Boeing: Docket 2003–NM–50–AD.

Applicability: Model 777–200 series airplanes, as listed in Boeing Service Bulletin 777–27–0057, dated August 22, 2002; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent damage to the stabilizer cutout circuit wires in the bundles due to contact between the bundles and the adjacent galley water drain tube and hydraulic tubes, which if followed by active fault in stabilizer command circuit, could result in undesired stabilizer motion that cannot be stopped, and could lead to loss of pitch control and loss of control of the airplane, accomplish the following:

Service Bulletin References

(a) The term ''service bulletin,'' as used in this AD, means the Accomplishment Instructions of Boeing Service Bulletin 777–27–0057, dated August 22, 2002.

Inspection

(b) Within 18 months of the effective date of this AD, perform a one-time general visual inspection of the wire bundles that route aft of electrical disconnect panel AC2162 to determine their installation and separation, in accordance with the service bulletin.

Note 1: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

(c) If wire bundles are installed in accordance with the service bulletin, no further action is required by this AD.

Corrective Action

(d) If any wire bundle is not installed in accordance with the service bulletin: Before further flight, perform the actions specified in paragraphs (d)(1) and (d)(2) of this AD.

(1) Perform a detailed inspection of the wire bundle for damage, and repair all damage, in accordance with the service bulletin.

Note 2: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

(2) Add clamps or tie strips to secure the wire bundles in accordance with the service bulletin.

Alternative Methods of Compliance

(e) In accordance with 14 CFR 39.19, the Manager, Seattle Aircraft Certification Office, FAA, is authorized to approve alternative methods of compliance for this AD.

Issued in Renton, Washington, on November 17, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–29342 Filed 11–24–03; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 36

Exempt Commercial Markets

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commodity Futures Trading Commission (''Commission'') is proposing two actions relating to electronic trading facilities that operate in reliance on the exemption in section 2(h)(3) of the Commodity Exchange Act (''the Act''). First, the Commission is proposing to amend Rule 36.3(b), which governs Commission access to information regarding transactions on such trading facilities, to provide for access to more relevant and useful information from all such markets. Second, the Commission is proposing rules that would require those electronic trading facilities that operate in reliance on the exemption in section 2(h)(3) and that perform a significant price discovery function for transactions in the underlying cash market to publicly disseminate certain specified trading data. These price discovery rules are being proposed pursuant to section 2(h)(4) of the Act, which authorizes the Commission to prescribe rules and regulations to ensure timely dissemination by such trading facilities of price, trading volume, and other trading data to the extent appropriate.

DATES: Comments must be received by January 26, 2004.

ADDRESSES: Comments should be sent to the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581, attention: Office of the Secretariat. Comments may be sent by facsimile transmission to 202–418–5521 or, by e-mail to *secretary@cftc.gov.* Reference should be made to ''Proposed Rules for Exempt Commercial Markets.''

FOR FURTHER INFORMATION CONTACT: Nancy E. Yanofsky, Chief Counsel (telephone 202–418–5292, e-mail *nyanofsky@cftc.gov*), or Don Heitman, Senior Special Counsel (telephone 202–418–5041, e-mail *dheitman@cftc.gov*), Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

The Commodity Futures Modernization Act of 2000 (''CFMA''), Pub. L. 106–554, created an exemption from the Commission's jurisdiction for transactions conducted on certain electronic commercial markets (''exempt commercial markets,'' ''ECMs'' or ''§ 2(h)(3) markets''). Specifically, § 2(h)(3) of the Act provides that, except to the extent provided in § 2(h)(4), nothing in the Act shall apply to a transaction in an exempt commodity [1] that is: (a) Entered into on a principal-to-principal basis solely between persons that are eligible commercial entities at the time the persons enter into the agreement, contract, or transaction; and (b) executed or traded on an electronic trading facility. Section 2(h)(4) provides that a transaction described in § 2(h)(3) shall be subject to certain specified provisions of the Act, such as the Act's antimanipulation and antifraud provisions, and furthermore, that such transactions shall be subject to price dissemination rules if the electronic trading facility serves a significant price discovery function for the underlying cash market. Section 2(h)(5) requires an electronic trading facility relying on the exemption in § 2(h)(3) to provide the Commission with certain information and to comply with information access provisions set out in § 2(h)(5)(B)(i).

II. Information Access Provisions

Section 2(h)(5)(B)(i) of the Act requires an electronic trading facility relying on the exemption provided in § 2(h)(3) to provide the Commission with information regarding trading activity on the facility. The statute establishes two alternatives for providing that information:

(I) provide the Commission with access to the facility's trading protocols and electronic access to the facility with respect to transactions conducted in reliance on the exemption set forth in paragraph (3); or

(II) provide such reports to the Commission regarding transactions executed on the facility in reliance on the exemption set forth

[1] Under the Act, exempt commodities generally are tangible, non-agricultural commodities and include energy and metals products. *See* § 1a(14) of the Act, 7 U.S.C. 1a(14).

in paragraph (3) as the Commission may from time to time request to enable the Commission to satisfy its obligations under this Act.

These two statutory alternatives are referred to hereafter as, respectively, the ''electronic access option'' and the ''reporting option.''

Regulation 36.3(b)(1), published on August 10, 2001, was intended to implement the foregoing statutory provisions. It provides as follows:

(b) *Required information.* (1) A facility operating in reliance on the exemption in section 2(h)(3) of the Act, initially and on an ongoing basis, must:

(i) Provide the Commission with access to the facility's trading protocols and electronic access to transactions conducted on the facility in reliance on such exemption; or

(ii) Attach its initial trading protocols and any amendments thereto in hard copy form to the notification required in paragraph (a) of this section and provide in a form and manner acceptable to the Commission, as determined by the Commission in response to a petition by the exempt market relying on the exemption in section 2(h)(3) of the Act, information regarding transactions by large traders on the facility.

