

Rules and Regulations

Federal Register

Vol. 78, No. 38

Tuesday, February 26, 2013

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COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 10, 12 and 171

Proceedings Before the Commodity Futures Trading Commission

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (“Commission”) is amending its Rules of Practice, Rules Relating to Reparation Proceedings, and its Rules Relating to Review of National Futures Association (“NFA”) Decisions in Disciplinary, Membership Denial, Registration and Membership Responsibility Actions, to simplify and clarify service, filing and formatting requirements, particularly those requirements applicable to electronic service and filing. The Commission is also amending its Rules Relating to Reparations Proceedings to clarify the authority of its Judgment Officers.

DATES: Effective February 26, 2013.

FOR FURTHER INFORMATION CONTACT: Jason Gizzarelli, Director, Office of Proceedings, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581. Telephone: (202) 418-5395.

SUPPLEMENTARY INFORMATION: In 2008, the Commission amended its rules to allow for service via electronic mail (“email”) for 17 CFR parts 10 and 12, and via facsimile (“fax”) for Part 12 (service by fax under Part 10 had been permitted by the Commission since 1998.) At that time, the Commission approved these additional means of service to take advantage of technological developments that would be faster and less costly than regular mail. Today, the Commission has amended 17 CFR Parts 10, 12 and 171 to simplify and refine the rules for

service, filing and formatting. Additionally, the Commission has amended 17 CFR Parts 10 and 12 to clarify the role and authority of its Judgment Officers. The Commission believes these rule amendments will increase efficiencies and lower costs for parties and for the Commission in administrative enforcement proceedings, in reparations proceedings, and in the appellate review of NFA decisions. Also, the Commission has designed the amendments to the reparations rules to make the reparations forum less legalistic and more user-friendly for *pro se* parties.

Confirmation of Service

To ease the burden on parties in reparations cases, many of whom appear *pro se*, the amended rules drop the requirement of a formal affidavit of service and now require parties to submit a signed “statement of service” that: (1) Confirms that service has been made; (2) identifies each person served; (3) sets forth the date of service; and (4) recites the manner of service. The less formal and less burdensome statement of service effectively serves the same purpose as an affidavit of service: promoting and assuring the full exchange of information among the parties by requiring service of submissions on all of the parties in the proceeding. A corresponding change has been made to the 17 CFR Part 10 rules regarding confirmation of service.

Electronic Service

The amendments to the service rules in 17 CFR parts 10 and 12 reflect the Commission’s experience with electronic filing since 2008, which generally has been positive. First, the amendments specifically provide that a party who consents to service by email must specify the email address to be used. Consent is required because it is not yet possible to assume universal access to electronic communication. Second, under these amendments, actual notice that an email or fax transmission was not received will defeat the presumption of receipt that service is complete on transmission and will compel the sender to take additional steps to affect service. Finally, consistent with 17 CFR 12.1(a), which provides that the reparations rules “shall be construed liberally so as to secure the just, speedy and

inexpensive determination of the issues,” the Commission expects that as electronic technology continues to advance, its Proceedings Clerk and its presiding officials will provide guidance to parties on standards governing such technical specifications as data formatting, speed of transmission, means to transmit attachments, and security of communication.

Filing and Formatting

The amended rules simplify and harmonize the filing and formatting requirements contained in 17 CFR parts 10 and 12. First, the amended rules provide that parties filing by personal delivery, mail or commercial delivery service are no longer required to file any copies of an original. Second, the amended rules explicitly provide that parties filing electronically should not also send paper copies of the same documents to the Proceedings Clerk. Third, the amended rules reduce the maximum length of briefs in administrative proceedings from 60 to 50 pages and in reparations proceedings from 35 to 25 pages. Fourth, the amended rules simplify the formatting of filed documents, such as font size, spacing and related issues. Fifth, the amendments clarify that documents that are delivered in person, or delivered by first-class mail, by a more expeditious form of United States mail, or by overnight or similar commercial delivery service will be considered timely filed if they are delivered in person or mailed to the Proceedings Clerk within the time prescribed for filing. Finally, the Commission is also amending 17 CFR 171.8 to allow filing and service by fax and email.

