N., long. 94°09′52″ W.; to the point of beginning.

Designated altitudes. 13,000 feet MSL to, but not including, FL 220.

Time of designation. Sunrise to sunset, daily; other times by NOTAM.

Controlling agency. FAA, Memphis ARTCC.

Using agency. Arkansas Air National Guard, 188th Fighter Wing, Ft. Smith, AR.

Issued in Washington, DC, on March 19, 2010.

Edith V. Parish,

Manager, Airspace and Rules Group.

[FR Doc. 2010–7075 Filed 3–29–10; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 38 and 140

RIN 3038—AC68

Delegations of Authority To Disclose Confidential Information

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") is proposing to amend its regulations governing delegations of authority to disclose confidential information to permit CFTC staff to provide confidential information to "registered entities," including exempt commercial markets offering significant price discovery contracts, and to require that registered entities update their lists of confidential data recipients on an annual basis. The Commission's proposal would also clarify that confidential information provided by the Commission to registered entities may only be used for market surveillance, audit, investigative or rule enforcement purposes and would remove the requirement that disclosures of confidential information to foreign government agencies and foreign futures authorities require the concurrence of the Commission's Division of Enforcement. Finally, the proposal would make certain other technical and conforming amendments to the Commission's rules.

DATES: Comments must be received by April 29, 2010.

ADDRESSES: Comments should be submitted to David Stawick, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Comments also may be sent by facsimile to (202) 418–5521, or by e-mail to *confidentialinforules@cftc.gov.* Reference should be made to "Delegations of Authority to Disclose Confidential Information." Comments may also be submitted through the Federal eRulemaking Portal at *http://www.regulations.gov.* All comments must be in English.

FOR FURTHER INFORMATION CONTACT: Donald Heitman, Senior Special Counsel, Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone: (202) 418–5041. E-mail: *dheitman@cftc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. The Commodity Exchange Act's Confidentiality Provisions

Section 8(a) of the Commodity Exchange Act ("CEA" or "Act") prohibits the Commission from disclosing information that would separately disclose the business transactions or market positions of any person or trade secrets or names of customers.[1] Despite this general prohibition, the CEA recognizes the need to share confidential information with registered entities and certain other self-regulatory bodies under specified circumstances. Section 8a(6) of the Act therefore authorizes the Commission to communicate to the proper officials of "registered entities" [2] and other self-regulatory bodies [3] the full facts regarding a particular transaction or market operation, "which in the judgment of the Commission disrupts or tends to disrupt any market or is otherwise harmful or against the best interests of producers, consumers, or investors, or which is necessary or appropriate to effectuate the purposes of [the] Act." Disclosure under this provision is subject to the caveat that information furnished by the Commission may not be disclosed by the receiving registered entity, registered futures association or self-regulatory organization except in a self-regulatory action or proceeding.

Commission regulation 140.72 implements these statutory provisions, delegates to specified senior staff the authority to make disclosures to "a contract market, registered futures association or self-regulatory organization," and establishes the standards and protocols governing such disclosures. However, regulation 140.72 has never been amended to replace the reference to "contract market" with a reference to the more inclusive defined term, "registered entity," which includes not only designated contract markets, but several other types of entities as well (*see* note 2 above). The term, "registered entity," was added to the Act by the Commodity Futures Modernization Act of 2000 ("CFMA").[4] The registered entity definition was subsequently expanded by the CFTC Reauthorization Act of 2008 ("2008 Reauthorization Act"),[5] which incorporated electronic trading facilities trading significant price discovery contracts into the registered entity definition as section 1a(29)(E).

The CEA also recognizes the need to share confidential information with other Federal or state regulatory authorities, acting within the scope of their jurisdiction, as well as foreign futures authorities, and in section 8(e) authorizes the Commission to make such disclosures on request, provided the Commission is satisfied that the information will not be disclosed except in connection with an action or proceeding brought under the laws governing the receiving authority, to which that receiving authority is a party. Commission regulation 140.73 implements the provisions of CEA section 8(e), delegates to specified senior staff the authority to make disclosures and establishes the standards and protocols governing disclosure to a requesting regulator.