To date, those trading facilities that have sought to comply with this regulation have generally chosen the former, the electronic access option. In applying the electronic access option, the Commission has generally accepted from ECMs electronic access to their trading protocols (*i.e.*, the trading agreements and/or other terms and conditions applicable to trades on the facility, generally available on their Web sites) in addition to view-only electronic access to the data stream of trades taking place on the system. The Commission suggested, when it adopted Part 36, that such electronic access would provide information similar to that provided by large trader reports filed with the Commission with respect to trading on designated contract markets:

The [electronic] access requirement provides the Commission with information on a routine, ongoing basis, thereby serving many of the functions that large trader reports serve on the regulated markets. Using this access, the Commission is able to surveil transactions on the market in order to enforce its anti-manipulation authority.[2]

In practice, however, the Commission's Division of Market Oversight (''Division'') has found that the view-only information provided under the electronic access option, by those trading facilities that have filed notifications under section 2(h)(3) over the last 24 months, is neither as relevant,[3] nor as useful,[4] as anticipated.

Therefore, the Commission is proposing to amend its regulations to focus Rule 36.3(b)(1) more precisely so as to provide the Commission with access to more relevant and useful information regarding trading activity on exempt commercial markets. Under the amended rules, an electronic trading facility filing a notification with the Commission under Rule 36.3 would be required, initially and on an ongoing basis, to: (1) Provide the Commission with access to the facility's trading protocols, either electronically or in hard copy form; (2) identify those transactions conducted on the facility with respect to which it intends to rely on the exemption in section 2(h)(3); and (3) inform the Commission whether it intends to satisfy the information access requirement of section 2(h)(5)(B)(i) of the Act with respect to such transactions through the electronic access option provided in paragraph 36.3(b)(1)(ii)(B), or the reporting option provided in paragraph 36.3(b)(1)(ii)(A), as described below.

The trading facility would not be required to include among the agreements, contracts or transactions for which it is seeking an exemption those agreements, contracts or transactions that are not contracts for future delivery of a commodity, or options, and are, therefore, not subject to the Commission's exclusive jurisdiction. Thus, for example, the trading facility would not be required to identify, or provide information with respect to, agreements, contracts or transactions involving ''any sale of any cash commodity for deferred shipment or delivery.'' Such transactions are excluded from the Commission's exclusive jurisdiction under section 1a(19) of the Act (commonly referred to as ''the forward contract exclusion''). Neither would a trading facility be required to identify, or provide information with respect to, agreements, contracts or transactions that constitute cash or spot transactions, which are contracts for present, rather than future, delivery and likewise are not subject to the Commission's exclusive jurisdiction.

In complying with amended Rule 36.3, trading facilities shall make their best effort to identify to the Commission only those agreements, contracts or transactions that are subject to the Commission's exclusive jurisdiction and with respect to which they intend to rely on the exemption provided in section 2(h)(3). Should a new agreement, contract or transaction be added, or an existing one amended, that would be traded in reliance on the exemption, the trading facility should amend its notice accordingly.

A trading facility that does not offer trading in any futures or option contracts subject to the Commission's exclusive jurisdiction—for example, a facility where only cash or forward contracts are traded—is not required to file a notification under Rule 36.3. Such a facility is not subject to the Commodity Exchange Act.

Consistent with section 2(i) of the Act,[5] the mere fact that it was identified as being traded in reliance on the section 2(h)(3) exemption would not be construed as creating a presumption that any agreement, contract or transaction is or otherwise would be subject to the Act. Thus, for example, in any enforcement action involving any such agreement, contract or transaction, the Commission would be required to prove its jurisdiction independently of an ECM's identification of that agreement, contract or transaction for purposes of information access under Rule 36.3. Also, should a trading facility seeking in good faith to comply with Rule 36.3 fail to identify for information access purposes a particular agreement, contract or transaction, which is later determined to be a futures or option contract subject to the Commission's exclusive jurisdiction, such failure would not be construed by the Commission as a violation of section

[2] 66 FR 42264, Aug. 10, 2001.

[3] The electronic access option, as currently applied, gives the Commission information regarding all contracts traded on an ECM's trading facility. This may include a large amount of irrelevant, extraneous data regarding contracts that are not contracts for future delivery of a commodity, or options, and are, therefore, not within the Commission's exclusive jurisdiction.

[4] The Division's surveillance staff have determined that the information available through the current view-only electronic access to ECM trading facilities is not, in fact, equivalent to the large trader information received with respect to designated contract markets.

[5] Section 2(i) of the Commodity Exchange Act provides that:

(1) No provision of this Act shall be viewed as implying or creating any presumption that —

(A) any agreement, contract or transaction that is excluded from this Act under section 2(c), 2(d), 2(e), 2(f), or 2(g) of this Act or Title IV of the Commodity Futures Modernization Act of 2000, or exempted under section 2(h) or 4(c) of this Act; or

(B) any agreement, contract or transaction, not otherwise subject to this Act, that is not so excluded or exempted is or would otherwise be subject to this Act.

(2) No provision of, or amendment made by, the Commodity Futures Modernization Act of 2000 shall be construed as conferring jurisdiction on the Commission with respect to any such agreement, contract or transaction, except as expressly provided in section 5a of this Act (to the extent provided in section 5a(g) of this Act), 5b of this Act, or 5d of this Act.

4(a) of the Act.[6] However, such transaction would still remain subject to the Commission's antifraud and antimanipulation authority.

Trading facilities electing to provide information under the reporting option would be required to file weekly reports containing information that could be useful to the Commission in enforcing its antifraud and antimanipulation authority with respect to those trading facilities. Such reports would include, in a form and manner approved by the Commission, a report for each business day, showing for each transaction executed on the facility in reliance on the exemption set forth in section 2(h)(3) the following information: the commodity, the location,[7] the maturity date, whether it is a financially settled or physically delivered instrument, the date of execution, the time of execution, the price, the quantity, and such other information as the Commission may determine, and for an option instrument, the type of option (call or put) and the strike price. Each such report would be required to be electronically transmitted weekly, within such time period as is acceptable to the Commission following the end of the week to which the data applies.