Judgment Officer

On October 12, 2011, to promote the efficient use of the Commission’s budget and personnel resources, the Commission amended 17 CFR part 12 to authorize its Judgment Officers to conduct formal decisional proceedings. The new 17 CFR part 12 amendments issued today conform the definition of “Judgment Officer” to the authority of Judgment Officers to conduct formal decisional proceedings. These new amendments also provide that Judgment Officers may conduct *sua sponte* discovery in voluntary decisional proceedings, as they can in summary and formal decisional proceedings. This

amendment will help ensure that the evidentiary record is adequately developed in voluntary decisional proceedings.

The amendment to 17 CFR 10.8, which authorizes the Commission to appoint a Presiding Officer other than an administrative law judge (“ALJ”) to conduct proceedings within the scope of 17 CFR part 10, unless some other provision of law requires the use of an ALJ in a particular category of proceeding,¹ clarifies that Presiding Officers who are not ALJs can carry out the same functions as ALJs in certain proceedings to deny, condition, suspend, revoke or place restrictions on registration. Registration-related proceedings are subject to procedural rules set forth in the Commission’s rules at 17 CFR part 3, as well as the 17 CFR part 10 Rules of Practice.² This amendment will make clear the Commission’s intent that references to ALJs in both 17 CFR part 10 and part 3 shall apply to non-ALJ Presiding Officers when the Commission appoints such Presiding Officers in registration-related proceedings.

Prior to this amendment, the second sentence of 17 CFR 10.8 stated:

If the Commission determines that a proceeding within the scope of this subpart shall be conducted before a Presiding Officer who is not an Administrative Law Judge, all provisions of this part that refer to and grant authority to or impose obligations upon an Administrative Law Judge shall be read as referring to and granting authority to and imposing obligations upon the designated Presiding Officer.

This amendment adds the phrase “or of Part 3 of this title” following the words “this part” in this sentence.

¹ 17 CFR 10.2(n) defines a “Presiding Officer” as “a member of the Commission, an Administrative Law Judge, or a hearing officer designated by the Commission to conduct a hearing on a specific matter, or the Commission itself * * *.” In some types of proceedings, statutory provisions constrain the choice of Presiding Officer. For example, section 6(c)(4)(C)(iii) of the Commodity Exchange Act (“CEA”), 7 U.S.C. 9(4)(C)(iii), requires that proceedings pursuant to section 6(c)(4), 7 U.S.C. 9(4), must be heard by either the Commission or an ALJ. By contrast, other provisions of the CEA leave the choice of Presiding Officer to the discretion of the Commission. For example, CEA section 8a(2), 7 U.S.C. 12a(2), which applies in certain circumstances where a court or administrative agency has previously made a determination regarding a registrant’s conduct, authorizes the Commission to revoke registration “with such a hearing as may be appropriate” and does not specify what type of official must preside.

² See generally 17 CFR 3.55 through 3.64 and 17 CFR 10.1(a).

Related Matters

A. No Notice Is Required Under 5 U.S.C. 553

The Commission has determined that these amendments are exempt from the provisions of the Administrative Procedure Act, 5 U.S.C. 553, which generally require notice of proposed rulemaking and provide other opportunities for public participation. According to the exemptive language of 5 U.S.C. 553, these amendments pertain to “rules of agency organization, procedure, or practice,” as to which there exists agency discretion not to provide notice. In addition, notice and public procedure are unnecessary in this case because the proposed amendments are self-explanatory. If made effective immediately, they will promote efficiency and facilitate the Commission’s core mission without imposing a new burden. For the above reasons, the notice requirements under 5 U.S.C. 553 are inapplicable.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (“RFA”), 5 U.S.C. 601 *et seq.*, requires agencies with rulemaking authority to consider the impact those rules will have on small businesses. With respect to persons seeking Commission review of final exchange and NFA decisions, and initial decisions in reparation and administrative enforcement matters, the amendments impose no additional burden and in fact ease existing burdens by providing more options, greater certainty and increased predictability concerning filing and service. Accordingly, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the amendments will not have a significant economic impact on a substantial number of small businesses.

C. Paperwork Reduction Act

The amendments to 17 CFR parts 10, 12 and 171 do not impose a burden within the meaning and intent of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501, *et seq.*

D. Cost-Benefit Analysis

Section 15(a) of the CEA, 7 U.S.C. 19(a), requires the Commission to consider the costs and benefits of its action before issuing a new regulation. CEA section 15(a) further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk

management practices; and (5) other public interest considerations.

