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FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 380

RIN 3064-AD89

Mutual Insurance Holding Company Treated as Insurance Company

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Final rule.

SUMMARY: The FDIC is issuing a final rule (“Final Rule”) that treats a mutual insurance holding company as an insurance company for purposes of Section 203(e) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”). The Final Rule clarifies that the liquidation and rehabilitation of a covered financial company that is a mutual insurance holding company will be conducted in the same manner as an insurance company. The Final Rule harmonizes the treatment of mutual insurance holding companies under Section 203(e) of the Dodd-Frank Act with the treatment of such companies under state insurance company insolvency laws.

DATES: The effective date of the Final Rule is May 30, 2012.

FOR FURTHER INFORMATION CONTACT: R. Penfield Starke, Assistant General Counsel, Legal Division, (703) 562-2422; Mark A. Thompson, Counsel (703) 562-2529; Elizabeth Falloon, Counsel (703) 562-6148; Timothy F. Danello, Counsel (703) 562-6338, Legal Division; or Hashim Hamandi, Section Chief Policy Section, Office of Complex Financial Institutions, (202) 898-6884.

SUPPLEMENTARY INFORMATION:

I. Background

Title II of the Dodd-Frank Act provides for the appointment of the FDIC as receiver of a nonviable financial company that poses significant risk to

the financial stability of the United States (a “covered financial company”), outlines the process for the orderly liquidation of a covered financial company following the FDIC’s appointment as receiver and provides for additional implementation of the orderly liquidation authority by rulemaking. The Final Rule is promulgated pursuant to Section 209¹ of the Dodd-Frank Act, which authorizes the FDIC, in consultation with the Financial Stability Oversight Council, to prescribe such rules and regulations as the FDIC considers necessary or appropriate to implement Title II. Section 209 of the Dodd-Frank Act further provides that, to the extent possible, the FDIC should seek to harmonize rules and regulations promulgated under Section 209 with the insolvency laws that would otherwise apply to a covered financial company.

On December 13, 2011, the FDIC published a Notice of Proposed Rulemaking (“NPR”) in the **Federal Register**² setting forth the conditions under which a mutual insurance holding company would be resolved as an insurance company under Section 203(e) of the Dodd-Frank Act. The comment period for the NPR closed on February 13, 2012, and the FDIC received four comment letters. Additionally, the FDIC held a conference call with representatives of the National Association of Insurance Commissioners on January 17, 2012 and received their comments on the NPR.

In light of the comments received and pursuant to the authority granted to it by Section 209 of the Dodd-Frank Act, the FDIC is issuing the Final Rule.

History of Mutual Insurance Holding Company

The mutual insurance industry traces its roots back to England, where, in 1696, the first mutual fire insurer was established. The first American mutual insurance company, the Philadelphia Contributionship for the Insurance of Houses from Loss by Fire, was founded in 1752.³

Mutual insurance companies have no equity interests. Membership rights are held by their policyholders.

Policyholders are entitled to vote for members of the company’s board of directors and may receive special dividends in the form of capital distributions or reductions of policy premiums.

The mutual insurance holding company structure was first created in Iowa in 1995.⁴ A mutual insurance holding company is created through the restructuring of a mutual insurance company into two entities, a mutual insurance holding company and a stock insurance company that is converted from the original mutual insurance company. In a variation of this restructuring, a third entity may be formed, an intermediate insurance stock holding company. In this three-entity structure, in most instances, the mutual insurance holding company initially owns 100% of the intermediate insurance stock holding company, and the intermediate insurance stock holding company initially owns 100% of the stock of the converted mutual insurance company. The purpose of the restructuring is to preserve the benefits of a mutual form of organization while allowing the converted mutual insurance company access to capital markets either through sale of its stock or, in a three-entity structure, the sale of the stock of the intermediate insurance stock holding company.

Consistent with the mutual insurance company, a mutual insurance holding company also has no equity interests. Membership rights are held by the policyholders of the converted mutual insurance company who have rights similar to those they had as policyholders of the mutual insurance company before conversion. Policyholders of the converted mutual insurance company are entitled to vote for members of the mutual insurance holding company’s board of directors, and may receive special dividends in the form of capital distributions or reductions of policy premiums.