Those trading facilities wishing to provide information pursuant to the electronic access option (Rule 36.3(b)(1)(ii)(B)) would be required, initially and on an ongoing basis, to provide the Commission with electronic access to those transactions conducted on the facility in reliance on the exemption in section 2(h)(3). Such access must be structured so as to permit the Commission to capture in permanent form a continuing record of trades on the facility such that the Commission would be able to reconstruct and compile the same information regarding transactions on the trading facility that would otherwise be provided by the trading facility under the reporting option (Rule 36.3(b)(1)(ii)(A)) described above.

The Commission expects that the information that will be provided by ECMs in reports required under Rule 36.3(b)(1)(ii)(A), or compiled by the Commission through electronic access provided under Rule 36.3(b)(1)(ii)(B), will be useful in identifying aberrant price behavior, including intraday price spikes. Such price anomalies may serve as indicators of the need for further Commission investigation. In such instances, the Commission may, among other things, use the special call authority provided by section 2(h)(5)(B)(iii) to determine whether a manipulation may have occurred warranting appropriate enforcement action.

This reactive oversight differs from that applicable to Designated Contract Markets (''DCMs'') and registered Derivatives Transaction Execution Facilities (''DTFs''). Those markets are subject to a greater degree of regulatory oversight than ECMs and, accordingly, are required to provide more frequent and detailed transaction data, which enables the Commission not only to investigate and punish manipulation after-the-fact, but to detect and prevent it as well.

Proposed Rule 36.3(b)(1)(iii) would require a trading facility to maintain a record of allegations or complaints concerning instances of suspected fraud or manipulation. The record would be required to include the name of the complainant, if provided, the date of the complaint, the market instrument, the substance of the allegations, and the name of the person at the trading facility who received the complaint. The intent of this provision is to make clear that the language of section 2(h)(5)(B)(ii) of the Act, which requires a trading facility to maintain ''records of activities related to its business as an electronic trading facility exempt under paragraph (3),'' extends to maintaining records relating to allegations or complaints of fraud or manipulation in trading activity on the facility.

Proposed Rule 36.3(b)(1)(iv) would require a trading facility to provide to the Commission a copy of the record of each substantive complaint no later than three days after the complaint is received. The basis for this requirement is the language appearing at the end of section 2(h)(5)(B)(i)(II) (the reporting option), which states that reports regarding transactions executed on the facility are provided ''to enable the Commission to satisfy its obligations under this Act.'' The purpose expressed in this language seems to apply not only to the reporting subparagraph in which it appears, but also to the electronic access subparagraph that precedes it. Clearly, the two subparagraphs are intended to provide alternative methods of reaching the same objective, which is to impart information to the Commission that will enable it to perform its duties under the Act.

Given the Commission's duty to enforce the antifraud and antimanipulation provisions of the Act with respect to transactions conducted in reliance on the section 2(h)(3) exemption, the Commission believes it is crucial that ECMs report complaints of such activities. Reports to the Commission are consistent with an ECM's ongoing obligations under section 2(h)(5)(D) both to comply with paragraph 2(h)(5) itself and to require participants trading on the facility in reliance on the section 2(h)(3) exemption to ''agree to comply with all applicable law.'' Such reports are especially important given the after-the-fact nature of the Commission's oversight of such trading activity. It is also significant that the ECMs receiving these complaints (unlike more highly-regulated DCMs or DTFs) have no self-regulatory responsibility or authority, and thus no ability to respond to such complaints themselves beyond denying the violator future access to the trading facility. This creates an even greater need for the Commission to receive information that will enable it to take action in response to such suspected manipulation or fraud.

It should be noted that the reporting requirement is limited to ''substantive'' claims of manipulation or fraud. The Commission's intent in including this limitation is to allow an ECM to exercise its judgment to weed out clearly frivolous claims.[8]

III. Price Discovery Provisions

With respect to price dissemination rules, section 2(h)(4)(D) specifically provides that a transaction described in section 2(h)(3) shall be subject to:

> such rules and regulations as the Commission may prescribe if necessary to ensure timely dissemination by the electronic trading facility of price, trading volume, and other trading data to the extent appropriate, if the Commission determines that the electronic trading facility performs a significant price discovery function for transactions in the cash market for the commodity underlying any agreement, contract, or transaction executed or traded on the electronic trading facility.

On August 10, 2001, the Commission published Rule 36.3, which implements the notification, information and other provisions of the CFMA related to section 2(h)(3) exempt commercial markets. *See* 66 FR 42255. Subsection (c)(2) of Rule 36.3 provides that the Commission may make a determination that such a trading facility performs a significant price discovery function under section 2(h)(4)(D) by order, and that such finding shall be made after notice and an opportunity for a hearing

[6] Section 4(a) of the Act makes it unlawful to trade a contract for future delivery of a commodity in the U.S. unless on a contract market designated by, or a derivatives transaction execution facility registered with, the Commission.

[7] In this context, ''location'' means the delivery or the price-basing location specified in the agreement, contract or transaction.

[8] An ECM could, as an alternative to exercising such judgment, choose to forward all complaints to the Commission.

through submission of written data, views and arguments.

To date, ten electronic commercial markets have notified the Commission of their intent to operate as ECMs in reliance on the section 2(h)(3) exemption. The Commission has issued acknowledgment letters to seven ECMs, and is considering the issuance of acknowledgment letters to the other three markets. In view of the Commission's receipt of these section 2(h)(3) notifications, the Commission now is proposing to add specificity to its price discovery rules in several ways. First, the Commission is proposing to adopt two criteria that the Commission will use to determine whether a section 2(h)(3) market performs a significant price discovery function for the underlying cash market. Second, the Commission is proposing to specify the information that must be disseminated by section 2(h)(3) markets that serve such a significant price discovery function. Third, the Commission is proposing certain amendments to its procedures for making a price discovery determination.[9]

A. The Elements of Price Discovery

Price discovery commonly is defined as the process of determining prices through the interaction of buyers and sellers. Prices may be discovered by a single buyer and seller in a privately negotiated bilateral cash market transaction, or through the simultaneous interaction of multiple buyers and sellers in organized markets.