As discussed below, the principal amendments to regulation 140.72 are being proposed: (1) To conform the Commission's rule to the CEA, as amended by the CFMA and the 2008 Reauthorization Act, by applying the regulation to "registered entities;" (2) to require that registered entities update their lists of confidential data recipients on an annual basis and notify the Commission within 10 business days of any changes to the list; and (3) to clarify that confidential information provided by the Commission to registered entities

[1] 7 U.S.C. 12(a).

[2] Section 1a(29) of the Act defines the term registered entity to mean: "(A) a board of trade designated as a contract market under section 5; (B) a derivatives transaction execution facility registered under section 5a; (C) a derivatives clearing organization registered under section 5b; (D) a board of trade designated as a contract market under section 5f; and (E) with respect to a contract that the Commission determines is a significant price discovery contract, any electronic trading facility on which the contract is executed or traded."

[3] In addition to "registered entities," the Commission is authorized to share confidential information with registered futures associations (*see* section 17 of the Act, 7 U.S.C. 21) and self-regulatory organizations as defined in section 3(a)(26) of the Securities Exchange Act of 1934. 7 U.S.C. 12a(6).

[4] Public Law 106–554, 114 Stat. 2763 (2000).

[5] Incorporated as Title XIII of the Food, Conservation and Energy Act of 2008, Public Law 110–246, 122 Stat. 1624 (June 18, 2008).

may only be used for market surveillance, audit, investigative or rule enforcement responsibilities of the registered entity. The Commission additionally is proposing technical amendments to both regulations 140.72 and 140.73.

B. Part 38 of the Commission's Regulations

As noted above, by its terms, regulation 140.72 includes procedural requirements for DCMs that relate to the receipt and use of information furnished by the CFTC.[6] As a result of the passage of the CFMA, the Commission adopted regulations that exempted DCMs from all Commission regulations that were not specifically reserved in regulation 38.2. Regulation 140.72 was not specifically reserved in regulation 38.2. The Commission, however, believes that regulation 140.72 (both in its current form and as proposed to be amended herein) contains procedural safeguards that are intended to protect furnished information from improper use and disclosure. In that regard, the Commission attaches particular importance to the requirement that registered entities (including DCMs) must formally identify the officials within the organization who are specifically authorized to receive information from Commission staff and update that contact information annually. The Commission therefore proposes to add regulation 140.72 to the list of regulations reserved in regulation 38.2.

II. Discussion

A. Amendments Necessitated by the CFMA and the CFTC Reauthorization Act of 2008

The 2008 Reauthorization Act directs the CFTC to extend its regulatory oversight to the trading of significant price discovery contracts ("SPDCs") on exempt commercial markets ("ECMs") and, among other statutory amendments, adds ECMs with SPDCs to the definition of "registered entity" in section 1(a)(29) of the CEA.[7] Accordingly, with respect to a contract that the Commission determines is a SPDC, the ECM on which it is traded or executed becomes a registered entity subject to all the provisions of the CEA applicable to registered entities—including section 8a(6) of the Act. Consistent with this statutory change, the proposed amendments to regulation 140.72 would make its provisions applicable to "registered entities" and would permit staff to disclose confidential information to ECMs insofar as the disclosures relate to the ECM's SPDCs.

Regulation 140.72(b) provides that disclosures shall only be made to a contract market, registered futures association or self-regulatory organization official who is named in a list filed with the Commission by the chief executive officer of the entity. By amending paragraph (b) to refer to "registered entities" (instead of "contract markets") the proposed amendments would apply the disclosure rules to all such registered entities, including, among others, derivatives clearing organizations ("DCOs") and ECMs with respect to their SPDCs. Thus, for example, all registered entities would be required to provide to the Commission a list of officials within their organization authorized to receive disclosures of confidential information. The proposed rules would also require that the lists of officials authorized to receive disclosures must be updated annually. Finally, the proposed amendments would clarify that the chief executive officer of the registered entity must notify the Commission within ten business days of any additions or deletions to the list.