The amendments to 17 CFR parts 10, 12 and 171 will not create any significant change in the Commission’s adjudicatory process. In fact, the amendments will enhance the protection of market participants and the public by making filing and service more certain, faster and cheaper. The amendments do not bear directly upon the risk-benefit factors, but reduce costs and increase the efficiency of litigation that arises pursuant to the operation of futures markets.

List of Subjects

17 CFR Part 10

Administrative practice and procedure, Authority delegations (Government agencies), Commodity futures.

17 CFR Part 12

Administrative practice and procedure, Commodity futures, Consumer protection.

17 CFR Part 171

Administrative practice and procedure, Commodity futures.

For the reasons discussed in the preamble, the Commodity Futures Trading Commission amends 17 CFR parts 10, 12 and 171 as follows:

PART 10—RULES OF PRACTICE

- 1. The authority citation for part 10 continues to read as follows:

Authority: Pub. L. 93–463, sec. 101(a)(11), 88 Stat. 1391; 7 U.S.C. 2(a)(12).

Section 10.102 also issued under 7 U.S.C. 4a, 12a; 5 U.S.C. 10.

- 2. Revise § 10.4 to read as follows:

§ 10.4 Business address; hours.

The Office of Proceedings is located at Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581. Faxes must be sent to (202) 418–5532, and emails must be sent to *PROC_filings@cftc.gov*. The office is open from 8:15 a.m. to 4:45 p.m., Eastern Time, Monday through Friday, except on federal holidays.

- 3. Amend § 10.8 by revising the introductory text to read as follows:

§ 10.8 Presiding officers.

Unless otherwise determined by the Commission, all proceedings within the scope of this Part shall be assigned to an Administrative Law Judge for hearing. If the Commission determines that a proceeding within the scope of this Part shall be conducted before a Presiding Officer who is not an Administrative Law Judge, all provisions of this part or

of part 3 of this chapter that refer to and grant authority to or impose obligations upon an Administrative Law Judge shall be read as referring to and granting authority to and imposing obligations upon the designated Presiding Officer.

* * * * *

■ 4. Amend § 10.12 by:

■ a. Revising paragraphs (a)(1), (a)(2)(ii) through (iv), and (a)(3);

■ b. Adding paragraphs (a)(4) through (6);

■ c. Revising paragraphs (b) through (f); and

■ d. Removing paragraph (g).

The revisions and additions read as follows:

§ 10.12 Service and filing of documents; form and execution.

(a) *Service by a party or other participant in a proceeding.* (1) When one party serves another with documents under these rules, a copy must be served on all other parties as well as filed with the Proceedings Clerk. Similarly, when a person files a document with the Office of Proceedings, the person must serve a copy of the document on all other parties.

(2) * * *

(ii) First-class or a more expeditious form of United States mail or an overnight or similar commercial delivery service;

(iii) Facsimile (“fax”); or

(iv) Electronic mail (“email”).

(3) Service by email or fax shall be permitted at the discretion of the Presiding Officer, with the parties’ consent. The consent of a party must specify the email address or fax number to be used. Signed documents that are served by email must be in PDF or other non-alterable form.

(4) Service will be complete at the time of personal service; upon deposit in the mail or with an overnight or similar commercial delivery service of a properly addressed document for which all postage or delivery service fees have been paid; or upon transmission by fax or email. Service by email or by fax will not be effective if the party making service learns that the attempted service did not reach the person to be served.

(5) Where service is effected by mail or a commercial delivery service (but not by fax or email), the time within which the person being served may respond shall be extended by five (5) days.

(6) *Statement of service.* A statement of service shall be made by filing with the Proceedings Clerk, simultaneously with the filing of the document, a statement signed by the party making

service or by his attorney or representative that:

(i) Confirms that service has been made,

(ii) Identifies each person served,

(iii) Sets forth the date of service, and

(iv) Recites the manner of service.

(b) *Service of decisions and orders.* A copy of all rulings, opinions and orders shall be served by the Proceedings Clerk on each of the parties.

(c) *Designation of person to receive service.* The first page of the first document filed in a proceeding by a party or participant must include the name and contact information of a person authorized to receive service on the party or participant’s behalf. Contact information must include a post office address and daytime telephone number, and should also include the person’s fax or email. Thereafter service of documents shall be made upon the person authorized unless service on the party himself is ordered by the Administrative Law Judge or the Commission, or unless no person authorized to receive service can be found, or unless the person authorized to receive service is changed by the party upon due notice to all other parties.