Organized markets, which include futures markets and certain cash markets where trading takes place in accordance with established rules, often perform an important role in facilitating price discovery in the broader cash markets. In particular, these markets facilitate price discovery in cash markets by efficiently incorporating supply and demand information for the underlying commodity into the transaction prices or bids and offers through the operation of a centralized market for the commodity. Thus, the price discovery process on organized markets may significantly enhance the efficiency of the overall cash market.

The extent to which price information is used in establishing prices for cash market transactions that occur outside of the organized markets provides a relevant factor for determining the contribution of that market to price discovery and for determining whether there is a federal interest in the dissemination of such price information.[10] Such price information may be used in varying degrees to facilitate the establishment of prices and may also serve as one of a number of sources of price information that are consulted by cash market participants in developing bids, offers, or transaction prices. In certain circumstances, such price information may be sufficiently well regarded by the industry that it serves as an important benchmark for cash market participants to consider in setting bids or offers or in negotiating cash market transaction prices.[11] In other circumstances, prices discovered on a market may be such an integral and indispensable part of the price determination process in the underlying cash market that bids, offers or cash market transaction prices have a relatively high correlation to the prices discovered on the market. This latter practice is known as price basing.

Price basing is a frequently observed practice in many futures markets and some cash markets. As indicated above, under price basing, commercial entities establish transaction prices for the underlying commodity, or a related commodity, based directly on the prices discovered on an organized market. These entities may or may not trade in the organized market. The cash market transaction prices established through price basing may be either spot or forward prices.

Prices discovered on futures or organized cash markets vary widely with regard to their influence on transaction prices established in broader cash markets. For instance, many long-established organized markets for agricultural, metal, and energy commodities appear to perform a crucial price discovery role for the broader cash markets, as reflected by the widespread practice of price basing in many of these markets. For example, for certain dairy products, the price discovery function of established organized cash markets is so significant that prices established on such markets are extensively used for price basing even though the organized market's prices may be based on a relatively small number of transactions. Similarly, prices established on actively traded futures markets for commodities like grains, oilseeds, natural gas and petroleum products are extensively used for price basing. In contrast, newly established organized markets may be less likely to perform a significant price discovery function for their associated cash markets in their early stages of development.

As indicated above, the relative significance of prices discovered on an organized market for its underlying cash market is directly related to the extent to which such prices are used in the establishment of transaction prices between commercial entities. As a result of this relationship, the use of a market's prices for price basing, either directly or indirectly, provides observable indicia that the market performs a significant price discovery function that would serve as a basis for such a determination under section 2(h)(4).

B. Proposed Criteria for Making Price Discovery Determination

While the Act authorizes the Commission to make a determination that a section 2(h)(3) market performs a significant price discovery function, it does not define that term or contain criteria to guide that determination. Accordingly, the Commission is proposing to establish the following two alternative criteria for determining that a section 2(h)(3) market performs a significant price discovery function:

(a) Cash market bids, offers or transactions are directly based on or quoted at a differential to the prices generated on the market on a more than occasional basis; or

(b) The market's prices are routinely disseminated in a widely distributed industry publication and are consulted by the industry on a more than occasional basis for pricing cash market transactions.

Under the proposed criteria, a section 2(h)(3) market would be deemed to be performing a significant price discovery function under section 2(h)(4)(D) when a market's prices are used for price basing on a more than occasional basis or are published in a widely distributed industry publication and consulted by the industry on a more than occasional basis for pricing purposes.[12] As

[9] The types of instruments traded on exempt commercial markets vary widely. Some of these instruments, but not all of them, are subject to the Commission's exclusive jurisdiction. The Commission's proposed rules are directed only to those instruments that are traded in reliance on the section 2(h)(3) exemption and are otherwise subject to the Commission's exclusive jurisdiction.

[10] It is this effect that section 2(h)(4) addresses when it provides that information shall be disseminated by an exempt commerciald market when ''the electronic trading facility performs a significant price discovery function for transactions in the cash market for the commodity underlying any agreement, contract or transaction executed.''

[11] If the price information discovered on a market is widely respected in an industry, such recognition by the industry in question may lead to the publication of such information in established industry publications.

[12] The Commission is aware of econometric techniques used by academics to measure the relative contribution to the price discovery process by various financial markets trading similar assets (See, *e.g.*, Hasbrouck, J., *One Security, Many Markets: Determining the Contribution to Price Discovery*, Journal of Finance, 50 P 1175–1199, 1995.). However, the Commission understands that these techniques would require price data for both the exempt commercial market and for the

Continued

discussed above, price basing as described under criterion (a) directly confirms that the prices being generated on the market have significant utility with regard to discovering prices in connection with cash market transactions. Furthermore, publication of a section 2(h)(3) market's prices in a widely distributed industry publication, and industry consulting those prices on a more than occasional basis, confirms that the prices are thought to be sufficiently reliable and acceptable to be considered to be a significant source of price discovery.

In evaluating a section 2(h)(3) market's price discovery role, assessments under criterion (a) would include an analysis of whether cash market participants are quoting bid or offer prices or entering into transactions at prices that are set, either explicitly or implicitly, at a differential to prices established on a section 2(h)(3) market. Cash market prices are set *explicitly* at a differential to the section 2(h)(3) market when, for instance, they are quoted in dollars and cents above or below the reference market's prices. Cash prices are set *implicitly* at a differential to a section 2(h)(3) market's prices when, for instance, they are arrived at after adding to, or subtracting from, the section 2(h)(3) market's price, but then quoted or reported as a flat price.[13] The Commission will also consider whether cash market entities are quoting cash prices based on a section 2(h)(3) market's prices on a more than occasional basis. [14]

With regard to criterion (b), consideration would be given to whether prices established on a section 2(h)(3) market are reported in a widely distributed industry publication, such as Platts Oil Gram, Inside FERC or the Lundberg Survey. In making this determination, the Commission would consider the reputation of the publication within the industry, how frequently it is published and whether the information contained in the publication is consulted by industry participants for pricing cash market transactions on a more than occasional basis.