B. Amendments Regarding the Use of Confidential Information

Recently, questions have arisen regarding the potential use of confidential information provided by the Commission to DCMs. In particular, DCM officials have inquired as to whether they might be allowed to use that information to assess the current composition of a given market with an eye to developing additional types of contracts. Consistent with the Section 8a(6), these proposed rules clarify that confidential information provided by the Commission to registered entities (including DCMs) can only be used for their market surveillance, audit, investigative or rule enforcement responsibilities, which do not include business development purposes. The Commission solicits comments regarding whether similar restrictions should be applied to confidential information generated internally by a registered entity.[8] In addition, registered entities should review their procedures for the handling of confidential information from the Commission to ensure that persons handling such information are properly "walled off" from the rest of the organization.

C. Technical and Conforming Amendments

Regulations 140.72(a) and 140.73(a) currently list, by title, a large number of senior staff members to whom the Commission delegates authority to disclose confidential information to the various regulatory and self-regulatory authorities listed in those respective regulations. Many of these titles have been rendered obsolete by subsequent CFTC organizational changes. In order to simplify the regulations and minimize the need for further regulatory amendments to conform to future organizational changes, the proposed regulations would delegate the authority to disclose confidential information to the heads of the major Commission Divisions or Offices involved and give those individuals the authority to sub-delegate that authority to such other employees of their respective Divisions or Offices as they may designate from time to time.

As noted above, regulation 140.73 delegates to specified senior staff the authority to disclose confidential information to United States, state and foreign government agencies and to foreign futures authorities. Regulation 140.73(b) currently requires that disclosures made pursuant to this section must be made with the concurrence of the Director of the Division of Enforcement or his or her designee. For efficiency, the Commission proposes to delete paragraph (b) of regulation 140.73.

The CFMA added a number of new definitions to section 1a of the CEA. As a result, the definition of "foreign futures authority," formerly found in section 1a(10) of the CEA, has been renumbered as section 1(a)(18). The Commission proposes a conforming amendment to regulation 140.73(a)(3),

[6] The amendments proposed herein would not alter those requirements since the amendments would replace the term, "contract market," with the term, "registered entity," which by definition includes contract markets.

[7] As noted above, the 2008 Reauthorization Act added the following provision to section 1(a)(29)'s definition of registered entity: "(E) with respect to a contract that the Commission determines is a significant price discovery contract, any electronic trading facility on which the contract is executed or traded." 7 U.S.C. 1(a)(29)(E).

[8] For example, Part 17 of the Commission's regulations requires that clearing members, FCMs, and foreign brokers file daily large trader reports with the Commission. The Kansas City Board of Trade (KCBT) and the Minneapolis Grain Exchange (MGX) rely on receiving daily transmissions of large trader reports from the Commission for monitoring speculative position limits and reportable positions. The remaining DCMs have adopted their own large trader reporting rules and independently collect large trader reports. Under this proposed rule, KCBT and MGX would be prohibited from using the confidential large trader reports they receive from the Commission for anything other than market surveillance, audit, investigative or rule enforcement purposes. DCMs that independently collect large trader reports would not be subject to the same prohibitions because they do not receive the data from the Commission.

which is applicable to foreign futures authorities, to correctly identify the definitional section.

III. Related Matters

A. Cost Benefit Analysis

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before issuing new regulations under the Act. Section 15(a) does not require the Commission to quantify the costs and benefits of new regulations or to determine whether the benefits of adopted regulations outweigh their costs. Rather, section 15(a) requires the Commission to consider the costs and benefits of the subject regulations 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 the market for listed derivatives; (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, not withstanding its costs, a particular regulation is necessary or appropriate to protect the public interest.