A majority of the states have adopted statutes providing for the formation of mutual insurance holding companies. Those statutes generally (a) provide for the regulation of a mutual insurance holding company at the holding company level by the insurance commissioner of the domiciliary state; (b) require that the mutual insurance

¹ 12 U.S.C. 5389.

² 76 FR 77442 (December 13, 2011).

³ The Philadelphia Contributionship, History, <http://www.contributionship.com/history/index.html>.

⁴ Iowa Code Ann. (West) § 521A.14.

holding company maintain voting control over the converted mutual insurance company; and (c) specifically subject a mutual insurance holding company to liquidation or rehabilitation under the state regime if the converted mutual insurance company is placed in liquidation or rehabilitation. In addition, either by statute, rule or regulation, in the liquidation of a converted mutual insurance company, the assets of the mutual insurance holding company generally are included in the estate of the converted mutual insurance company being liquidated.⁵

Treatment of an Insurance Company Under Section 203(e) of the Dodd-Frank Act

In providing for the orderly liquidation of a covered financial company under Title II of the Dodd-Frank Act, Congress recognized that insurance companies historically had been liquidated and rehabilitated pursuant to a state insolvency framework. As a result, Congress provided that “if an insurance company is a covered financial company or a subsidiary or affiliate of a covered financial company, the liquidation or rehabilitation of such insurance company, and any subsidiary or affiliate of such company that is [an insurance company], shall be conducted as provided under applicable State law.”⁶

The term “insurance company” is defined in Section 201(a)(13) of the Dodd-Frank Act to mean “any entity that is—(A) engaged in the business of insurance; (B) subject to regulation by a State insurance regulator; and (C) covered by a State law that is designed to specifically deal with the rehabilitation, liquidation, or insolvency of an insurance company.”⁷ The identical definition is found in Section 380.1 of Title 12 of the Code of Federal Regulations. Concerns have been raised with respect to the application of this definition to mutual insurance holding companies because, under applicable state laws, a mutual insurance holding company generally is prohibited from selling policies of insurance. Thus, a mutual insurance holding company arguably does not fit squarely within a literal reading of the statutory definition of insurance company under the Dodd-Frank Act.

The treatment of a mutual insurance holding company, under certain circumstances, as an insurance

company for purposes of Section 203(e) is consistent with the legislative intent of the Dodd-Frank Act.⁸ This treatment is appropriate given the legal structure that forms a mutual insurance holding company from a converted mutual insurance company and the continuing interest of the policyholders of the converted mutual insurance company in both the converted mutual insurance company, as its customers, and the mutual insurance holding company, as holders of its membership interests. From a regulatory policy perspective, the extensive regulation of the mutual insurance holding company by the insurance commissioner of its domiciliary state and the inclusion of the mutual insurance holding company and its assets in the liquidation of the converted mutual insurance company also support this treatment.

II. Notice of Proposed Rulemaking: Summary of Comments

On December 13, 2011, the FDIC invited public comment on a Notice of Proposed Rulemaking: Mutual Insurance Holding Company Treated as Insurance Company (the “Proposed Rule”).⁹ The comment period ended on February 13, 2012. The FDIC received four comment letters from several industry and trade organizations representing the insurance industry and one individual. In addition, the FDIC met with representatives of the National Association of Insurance Commissioners to discuss the Proposed Rule.

The Proposed Rule clarified that a mutual insurance holding company would be treated in the same manner applicable to insurance companies under Section 203(e) of the Dodd-Frank Act, which provides that “if an insurance company is a covered financial company or a subsidiary or affiliate of a covered financial company, the liquidation or rehabilitation of such insurance company, and any subsidiary or affiliate of such company that is [an insurance company], shall be conducted as provided under applicable State law.”¹⁰ This proposed treatment was limited to mutual insurance holding companies whose largest United States subsidiary (as measured by total assets as of the end of the previous calendar quarter) is an insurance company or an

intermediate insurance stock holding company, and whose investments are limited to the securities of an intermediate insurance stock holding company, the securities of the converted mutual insurance company and other assets and securities of the type authorized for holding and investment by an insurance company domiciled in its state of incorporation. The Proposed Rule also provided that this treatment apply only to mutual insurance holding companies that are regulated by and are subject to the insurance company insolvency laws of their states of domicile, and that are not subject to bankruptcy proceedings.