Under the proposal, an exempt commercial market would be required to notify the Commission when it has reason to believe that one or more of the markets that it is operating in reliance on section 2(h)(3) meet either of the specified criteria.[15] The Commission specifically asks commenters to discuss potential financial costs and legal risks created by the proposed notification requirement. Do the aforementioned factors, specifically, that prices be used on ''more than an occasional basis,'' and that they be ''widely distributed,'' provide enough specificity to enable trading facilities to make a determination regarding notification obligations. If not, what further guidance could be provided that would enable a determination?

Upon receipt of such a filing, the Commission's staff would conduct an assessment of the facility's markets operated in reliance on section 2(h)(3) to identify those markets that perform a significant price discovery function for the associated cash market. The scope of the inquiry conducted by the Commission would vary. In the course of its assessment, Commission staff might contact cash market participants to verify the extent to which they refer to the market for price basing. The assessment might also examine whether the section 2(h)(3) market, although occasionally performing a price discovery function, failed to do so on a more than occasional basis and thus does not perform a significant price discovery function.

If the available information indicates that a market is serving a significant price discovery function for the underlying cash market, the Commission would notify the section 2(h)(3) market that it appears to be performing a significant price discovery function and provide the market with an opportunity for a hearing through the submission of written data, views and arguments. The Commission, after consideration of all relevant information, would issue an order determining whether or not the section 2(h)(3) market serves a significant price discovery function.[16]

C. Information To Be Disseminated by a Price Discovery Market

The Commission has not previously addressed the nature and scope of the information that should be disclosed by a price discovery market subject to section 2(h)(4)(D), other than by incorporating in its rules the Act's requirement that the exempt commercial market disseminate publicly ''price, trading volume and other trading data to the extent appropriate with respect to transactions executed in reliance on the exemption as specified in the order.'' *See* Commission Rule 36.3(c)(2). In determining the nature and scope of the information that should be disclosed under the proposed rules, the Commission has looked to other provisions of the Act that impose public dissemination requirements on other categories of regulated and unregulated markets.

With respect to other markets, sections 5(d)(7) and (8) of the Act require designated contract markets to make available to the public: (i) Information concerning the terms and conditions of the contracts and the mechanisms for executing transactions; and (ii) daily information on settlement prices, volume, open interest, and opening and closing ranges for actively traded contracts. Sections 5a(d)(4) and (5) require registered derivatives transaction execution facilities to disclose publicly: (i) Information concerning contract terms and conditions, trading conventions, mechanisms and practices, financial integrity protections, and other information relevant to participation in trading on the facility; and (ii) if the Commission determines that the

individual transactions in the associated cash market. These transaction prices may not be published or otherwise available (indeed, cash market transaction prices may be proprietary), which would preclude application of these statistical techniques. Moreover, these techniques likely would not be familiar to industry participants and may be costly to perform. For these reasons, the Commission is not proposing to base its criteria on the econometric techniques used in the academic literature.

[13] For example, if crude oil prices were generated on a section 2(h)(3) market, price basing practices that would satisfy criterion (a) would include cases where cash market bids or offers would be explicitly quoted at a differential to the prices generated on that market (*e.g.*, ten cents per barrel above the exempt market's price for crude oil delivered in July). In addition, criterion (a) would encompass cases where cash market bids, offers or transaction prices are quoted as a whole price (*e.g.*, $30/barrel) and such price is calculated implicitly by adding to, or subtracting from, the section 2(h)(3) market's prices a specified price differential (*e.g.*, a $30/barrel quoted price is derived as the sum of a ten-cent per barrel differential plus the exempt market's price of $29.90/barrel).

[14] As in cash markets underlying many established futures markets, the differential for a particular cash market bid, offer or transaction may vary from time to time in response to changes in various factors that affect the relationship between cash market prices and prices discovered on a section 2(h)(3) market.

[15] In addition, the Commission may, at any time, *sua sponte*, conduct an assessment as to whether an exempt market is serving a significant price discovery function for the associated cash market. In this regard, the Commission would consider a number of factors in deciding whether to initiate a review of a market's price discovery function, including whether the market holds itself out as performing a price discovery function for the underlying cash market. To facilitate its review of a market's price discovery function in such cases, the Commission is proposing to require that an electronic trading facility operating in reliance on section 2(h)(3) notify the Commission when the facility commences holding its markets out as serving a price discovery function.

[16] The proposed rules would also provide the market with an opportunity to request at any time that the Commission review the continuing appropriateness of its determination in light of changed facts or circumstances.

contracts perform a significant price discovery function for transactions in the cash market for the commodity underlying the contracts, daily information on settlement prices, volume, open interest, and opening and closing price ranges for contracts traded on the facility. Section 5d(d) requires exempt boards of trade (''EBOTs'') to disseminate publicly on a daily basis information on trading volume, opening and closing ranges, open interest, and other trading data appropriate to the market if the Commission determines that the EBOT is a significant source of price discovery for transactions in the cash market for the commodity underlying the contracts.

As noted, the Act only stipulates that an ECM should make available ''price, trading volume and other trading data to the extent appropriate.'' However, as also noted above, this requirement is unclear as to what precisely is intended to be made available to the public by ECMs, especially with regard to the term ''price.'' Based on the information that is required to be made available by a comparably regulated market, the EBOT, the Commission requests comment on the reasonableness of requiring similar information, including trading activity measures, price information, and certain contextual information. The Commission also requests comment on what contextual information should be made available in order to assure that the public can accurately interpret the meaning of the trading activity and price information.

Specifically, the Commission is requesting comment on a requirement that the ECMs serving a price discovery function publicly disseminate the following information on a daily basis:

Contextual information:

- Contract terms and conditions or product descriptions; and
- Trading conventions, mechanisms, and practices.

Trading activity information:

- Trading volume; and
- Open interest, if available.

Price information:

- Opening and closing prices or price ranges;
- High and low prices;
- A volume-weighted average price; or
- Any other price information approved by the Commission.[17]

The types of contextual, trading activity and price information that the Commission proposes to require to be published potentially would be useful to the price basing process; *i.e.,* this information potentially would be useful for commercial entities that do not participate directly in a market, but use the market's prices as a basis for setting prices for cash market transactions. The reasoning regarding the individual elements of the proposed market information reporting requirements is discussed below.