As relevant here, the proposed amendments would extend the information-sharing provisions of regulation 140.72 to registered entities, including DCOs and exempt commercial markets with respect to their SPDCs, among others. The authority and benefits of the provisions regarding disclosure of confidential information derive from a determination that the transaction or market operation to be disclosed disrupts or tends to disrupt any market; or is otherwise harmful or against the best interests of producers, consumers, or investors; or that disclosure is necessary or appropriate to effectuate the purposes of the CEA. The other proposed amendments would clarify, consistent with the language of Section 8a(6) and regulation 140.72(d), that registered entities could only use the information for their market surveillance, audit, investigative or rule enforcement responsibilities and would enhance the reliability of the disclosure system by requiring registered entities to update their lists of confidential data recipients on an annual basis and to notify the Commission of any changes to such lists in a timely fashion. The costs associated with these proposed amendments are minimal. Extending the regulations' confidential disclosure requirements to registered entities, including ECMs with SPDCs, while clarifying the confidentiality protections and improving the reliability of the disclosure system, enhances the Commission's ability to prevent market disruptions and protect the interests of producers, consumers and the public.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601 *et seq.,* requires that agencies, in proposing rules, consider the impact of those rules on small entities. These amendments would extend CFTC staff's ability to share relevant information with additional registered entities, including ECMs with SPDCs, would further protect the confidentiality of disclosed information by requiring that registered entities could only use the information for their market surveillance, audit, investigative or rule enforcement responsibilities and would enhance the reliability of the disclosure system by requiring registered entities to update their lists of confidential data recipients on an annual basis. The proposed rules otherwise would make technical and conforming changes to rules 140.72 and 140.73. The Commission has previously determined that DCMs, derivatives transaction execution facilities ("DTEFs"), ECMs (with or without SPDCs) and DCOs are not small entities for purposes of the RFA.[9] Similarly, the Commission believes that the other type of registered entity listed in section 1a(29) of the Act, a board of trade designated as a contract market under section 5f,[10] is likewise not a small entity for purposes of the RFA. Accordingly, the Commission does not expect that these amendments will have a significant impact on a substantial number of small entities. For this reason, and pursuant to section 3(a) of the RFA, 5 U.S.C. 605(b), the Chairman, on behalf of the Commission, hereby certifies that these regulations will not have a significant economic impact on a substantial number of small entities. Nevertheless, the Commission solicits public comments as to whether a DTEF, a DCM designated under section 5f of the Act or an ECM with a SPDC should be considered a small entity for purposes of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 ("PRA"), 44 U.S.C. 3501 *et seq.,* imposes certain requirements on Federal agencies, including the Commission, in connection with conducting or sponsoring any collection of information as defined by the PRA. Rules 140.72 and 140.73 are not associated with an information collection as defined by the PRA. Accordingly, the Commission certifies that, for purposes of the PRA, these proposed amendments would not impose any new reporting or recordkeeping requirements.

List of Subjects

17 CFR Part 38

Block transactions, Commodity futures, Contract markets, Transactions off the centralized market, Reporting and recordkeeping requirements.

17 CFR Part 140

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

Accordingly, the Commission proposes to amend 17 CFR parts 38 and 140 as follows:

PART 38—DESIGNATED CONTRACT MARKETS

1. The authority citation for part 38 is revised to read as follows:

Authority: 7 U.S.C. 2, 5, 6, 6c, 7, and 12a, as amended by the Commodity Futures Modernization Act of 2000, Appendix E of Pub. L. 106–554, 114 Stat. 2763 (2000).

2. Section 38.2 is revised to read as follows:

§ 38.2 Exemption.

Agreements, contracts, or transactions traded on a designated contract market under Section 5 of the Act, the contract market and the contract market's operator are exempt from all Commission regulations for such activity, except for the requirements of this Part 38 and §§ 1.3, 1.12(e), 1.31, 1.37(c)–(d), 1.38, 1.52, 1.59(d), 1.60, 1.63(c), 1.67, 33.10, Part 9, Parts 15 through 21, Part 40, Part 41, § 140.72 and Part 190 of this chapter, including any related definitions and cross-referenced sections.

PART 140—ORGANIZATION, FUNCTIONS AND PROCEDURES OF THE COMMISSION

3. The authority citation for part 140 conitnues to read as follows:

Authority: 7 U.S.C. 2 and 12a.

4. Section 140.72 is revised to read as follows:

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[9] *See:* 47 FR 18618 at 18619 (April 30, 1982) with respect to DCMs; 66 FR 42255 at 42268 (August 10, 2001) with respect to DTEFs and ECMs; and 66 FR 45604 at 45609 (August 29, 2001) with respect to DCOs.

[10] Section 5f deals with "Designation of Securities Exchanges and Associations as Contract Markets."