(d) *Filing of documents with the Proceedings Clerk.* (1) All documents which are required to be served upon a party shall be filed concurrently with the Proceedings Clerk. A document shall be filed by delivering it in person or by first-class mail or a more expeditious form of United States mail or by overnight or similar commercial delivery service to Proceedings Clerk, Office of Proceedings, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581; or faxing the document to (202) 418–5532; or emailing it to *PROC_Filings@cftc.gov* in accordance with the conditions set forth in paragraph (a)(2) of this section.

(2) To be timely filed under this part, a document must be delivered in person; mailed by first-class or a more expeditious form of United States mail or by an overnight or similar commercial delivery service; or faxed or emailed to the Proceedings Clerk within the time prescribed for filing.

(e) *Formalities of filing.* (1) An original of all documents shall be filed with the Proceedings Clerk. If a party files a document with the Proceedings Clerk by fax or email, they should not also send paper copies.

(2) *First page.* The first page of all documents filed with the Proceedings Clerk must include the Commission’s name, the docket number, the title of proceeding, the subject of the document, and the name of the person on whose

behalf the document is being filed. In subsequent filings, the case title may be abbreviated by listing the name of the first respondent, followed by “et al.” In the complaint, the title of the action shall include the names of all the respondents, but in documents subsequently filed it is sufficient to state the name of the first respondent named in the complaint with an appropriate indication of other parties.

(3) *Format.* Documents must be legible and printed on normal white paper of eight and one half by eleven inches. The typeface, margins, and spacing of all documents presented for filing must meet the following requirements: all text must be 12-point type or larger, except for text in footnotes which may be 10-point type; all documents must have at least one-inch margins on all sides; all text must be double-spaced, except for headings, text in footnotes, or block quotations, which may be single-spaced. Emailed documents must be in PDF or other non-alterable form.

(4) *Signatures.* (i) The original of all documents must be signed by the person filing the same or by his duly authorized agent or attorney.

(ii) *Effect.* The signature on any document of any person acting either for himself or as attorney or agent for another constitutes certification by him that:

(A) He has read the document and knows the contents thereof;

(B) If executed in any representative capacity, it was done with full power and authority to do so;

(C) To the best of his knowledge, information, and belief, every statement contained in the document is true and not misleading; and

(D) The document is not being interposed for delay.

(5) *Length and form of briefs.* All briefs of more than fifteen pages shall include an index and a table of cases and other authorities cited. No brief shall exceed 50 pages in length without prior permission of the Presiding Officer or the Commission.

(f) *Official docket.* The Proceedings Clerk will maintain the official docket for each proceeding. The official docket is available for public inspection in the Commission’s Office of Proceedings.

■ 5. Amend § 10.102 by revising paragraph (c) to read as follows:

§ 10.102 Review of initial decisions.

* * * * *

(c) *Briefs.* An original of all briefs submitted under this section shall be filed with the Proceedings Clerk.

* * * * *

PART 12—RULES RELATING TO REPARATIONS

■ 6. The authority citation for Part 12 continues to read as follows:

Authority: 7 U.S.C. 2(a)(12), 12a(5), and 18.

■ 7. Amend § 12.2 by revising the definition of “Judgment Officer” to read as follows:

§ 12.2 Definitions.

* * * * *

Judgment Officer means an employee of the Commission who is authorized to conduct all reparations proceedings. In appropriate circumstances, the functions of a Judgment Officer may be performed by an Administrative Law Judge;

* * * * *

■ 8. Revise § 12.3 to read as follows:

§ 12.3 Business address; hours.

The Office of Proceedings is located at Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581. Faxes must be sent to (202) 418-5532, and emails must be sent to PROC_filings@cftc.gov. The office is open from 8:15 a.m. to 4:45 p.m., Eastern Time, Monday through Friday except on federal holidays.

■ 9. Revise § 12.10 to read as follows:

§ 12.10 Service.

(a) *General requirements.* (1) *When service is required; number of copies.* When one party serves another with documents under these rules, a copy must be served on all other parties as well as filed with the Proceedings Clerk. Similarly, when a person files a document with the Office of Proceedings, the person must serve a copy of the document on all other parties. This rule does not apply to a complaint filed pursuant to § 12.13 of these rules, which shall only be filed with the Commission.