Contextual information: Information regarding the terms and conditions of the contracts traded on a § 2(h)(3) market and the market's trading rules is necessary to facilitate the public's accurate interpretation of the meaning of data on prices and trading activity reported by markets. This information collectively defines the items being traded on a market as well as a contract's pricing basis and therefore is critical to those who would gather information for purposes of risk management, price basing, or speculation in the market. Ill-defined products and trading conventions will not result in prices with sufficient specificity to be useful for such purposes.

Trading activity: It appears appropriate to require that exempt commercial markets that serve a significant price discovery function disseminate information related to activity in the market, such as daily trading volume data and open interest (if such information is available). In this regard, in futures and option markets, trading activity most often is measured by volume of trading or open interest. Volume of trading, which is required by statute to be provided by exempt commercial markets, is the number of contracts transacted in a commodity in a market over a specified period of time, generally defined as a day. Daily trading volume data provide an indication of the level of past interest in trading in a particular market. Markets with consistently high trading volumes are generally considered to be more liquid[18] than those with lower levels of volume. Thus, the availability of such information, which can serve as a measure of the liquidity of the market on which prices are determined, is important for the interpretation of the reliability of the prices on the market and the general availability of this market statistic is important for an exempt commercial market's continued functioning as a price discovery mechanism.

Open interest is defined as the number of open contracts observed at the close of trading each day. Like trading volume, open interest also is often regarded as an indicator of market liquidity, as higher levels of open interest indicate, in part, traders' confidence that their positions can be readily liquidated without materially affecting the price they receive for such a transaction. Moreover, as noted, imposing a requirement that exempt commercial markets publish open interest data if available,[19] as well as data on trading volume, is consistent with the Act's requirements for EBOTs that are determined by the Commission to be serving a significant price discovery function.

Price information: With regard to price information, both the Act and the logic of price basing require access to price data. Reliable price information is also critical for speculative trading. In considering price-reporting requirements, the Commission has focused on the reporting of delayed price information, rather than real-time price data. In this regard, the Commission notes that the Act does not appear to require publication of real-time price data. The Commission also notes that many exchanges charge fees for real-time market data (usually bids, offers and transaction prices), and that such fees can be an important source of exchange revenues. The exchanges also make certain market summary data freely available to the public on a delayed basis (where the delay can be as little as 10 minutes). This delayed market information generally includes opening and closing prices or price ranges, daily high and low prices, settlement prices, daily trading volume

[17] The section 2(h)(3) market may satisfy the dissemination requirements by placing the information on its website, providing the information to a financial information service, or using a combination of these media. Furthermore, the section 2(h)(3) market may disseminate such additional information as it believes is appropriate for price discovery purposes. A section 2(h)(3) market may also publish all of the information specified in proposed rule 36.3(c)(2)(iv) whether or not the Commission has made a price discovery determination applicable to that market under rule 36.3(c)(2)(iii). Such voluntary dissemination by a section 2(h)(3) market may, in appropriate circumstances, obviate the need for the market to notify the Commission and for the Commission to make a price discovery determination.

[18] Liquidity is a measure of a market's ability to absorb large orders within a short period of time without requiring a substantial change in price. Liquid markets are often described as ''broad'' and/or ''deep,'' whereas illiquid markets re often described as ''thin.'' The liquidity of a market is an indication of the quality or the reliability of the prices determined thereon.

[19] Open interest data generally would be available for markets such as Designated Contract Markets (''DCMs''), which provide an exclusive forum for offset of positions thereon. However, the Commission understands that, unlike positions on a DCM—where contracts entered into on the exchange can only be offset on that exchange—positions established on an ECM can be offset away from the ECM, without the ECM's knowledge. Therefore, it might be impossible for an ECM to maintain accurate open interest data.

and open interest. The Commission interprets the Act as allowing exempt commercial markets to reap gains from the sale of real-time market data, but also to require these markets to publish the required market summary information noted above without charge to the marketplace on a delayed basis.

In view of the different types of exempt markets, the Commission proposes to provide flexibility in regard to the specific price information to be published by section 2(h)(3) markets. Specifically, the Commission proposes to require that markets publish opening and closing prices or price ranges, daily high and low prices, or volume weighted average prices over a period of time that is representative of trading on the market. In addition, on a case-by-case basis, the Commission proposes to permit markets to publish other price information, in lieu of the price measures enumerated above, subject to the Commission's approval.

As noted above, the Act requires that opening and closing price ranges be provided by the Act's other category of exempt market—EBOTs. However, because not all exempt markets will have such information available, as a consequence of the way trading is conducted, the Commission recommends that two alternative price measures, the day's high and low, or the day's volume weighted average price, be provided. Established exchanges commonly publish high and low prices for each trading session. In addition, high and low prices provide useful information regarding the range of daily trading activity. Volume weighted average prices provide a good estimate of the price applicable to most transactions executed on a market during daily trading sessions and, accordingly, may provide a better indication of the representative prices observed in a market on a given day than the other measures noted above. Finally, as noted, the Commission is proposing to give markets the flexibility of publishing alternative price measures, subject to Commission approval, if such measures would provide the public with an adequate indication of the market's daily price levels.

IV. Cost Benefit Analysis

Section 15 of the Act, as amended by section 119 of the CFMA, requires the Commission to consider the costs and benefits of its action before issuing a new regulation or order under the Act. By its terms, section 15(a) does not require the Commission to quantify the costs and benefits of its action or to determine whether the benefits of the action outweigh its costs. Rather, section 15(a) simply requires the Commission to ''consider the costs and benefits'' of the subject rule or order.

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

The proposed price dissemination rules are intended to facilitate the continued performance of an exempt market's price discovery function. As discussed above, this function involves social benefits that extend beyond the market and its users. Moreover, the information that the proposed rules require exempt markets to disseminate is virtually certain to either exist already or be a byproduct of the operation of the market, especially one performing a significant price discovery function. Finally, the Commission is proposing to accept website posting of the required information in satisfaction of the rule, as it currently does for designated contract markets and registered derivatives transaction execution facilities. Because the exempt markets subject to the proposed rule are by definition electronic markets, all of which maintain internet websites, dissemination costs should not be significant.