§ 140.72 Delegation of authority to disclose confidential information to a registered entity, registered futures association or self-regulatory organization.

(a) Pursuant to the authority granted under sections 2(a)(12), 8a(5) and 8a(6) of the Act, the Commission hereby delegates, until such time as the Commission orders otherwise, to the Director of the Division of Market Oversight, the Director of the Division of Clearing and Intermediary Oversight, the Director of the Division of Enforcement, the General Counsel, the Chief Economist and the Director of the Office of International Affairs, and to such other employees of their respective Divisions and Offices as they may designate from time to time, the authority to disclose to an official of any registered entity (as defined in section 1a(29) of the Act), registered futures association, or self-regulatory organization as defined in section 3(a)(26) of the Securities Exchange Act of 1934, any information necessary or appropriate to effectuate the purposes of the Act, including, but not limited to, the full facts concerning any transaction or market operation, including the names of the parties thereto. This authority to disclose shall be based on a determination that the transaction or market operation disrupts or tends to disrupt any market or is otherwise harmful or against the best interests of producers, consumers, or investors or that disclosure is necessary or appropriate to effectuate the purposes of the Act. The authority to make such a determination is also delegated by the Commission to the Commission employees identified in this section. A Commission employee delegated authority under this section may exercise that authority on his or her own initiative or in response to a request by an official of a registered entity, registered futures association or self-regulatory organization.

(b) Disclosure under this section shall only be made to a registered entity, registered futures association or self-regulatory organization official who is named in a list filed with the Commission by the chief executive officer of the registered entity, registered futures association or self-regulatory organization, which sets forth the official's name, business address and telephone number. The chief executive officer shall provide the Commission with an updated list annually, during the first month of the calendar year, and shall thereafter notify the Commission within 10 business days of any deletions or additions to the list of officials authorized to receive disclosures under this section. The original list, each annual update, and any supplemental list required by his paragraph shall be filed with the Secretary of the Commission, and a copy thereof shall also be filed with the Regional Administrator for the region in which the registered entity is located or in which the registered futures association or self-regulatory organization has its principal office.

(c) Notwithstanding the provisions of paragraph (a) of this section, in any case in which a Commission employee delegated authority under this section believes it appropriate, he or she may submit to the Commission for its consideration the question of whether disclosure of information should be made. Nothing in this section shall prevent the Commission from exercising the authority delegated in paragraph (a) of this section.

(d) For purposes of this section, the term "official" shall mean any officer or member of the staff, management or a committee of a registered entity, registered futures association or self-regulatory organization who is specifically charged with market surveillance, audit, investigative or rule enforcement responsibilities, or their duly authorized representative or agent, who is named on the list filed pursuant to paragraph (b) of this section or any supplement thereto.

(e) For the purposes of this section, the term "self-regulatory organization" shall mean the same as that defined in section 3(a)(26) of the Securities Exchange Act of 1934.

(f) Any registered entity, registered futures association or self-regulatory organization receiving information from the Commission under these provisions may use such information only for its market surveillance, audit, investigative or rule enforcement responsibilities and shall not disclose such information, except that disclosure may be made in any self-regulatory action or proceeding.

5. Section 140.73 is revised to read as follows:

§ 140.73 Delegation of authority to disclose information to United States, State, and foreign government agencies and foreign futures authorities.

(a) Pursuant to sections 2(a)(12), 8a(5) and 8(e) of the Act, the Commission hereby delegates, until such time as the Commission orders otherwise, to the General Counsel, the Director of the Division of Enforcement, the Director of the Division of Market Oversight, the Director of the Division of Clearing and Intermediary Oversight, the Chief Economist and the Director of the Office of International Affairs, and to such other employees of their respective Divisions and Offices as they may designate from time to time, the authority to furnish information in the possession of the Commission obtained in connection with the administration of the Act, upon written request, to:

(1) Any department or agency of the United States, including for this purpose an independent regulatory agency, acting within the scope of its jurisdiction;

(2) Any department or agency of any State or any political subdivision thereof, acting within the scope of its jurisdiction; or

(3) Any foreign futures authority, as that term is defined in section 1a(18) of the Act, or any department or agency of any foreign government or political subdivision thereof, acting within the scope of its jurisdiction, provided that the Commission official making the disclosure is satisfied that the information will not be disclosed except in connection with an adjudicatory action or proceeding brought under the laws of such foreign government or political subdivision to which such foreign government or political subdivision or any department or agency thereof, or foreign futures authority is a party.