The public comments supported the Proposed Rule’s objective of treating a mutual insurance holding company as an insurance company for purposes of Section 203(e) of the Dodd-Frank Act.¹¹ The comments focused on two elements of the Proposed Rule: The definitions of mutual insurance holding company and intermediate insurance stock holding company and the conditions imposed in order for a mutual insurance holding company to qualify as an insurance company under Section 203(e) of the Dodd-Frank Act.

Most of the commenters suggested that the definition of mutual insurance holding company be modified with respect to the requirement that the mutual insurance holding company “hold either (i) At least 51% of the issued and outstanding voting stock of the intermediate insurance stock holding company, if any, or (ii) if there is no intermediate insurance stock holding company, at least 51% of the issued and outstanding voting stock of the converted mutual insurance company.” Several commenters noted that many state laws only require the mutual insurance holding company to own a majority of the voting stock of the intermediate insurance stock holding company, if any, or, if there is no intermediate insurance stock holding company, a majority of the voting stock of the converted mutual insurance company. One commenter recommended substituting “a majority of the voting stock” for “51% of the issued and outstanding voting stock” where the phrase appears within the definition of mutual insurance holding company. Another commenter recommended substituting “a majority of the voting power in the election of directors” for “51% of the issued and outstanding voting stock” where the phrase appears within the definition of mutual insurance holding company.

⁵ E.g., Iowa Code Ann. (West) 521A.14(4), 215 Ill. Comp. Stat. Ann. (West) 5/59.2(1)(f)(v), and Neb. Rev. Stat. § 44-6125(6)(g).

⁶ 12 U.S.C. 5383(e)(1).

⁷ 12 U.S.C. 5381(a)(13).

⁸ There is support in the legislative history of the Dodd-Frank Act for interpreting the term “insurance company” under Section 201(a)(13) to include a mutual insurance holding company. See statement of Rep. Barney Frank, 111 Cong. Rec. H5216 (daily ed. June 30, 2010) and statement of Sen. Christopher Dodd, 111 Cong. Rec. S5903 (daily ed. July 15, 2010).

⁹ 76 FR 77442 (December 13, 2011).

¹⁰ 12 U.S.C. 5383(e)(1).

¹¹ 12 U.S.C. 5383(e).

Several commenters suggested that the definition of intermediate insurance stock holding company be modified with respect to the requirement that the intermediate insurance stock holding company “hold all of the issued and outstanding voting stock of the converted mutual insurance company.” One commenter suggested that the word “all” be changed to “a majority” to be more consistent with the requirements of state law. Another commenter suggested retaining the concept of “all of the issued and outstanding voting stock” but allow the ownership to be “directly or indirectly.”

One commenter suggested that the definition of intermediate insurance stock holding company be modified to clarify that an intermediate insurance stock holding company can be formed either at the time of or at any time after the conversion of the mutual insurance company into a stock insurance company. Another commenter suggested deleting the phrase “For purposes of this subpart” from the definition of intermediate insurance stock holding company to be consistent with other definitions in § 380.1.

Several commenters suggested that the definition of mutual insurance company be modified. One commenter suggested that the word “association” should be changed to “corporation” because a mutual insurance company is a non-stock corporation and not an association. The same commenter suggested changing the words “in which equity and voting rights are vested in the policyholders” to “in which rights in surplus and membership interests are vested in the policyholders” because a mutual insurance company has “surplus” not “equity” and the interests of the members may be broader than just voting rights. Another commenter suggested changing the words “in which equity and voting rights are vested in the policyholders” to “in which equity, voting rights and control are vested in the policyholders” to emphasize that “policyholders actually exercise effective control, rather than have that power merely conferred by charter or otherwise.” One commenter suggested deleting the word “domestic” in the phrase “a domestic insurance company organized under the laws of a State” because it was redundant.