In formulating the proposed price dissemination rules, the Commission also has taken into consideration that organized markets must produce prices before they can disseminate them. The Commission acknowledges that price discovery, *i.e.*, the production of prices, is a costly activity requiring considerable investment by an organized market. Restrictions on the dissemination of prices discovered on an organized exchange can be viewed as a legitimate means of protecting the exchange's investment in the production of accurate prices. The Commission acknowledges the concerns raised in certain academic studies showing that some forms of mandated price dissemination rules can produce unintended consequences such as: (1) Less accurate prices; (2) higher trading costs; (3) wealth transfers from those who produce prices to those who consume the information contained in prices discovered elsewhere; and (4) wealth transfers from some classes of market participants to others.[20] These studies apply to rules concerning the dissemination of highly valuable real-time prices. Since the proposed rule applies only to the dissemination of less valuable delayed prices, the possibilities of this rule producing significant unintended consequences appear to be low.

The Commission also has considered the costs and benefits of the proposed amendments to regulation 36.3(b)(1), regarding information access, in light of the above-noted specific areas of concern identified in section 15. The Commission intends that the amended rules would impose the minimum requirements necessary to enable it to perform its oversight functions and to carry out its mandate to protect the public interest in markets that are free of fraud, abuse and manipulation.

After considering these factors, the Commission has determined to propose the rules and rule amendments set forth below.

The Commission specifically invites public comment on its application of the criteria contained in the Act for consideration. Commenters are also invited to submit any quantifiable data that they may have concerning the costs and benefits of the proposed rules with their comment letter.

V. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires federal agencies, in promulgating rules, to consider the impact of those rules on small entities. The rules proposed herein would affect exempt commercial markets. The Commission has previously determined that exempt commercial markets are not small entities for purposes of the RFA.[21] Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that the proposed rules will not have a

[20] *See* J. Harold Mulherin, Jeffry Netter, and James A. Overdahl, *Prices are Property: the Organization of Financial Exchanges from a Transaction Cost Perspective*, Journal of Law and Economics 34 (October 1991) 591–644; and J. Harold Mulherin, *Market Transparency: Pros. Cons. and Property Rights*, Journal of Applied Corporate Finance Volume 5 Number 4 (Winter 1993) 94–97.

[21] 66 FR 42256, 42268 (Aug. 10, 2001).

significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), which 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, does not apply to this rule. The proposed rules do not appear to contain information collection requirements that require the approval of the Office of Management and Budget.

List of Subjects in 17 CFR Part 36

Commodity futures, Commodity Futures Trading Commission.

In consideration of the foregoing, and pursuant to the authority in the Commodity Exchange Act and, in particular, sections 2(h)(3)–(5) of the Act, the Commission hereby proposes to amend Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 36—EXEMPT MARKETS

1. The authority citation for part 36 continues to read as follows:

Authority: 7 U.S.C. 2, 6, 6c, and 8a.

2. Section 36.3 is proposed to be amended by revising paragraphs (b)(1)(i) and (ii), by adding new paragraphs (b)(1)(iii) and (iv), by redesignating paragraphs (b)(2) and (b)(3) as paragraphs (b)(3) and (b)(4), by adding a new paragraph (b)(2), by adding a heading to paragraph (c)(1), by revising paragraph (c)(2), and by adding a heading to paragraph (c)(3) to read as follows:

§ 36.3 Exempt commercial markets.

* * * * *

(b) * * *

(1) * * *

(i) Provide the Commission with access to the facility's trading protocols, either electronically or in hard copy form;

(ii) Identify to the Commission those transactions conducted on the facility with respect to which it intends to rely on the exemption in section 2(h)(3) of the Act and, with respect to such transactions, either:

(A) Submit to the Commission, in a form and manner acceptable to the Commission, a report for each business day, showing for each transaction executed on the facility in reliance on the exemption set forth in section 2(h)(3) of the Act the following information: The commodity, the location, the maturity date, whether it is a financially settled or physically delivered instrument, the date of execution, the time of execution, the price, the quantity, and such other information as the Commission may determine, and for an option instrument the type of option (call or put) and the strike price. Each such report shall be electronically transmitted weekly, within such time period as is acceptable to the Commission after the end of the week to which the data applies; or

(B) Provide the Commission, in a form and manner acceptable to the Commission, with electronic access to those transactions conducted on the facility in reliance on the exemption in section 2(h)(3) of the Act, which access would allow the Commission to compile the information described in paragraph (b)(1)(ii)(A) of this section and create a permanent record thereof;

(iii) Maintain a record of allegations or complaints received by the trading facility concerning instances of suspected fraud or manipulation in trading activity conducted in reliance on the exemption set forth in section 2(h)(3) of the Act. The record shall contain the name of the complainant, if provided, the date of the complaint, the market instrument, the substance of the allegations, and the name of the person at the trading facility who received the complaint; and

(iv) Provide to the Commission, either electronically or in hard copy form, a copy of the record of each substantive complaint received pursuant to paragraph (b)(1)(iii) of this section no later than three business days after the complaint is received.

(2) The Commission hereby delegates, until the Commission orders otherwise, the authority to determine the form and manner of submitting reports, the time within which such reports shall be filed, and the form and manner of providing electronic access, under paragraph (b)(1) of this section, to the Director of the Division of Market Oversight and such members of the Commission's staff as the Director may designate. The Director may submit to the Commission for its consideration any matter that has been delegated by this paragraph. Nothing in this paragraph prohibits the Commission, at its election, from exercising the authority delegated in this paragraph.

* * * * *

(c) * * *

(1) *Prohibited representation.* * * *

(2) *Market data dissemination.* (i) *Criteria for price discovery determination.* An electronic trading facility operating in reliance on the exemption in section 2(h)(3) of the Act performs a significant price discovery function for transactions in the cash market for a commodity underlying any agreement, contract, or transaction executed or traded on the electronic trading facility when:

(A) Cash market bids, offers or transactions are directly based on, or quoted at a differential to, the prices generated on the market on a more than occasional basis; or

(B) The market's prices are routinely disseminated in a widely distributed industry publication and are consulted by the industry on a more than occasional basis for pricing cash market transactions.