(b) In furnishing information under this delegation pursuant to paragraphs (a)(1) and (2) of this section, the Commission official making the disclosure shall remind the department or agency involved that section 8(e) of the Act prohibits the disclosure by such department or agency of information that would separately disclose the business transactions or market positions of any person and trade secrets or names of customers except in an action or proceeding under the laws of the United States, the State, or a political subdivision thereof to which the department or the agency of either the state or political subdivision, the Commission, or the United States is a party.

(c) This delegation shall not affect any other delegation that the Commission has made or may make, which authorizes any other officer or employee of the Commission to furnish information to governmental bodies on the Commission's behalf.

(d) Notwithstanding the provisions of paragraph (a) of this section, in any case in which any employee delegated authority therein believes it appropriate, the matter may be submitted to the Commission for its consideration. Nothing in this section shall prohibit the Commission from exercising the authority delegated in paragraph (a) of this section.

Issued in Washington, DC, on March 22, 2010, by the Commission.

David A. Stawick,

Secretary of the Commission.

[FR Doc. 2010–6813 Filed 3–29–10; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. FDA–2010–N–0099]

RIN 0910–AG15

Revision of the Requirements for Constituent Materials

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations to permit the Director of the Center for Biologics Evaluation and Research (CBER) or the Director of the Center for Drug Evaluation and Research (CDER), as appropriate, to approve exceptions or alternatives to the regulation for constituent materials. FDA is taking this action due to advances in developing and manufacturing safe, pure, and potent biological products licensed under a section of the Public Health Service Act (the PHS Act) that, in some instances, render the existing constituent materials regulation too prescriptive and unnecessarily restrictive. This rule provides manufacturers of licensed biological products with flexibility, as appropriate, to employ advances in science and technology as they become available, without diminishing public health protections.

DATES: Submit electronic or written comments on the proposed rule on or before June 28, 2010. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by April 29, 2010, (see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0099 and/or RIN number 0910–AG15, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Information Collection Provision: The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax comments regarding information collection by April 29, 2010, to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

Constituent materials regulated under § 610.15 (21 CFR 610.15) include ingredients, preservatives, diluents, adjuvants, extraneous protein and antibiotics that are contained in a biological product. FDA is proposing to amend the regulation for constituent materials at § 610.15 to allow the Director of CBER or the Director of CDER, as appropriate, to approve an exception or alternative to the requirements under § 610.15, when data submitted with the exception or alternative establish the safety, purity, and potency of the biological product. This proposed rule provides manufacturers of biological products with flexibility, as appropriate, to employ advances in science and technology as they become available, without diminishing public health protections. Examples of how the proposed rule would provide flexibility to manufacturers in the use of preservatives and aluminum in biological products are provided below. However, the proposed rule would also provide flexibility to the existing requirements regarding extraneous protein and antibiotics (§ 610.15(b) and (c)), provided that each request for an alternative or exception to these requirements is submitted with data that establish the safety, purity, and potency of the biological product.

Standards for certain constituent materials present in biological products are provided under § 610.15. Section 610.15(a) requires that all ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, meet generally accepted standards of purity and quality. Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, and in the combination used it shall not denature the specific substances in the product to result in a decrease below the minimum acceptable potency within the dating period when stored at the recommended temperature. Products in multiple-dose containers shall contain a preservative, except that a preservative need not be added to Yellow Fever Vaccine; Poliovirus Vaccine Live Oral; viral vaccines labeled for use with the jet injector; dried vaccines when the accompanying diluent contains a preservative; or to an Allergenic Product in 50 percent or more volume in volume glycerin. An adjuvant shall not be introduced into a product unless there is satisfactory evidence that it does not affect adversely the safety or potency of the product.

These regulations also require that the amount of aluminum in the recommended individual dose of a biological product not exceed the following: