Commission.

(4) The request must be made by or on behalf of the person whose activities or transactions are the subject of the request. Commission staff will not respond to a request for a Letter that is made by or on behalf of an unidentified person.

(5)(i) The request must set forth as completely as possible all material facts and circumstances giving rise to the request.

(ii) Commission staff will not respond to a request based on a hypothetical situation. However, a requester may set forth one or more alternative structures or fact situations for a proposed transaction or activity; *Provided*, That the request complies with this section with respect to each alternative structure or fact situation.

(c) *Information Requirements.* Each request for a Letter must comply with the following information requirements:

(1)(i) A request made by the person on whose behalf the Letter is sought must contain:

(A) The name, main business address, main telephone number and, if applicable, the National Futures Association registration identification number of such person; and

(B) The name and, if applicable, the National Futures Association registration identification number of each other person for whose benefit the person is seeking the Letter.

(ii) When made by a requester other than the person on whose behalf the Letter is sought, the request must contain:

(A) The name, main business address and main business telephone number of the requester;

(B) The name and, if applicable, the National Futures Association registration identification number of the

person on whose behalf the Letter is sought; and

(C) The name and, if applicable, the National Futures Association registration identification number of each other person for whose benefit the requester is seeking the Letter.

(iii) The request must provide the name, address and telephone number of a contact person from whom Commission staff may obtain additional information if necessary.

(2) The section number of the particular provision of the Act and/or Commission rules, regulations or orders to which the request relates must be set forth in the upper right-hand corner of the first page of the request.

(3) The request must be accompanied by:

(i) A certification by a person with knowledge of the facts that the material facts as represented in the request are true and complete. The following form of certification is sufficient for this purpose:

I hereby certify that the material facts set forth in the attached letter dated _____ are true and complete to the best of my knowledge.
(name and title) _____

and

(ii) An undertaking made by the person on whose behalf the Letter is sought or by that person's authorized representative that, if at any time prior to issuance of a Letter, any material representation made in the request ceases to be true and complete, the person who made the undertaking will ensure that Commission staff is informed promptly in writing of all materially changed facts and circumstances. If a material change in facts or circumstances occurs subsequent to issuance of a Letter, the person on whose behalf the Letter is sought (or that person's authorized representative at the time of the change) must promptly so inform Commission staff.

(4) The request must identify the type of relief requested and Letter sought and must clearly state why a Letter is needed. The request must identify all relevant legal and factual issues and discuss the legal and public policy bases supporting issuance of the Letter.

(5) The request must contain references to all relevant authorities, including applicable provisions of the Act, Commission rules, regulations and orders, judicial decisions, administrative decisions, relevant statutory interpretations and policy statements. Adverse authority must be cited and discussed.

(6) The request must identify prior publicly available Letters issued by

Commission staff in response to circumstances similar to those surrounding the request (including adverse Letters), and must identify any conditions imposed by prior Letters as prerequisites for the issuance of those Letters. Citation of a representative sample of prior Letters is sufficient where a comprehensive recitation of prior Letters on a given topic would be repetitious or would not assist the staff in considering the request.

(7) Requests may ask that, if the requested exemptive relief, no-action position or interpretative guidance is denied, the staff consider granting alternative relief or adopting an alternative position.

(d) *Filing Requirements.* Each request for a Letter must comply with the following filing requirements:

(1) The request must be in writing and signed.

(2) The request must be filed with the Director, Division of Trading and Markets, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Request must be submitted electronically using the e-mail address tmletters@cftc.gov; *Provided*, That a properly signed paper copy of the request is provided to the Division of Trading and Markets within ten days for purposes of verification of the electronic transmission. The Director will route the request to the appropriate Division or the Office of the General Counsel.

(e) *Form of Staff Response.* No response to any request governed by this section is effective unless it is in writing, signed by appropriate Commission staff, and transmitted in final form to the recipient. Failure by Commission staff to respond to a request for a Letter does not constitute approval of the request. Nothing in this section shall preclude Commission staff from responding to a request for a Letter by way of endorsement or any other abbreviated, written form of response.

(f) *Withdrawal of Requests.* (1) A request for a Letter may be withdrawn by filing with Commission staff a written request for withdrawal, signed by the person on whose behalf the Letter was sought or by that person's authorized representative, that states whether the person on whose behalf the Letter was sought will proceed with the proposed transaction or activity.

(2) Where a request has been submitted by an authorized representative of the person on whose behalf a Letter is sought, the authorized representative may withdraw from representation at any time without explanation, *Provided*, That

Commission staff is promptly so notified.

(g) *Failure to Pursue a Request.* In the event that Commission staff requests additional information or analysis from a requester and the requester does not provide that information or analysis within thirty calendar days, Commission staff generally will issue a denial of the request; *Provided*, however, that Commission staff in its discretion may issue an extension of time to provide the information and or analysis.

(h) *Confidential Treatment.* Confidential treatment of a request for a Letter must be requested separately in accordance with § 140.98 or § 145.9 of this chapter, as applicable.

(i) *Applicability to Other Sections.* The provisions of this section shall not affect the requirements of, or otherwise be applicable to:

(A) Notice filings required to be made to claim relief from the Act or from a Commission rule, regulation or order including, without limitations, §§ 4.5, 4.7(a), 4.7(b), 4.12(b), 4.13(b) and 4.14(a)(8) of this chapter; or

(B) Requests for exemption pursuant to Section 4(c) of the Act.

Issued in Washington, DC on December 2, 1998 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 98-32587 Filed 12-9-98; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Gentamicin Sulfate Injection

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 a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides for use of gentamicin sulfate injection in the neck of 1 to 3-day-old turkey poults for prevention of early mortality due to susceptible *Arizona paracolon* infections.

EFFECTIVE DATE: December 10, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, filed supplemental NADA 200-147 that provides for subcutaneous use of Genta-Ject® (gentamicin sulfate) injectable solution in the neck of 1 to 3-day-old turkey poults as an aid in the prevention of early mortality due to *A. paracolon* infections susceptible to gentamicin. The supplemental NADA is approved as of October 30, 1998, and the regulations are amended in 21 CFR 522.1044(b)(4) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. Section 522.1044 is amended by revising paragraph (b)(4) to read as follows:

§ 522.1044 Gentamicin sulfate injection.

* * * * *

(b) * * *

(4) See No. 050604 for use of 100 milligram-per-milliliter solution in turkeys as in paragraph (d)(2) of this section and in chickens as in paragraph (d)(3) of this section.

* * * * *