(ii) *Notification.* An electronic trading facility operating in reliance on section 2(h)(3) of the Act shall notify the Commission when it has reason to believe that:

(A) Cash market bids, offers or transactions are directly based on, or quoted at a differential to, the prices generated on the market on a more than occasional basis;

(B) The market's prices are routinely disseminated in a widely distributed industry publication; or

(C) The market holds itself out to the public as performing a price discovery function for the cash market for the commodity.

(iii) *Price discovery determination.* Following receipt of a notice under paragraph (c)(2)(ii) of this section, or on its own initiative, the Commission may notify an electronic trading facility operating in reliance on section 2(h)(3) of the Act that the trading facility appears to meet the criteria for performing a significant price discovery function under paragraph (c)(2)(i)(A) or (B) of this section. Before making a final price discovery determination under this paragraph, the Commission shall provide the electronic trading facility with an opportunity for a hearing through the submission of written data, views and arguments. Any such written data, views and arguments shall be filed with the Secretary of the Commission in the form and manner and within the time specified by the Commission. After consideration of all relevant matters, the Commission shall issue an order containing its determination whether the electronic trading facility performs a significant price discovery function under the criteria of paragraph (c)(2)(i)(A) or (B) of this section.

(iv) *Price dissemination.* An electronic trading facility that the Commission has determined performs a significant price discovery function under paragraph (c)(2)(iii) of this paragraph shall disseminate publicly and on a daily basis all of the following

information with respect to transactions executed in reliance on the exemption:

(A) Contract terms and conditions, or a product description, and trading conventions, mechanisms and practices;

(B) Trading volume by commodity and, if available, open interest; and

(C) The opening and closing prices or price ranges, the daily high and low prices, a volume-weighted average price that is representative of trading on the market, or such other daily price information as proposed by the facility and approved by the Commission.

(v) *Modification of price discovery determination.* A trading facility that the Commission has determined performs a significant price discovery function under paragraph (c)(2)(iii) of this section may petition the Commission at any time to modify or vacate that determination. The petition shall contain an appropriate justification for the request. The Commission, after notice and opportunity for a hearing through the submission of written data, views and arguments, shall grant, grant subject to conditions, or deny such request.

(3) *Required representation.* * * *

Issued in Washington, DC, on November 20, 2003, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 03–29437 Filed 11–24–03; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2003N–0496]

RIN 0910–AF09

Food Labeling: Health Claims; Dietary Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also is soliciting comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional food and dietary supplement labels. Comments on the regulatory alternatives and the additional topics will inform FDA's rulemaking to establish regulations for qualified health claims, as well as any policy initiative(s) that FDA may undertake to provide information to consumers to help them make wise food choices.

DATES: Submit written or electronic comments by January 26, 2004.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Paulette Gaynor, Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

The Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535)[1] directed FDA to issue regulations authorizing health claims (i.e., labeling claims that characterize the relationship of a substance to a disease or health-related condition) only if the agency determines, based upon the totality of publicly available scientific evidence (including evidence from well designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement (SSA), among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence (21 U.S.C. 343(r)(3)(B)(i)). Congress delegated to FDA the authority to establish the procedure and standard for health claims for dietary supplements (21 U.S.C. 343(r)(5)(D)). In accordance with the NLEA, FDA issued regulations establishing general requirements for health claims in labeling for conventional foods (58 FR 2478, January 6, 1993). By regulation (59 FR 395, January 4, 1994), and under Congressional authority[2], FDA adopted the same general requirements, including the procedure and standard, for health claims in dietary supplement labeling that Congress had prescribed in the NLEA for health claims in the labeling of conventional foods. (See 21 U.S.C. 343(r)(3) and (r)(4).)

The procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling (§ 101.14(d) and (e) and 101.70) (21 CFR 101.14(d) and (e), 101.70)). The standard requires a finding of ''significant scientific agreement'' (SSA) before FDA may authorize a health claim by regulation (§ 101.14(c)). FDA's current regulations, which mirror the statutory language in 21 U.S.C. 343(r)(3)(B)(i), provide that this standard is met only if FDA determines that there is SSA, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles (§§ 101.14(c) and 101.70(f)).

Among its provisions regulating claims, the NLEA required FDA to determine whether claims respecting 10 specific substance/disease relationships met the requirements for a health claim (NLEA section 3(b)(1)(A)(vi) and (x), Pub. L. 101–535). FDA conducted these statutorily required analyses. Not all relationships that Congress required the agency to consider were found to meet the standard of SSA, and, so, not all were authorized by FDA. Some of the substance/disease relationships that were found to lack SSA became the subject of a lawsuit, *Pearson* v. *Shalala* (*Pearson*), brought by dietary supplement marketers and health advocacy organizations.

In *Pearson*, the plaintiffs challenged FDA's general health claims regulations for dietary supplements and FDA's decision not to authorize health claims for four specific substance/disease relationships. Although the U.S. District Court for the District of Columbia initially ruled in favor of FDA (14 F. Supp. 2d 10 (D.D.C. 1998)), the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision (*Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999)).[3] The appeals court held

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[1] The NLEA authorized health claims in food labeling by amending the Federal Food, Drug, and Cosmetic Act (the act) to add section 403(r) to the act (21 U.S.C. 343(r)). This section specifies, in part, that a food is misbranded if it bears a claim that expressly or by implication characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) (for conventional foods) or 403(r)(5)(D) (for dietary supplements).

[2] FDA issued regulations establishing general requirements for health claims in dietary supplement labeling (59 FR 395) under the NLEA and the Dietary Supplement Act of 1992 (Public Law 102–571).

[3] The appellate court decided the case on January 15, 1999. On March 1, 1999, the Government filed a petition for rehearing en banc. The U.S. Court of Appeals for the D.C. Circuit denied the petition for