(2) *How service is made.* Service shall be made by:

(i) Personal service;

(ii) First-class or a more expeditious form of United States mail or an overnight or similar commercial delivery service;

(iii) Facsimile (“fax”); or

(iv) Electronic mail (“email”).

(3) Service by fax or email shall be permitted at the discretion of the Presiding Officer, with the parties’ consent. The consent of a party must specify the email address or fax number to be used. Signed documents that are served by email attachment must be in PDF or other non-alterable form.

(4) Service will be complete at the time of personal service; upon deposit

in the mail or with an overnight or similar commercial delivery service of a properly addressed document for which all postage or delivery service fees have been paid; or upon transmission by fax or email. Service by email or by fax will not be effective if the party making service learns that the attempted service did not reach the person to be served.

(5) Where service is effected by mail or commercial delivery service (but not by fax or email), the time within which the person served may respond thereto shall be extended by five (5) days.

(6) *Statement of Service.* A statement of service shall be made by filing with the Proceedings Clerk, simultaneously with the filing of the document, a statement signed by the party making service or by his attorney or representative that:

(i) Confirms that service has been made;

(ii) Identifies each person served;

(iii) Sets forth the date of service; and

(iv) Recites the manner of service.

(b) *Service of orders and decisions.* A copy of all notices, rulings, opinions, and orders of the Proceedings Clerk, the Director of the Office of Proceedings, a Judgment Officer, an Administrative Law Judge, the General Counsel or any employee under the General Counsel’s supervision as the General Counsel may designate, or the Commission shall be served by the Proceedings Clerk on each of the parties. The Commission, in its discretion and with due consideration for the convenience of the parties, may serve the aforementioned documents to the parties by electronic means.

(c) *Designation of person to receive service.* The first page of the first document filed in a proceeding by a party or participant shall include the contact information of a person authorized to receive service on their behalf. Thereafter, service of documents shall be made upon the person authorized unless service on the party himself is ordered by a Judgment Officer, an Administrative Law Judge or the Commission, or unless no person authorized to receive service can be found, or unless the person authorized to receive service is changed by the party upon due notice to all other parties.

■ 10. Revise § 12.11 to read as follows:

§ 12.11 Formalities of filing of documents with the Proceedings Clerk.

(a) If a party files by personal delivery or mail, an original of all documents shall be filed with the Proceedings Clerk. If a party files a document by fax or email in accordance with § 12.10(a)(2), they should not also send paper copies.

(b) *First page.* The first page of all documents filed with the Proceedings Clerk must include the Commission’s name, the docket number, the title of the proceeding, the subject of the document and the name of the person on whose behalf the document is being filed. In the complaint, the title of the proceeding shall include the names of all the complainants and respondents, but in documents subsequently filed it is sufficient to state the name of the first complainant and first respondent named in the complaint.

(c) *Format.* Documents must be legible and printed on normal white paper of eight and one half by eleven inches. Documents emailed in accordance with the requirements of § 12.10(a)(2) must be in PDF or other non-alterable form. The typeface, margins, and spacing of all typed documents presented for filing should meet the following requirements: all text should be 12-point type or larger, except for text in footnotes which may be 10-point type; all documents should have at least one-inch margins on all sides; all text must be double-spaced, except for headings, text in footnotes, or block quotations, which may be single-spaced.

(d) *Signature.* (1) The original of all papers must be signed by the person filing the same or by his duly authorized agent or attorney.

(2) *Effect.* The signature on any document of any person acting either for himself or as attorney or agent for another constitutes certification by him that:

(i) He has read the document and knows the contents thereof;

(ii) If executed in any representative capacity, it was done with full power and authority to do so;

(iii) To the best of his knowledge, information, and belief, every statement contained in the document is true and not misleading; and

(iv) The document has been filed in good faith and has not been filed to cause delay.

(e) *Length and form of briefs.* All briefs filed containing more than 15 pages shall include an index and a table of cases and other authorities cited. No brief shall exceed 25 pages in length without prior permission of the Presiding Officer.

(f) All documents which are required to be served upon a party shall be filed concurrently with the Proceedings Clerk. A document shall be filed by delivering it in person or by first-class mail or a more expeditious form of United States mail or by overnight or similar commercial delivery service to Proceedings Clerk, Office of Proceedings, Three Lafayette Centre,

1155 21st Street NW., Washington, DC 20581; or faxing the document to (202) 418-5532; or emailing it to PROC_Filings@cftc.gov in accordance with the conditions set forth in paragraph (a)(2) of this section.

(g) To be timely filed under this part, a document must be delivered in person; mailed by first-class or a more expeditious form of United States mail or by an overnight or similar commercial delivery service; or faxed or emailed to the Proceedings Clerk within the time prescribed for filing.

■ 11. Amend § 12.34 by revising paragraph (a) to read as follows:

§ 12.34 Discovery by a decisionmaking official.

(a) *Applicability.* The provisions of this rule shall apply to all decisional proceedings commenced pursuant to § 12.26. For the purposes of this rule, the term “decisionmaking official” shall mean a Judgment Officer or Administrative Law Judge assigned to render a decision in the proceeding.

* * * * *

■ 12. Amend § 12.101 by revising paragraphs (a) through (c) to read as follows:

§ 12.101 Functions and responsibilities of the Judgment Officer.

* * * * *

(a) To rule upon discovery-related motions, and to take such action pursuant to § 12.35 as is appropriate if a party fails to comply with a discovery order;

(b) To issue orders for the production of documents and tangible things and orders for written testimony, as provided in § 12.34;

(c) To issue subpoenas pursuant to § 12.34 and § 12.36;

* * * * *

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

■ 13. The authority citation for Part 171 continues to read as follows:

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

■ 14. Amend § 171.8 by revising paragraph (a) to read as follows:

§ 171.8 Filing with the Proceedings Clerk.

(a) *How to file.* Any document that is required by this part to be filed with the Proceedings Clerk shall be filed by delivering it in person or by first-class mail or a more expeditious form of United States mail, or by overnight or

similar commercial delivery service to: Proceedings Clerk, Office of Proceedings, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581; or faxing the document to (202) 418-5532 or emailing it to PROC_Filings@cftc.gov. To be timely filed under this part, a document must be delivered or mailed to the Proceedings Clerk within the time prescribed for filing.

* * * * *

Issued in Washington, DC, on February 20, 2013, by the Commission.

Melissa D. Jurgens,

Secretary of the Commission.

[FR Doc. 2013-04252 Filed 2-25-13; 8:45 am]

BILLING CODE 6351-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50 and 56

[Docket No. FDA-2000-N-0009] (formerly 2000N-0074)

RIN 0910-AG71

Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to provide additional safeguards for children enrolled in clinical investigations of FDA-regulated products. This rule finalizes the interim rule published in 2001 to bring FDA regulations into compliance with provisions of the Children’s Health Act of 2000 (the Children’s Health Act). The Children’s Health Act requires that all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services (HHS) be in compliance with HHS regulations providing additional protections for children involved as subjects in research. FDA is taking this action both to comply with the congressional mandate and because of increases in the enrollment of children in clinical investigations as a result of ongoing pediatric initiatives.

DATES: This rule is effective March 28, 2013.

FOR FURTHER INFORMATION CONTACT: Robert M. Nelson, Office of Pediatric Therapeutics, Food and Drug

Administration, 10903 New Hampshire Ave. Bldg. 32, rm. 5126, Silver Spring, MD 20993-0002, 301-796-8659.

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I. Background

In the **Federal Register** of April 24, 2001 (66 FR 20589), FDA published an interim rule amending its regulations to provide additional safeguards for children enrolled in clinical investigations of FDA-regulated products (part 50 (21 CFR part 50, subpart D (FDA subpart D))). The interim rule brought FDA regulations into compliance with provisions of the Children’s Health Act (Pub. L. 106-310). Title XXVII, section 2701 of the Children’s Health Act required that within 6 months of its enactment all research involving children conducted, supported, or regulated by HHS be in compliance with HHS regulations providing additional protections for children involved as subjects in research (45 CFR part 46, subpart D (HHS subpart D)). The interim rule was effective on April 30, 2001. Interested parties were given until July 23, 2001, to comment on the interim rule.

FDA is finalizing its interim final rule both to comply with the congressional mandate in the Children’s Health Act and because of increases in the enrollment of children in clinical investigations, in part as a result of ongoing pediatric initiatives. Some of these pediatric initiatives were described in detail in the interim rule (66 FR 20589), including the Food and Drug Administration Modernization Act of 1997 (FDAMA) and FDA’s 1998 pediatric rule (63 FR 66632, December 2, 1998).

FDAMA established economic incentives for manufacturers to conduct pediatric studies on drugs for which exclusivity or patent protection is