With respect to the conditions that must exist for a mutual insurance holding company to be treated as an insurance company for the purpose of Section 203(e) of the Dodd-Frank Act as set forth in § 380.11, several commenters suggested modifying one or more of the conditions. One commenter suggested removing the condition that

the company is not subject to bankruptcy proceedings under Title 11 of the United States Code, i.e., the U.S. Bankruptcy Code. The commenter noted that the issue of whether a mutual insurance holding company is excluded from coverage under the U.S. Bankruptcy Code is unsettled. Thus, in the commenter’s view, imposing the condition in § 380.11 introduced uncertainty about whether a mutual insurance holding company would be treated as an insurance company for the purpose of Section 203(e) of the Dodd-Frank Act.

Several commenters suggested modifying the requirement in § 380.11 that the mutual insurance holding company limit its assets and investments to the securities of an intermediate insurance stock holding company, the securities of the converted mutual insurance company “and other assets and securities of the type authorized for holding and investment by an insurance company domiciled in its state of incorporation.” The commenters noted that the requirement is not mandated by state law although some states do limit a mutual insurance holding company’s investment in non-insurance assets. One of those commenters suggested that the mutual insurance holding company be allowed to make any investment “permitted under applicable State law.”

The FDIC has carefully considered the comments and made appropriate revisions to the Final Rule as described below.

III. Description of Final Rule

A. Overview

The Final Rule modifies Part 380 of Title 12 of the Code of Federal Regulations, and provides generally that a mutual insurance holding company that meets the requirements of the Final Rule will be treated as an insurance company for the purpose of Section 203(e) of the Dodd-Frank Act.

B. Section-by-Section Analysis of the Final Rule

The Final Rule adds three definitions to Section 380.1 of Title 12 of the Code of Federal Regulations: intermediate insurance stock holding company; mutual insurance company; and mutual insurance holding company. The definition of mutual insurance holding company has been modified in the Final Rule to provide that the company could own a “majority” of the stock of the intermediate insurance stock holding company and the converted mutual insurance company instead of the specific threshold of “at least 51%”

included in the Proposed Rule. The definition of the intermediate insurance stock holding company was also modified in the Final Rule to delete an unnecessary introductory phrase “For purposes of this subpart” and to indicate that such company could be organized either at the time of or after the organization of the mutual insurance holding company and could hold “a majority” rather than “all” of the stock of the converted mutual insurance company. In addition, the definition of the mutual insurance company was amended to reflect that it is organized as a non-stock mutual corporation, not an association, and that its policyholders hold the surplus, not “equity” in this company. The Final Rule does not include any additional changes suggested by the public comments to permit the mutual insurance holding company to hold the voting stock of the intermediate insurance stock holding company directly or indirectly or to permit the intermediate insurance stock holding company to hold the voting stock of the converted mutual insurance company directly or indirectly. These changes appear inconsistent with the existing mutual insurance holding company structure. Likewise, the Final Rule does not remove the term “voting rights” and substitute the term “membership interests” since voting rights remain essential to defining the control of the mutual insurance company and the intermediate insurance stock holding company.

The Final Rule adds Section 380.11 to provide that a mutual insurance holding company shall be treated as an insurance company for the purpose of Section 203(e) of the Dodd-Frank Act, 12 U.S.C. 5383(e); provided that: (a) it is subject to the insurance laws of the state of its domicile, including specifically and without limitation, a statutory regime for the rehabilitation or liquidation of insurance companies that are in default or in danger of default; (b) it is not subject to bankruptcy proceedings under Title 11 of the United States Code; (c) its largest United States subsidiary (as measured by total assets as of the end of the previous calendar quarter) is an insurance company or an intermediate insurance stock holding company; and (d) its investments are limited to the securities of an intermediate insurance stock holding company, the securities of the converted mutual insurance company and other assets and securities of the type authorized for holding and investment by an insurance company domiciled in its state of incorporation.

The first proviso requires that the mutual insurance holding company be subject to the insurance laws of the state of its domicile, including specifically and without limitation, a statutory regime for the rehabilitation or liquidation of insurance companies that are in default or in danger of default and is included in the Final Rule to be consistent with two of the three prongs of the definition of “insurance company” set forth in Section 201(a)(13) of the Dodd-Frank Act. The reference to companies that are “in default or in danger of default” ensures that the state resolution process will be applicable in a time and manner comparable to the Title II orderly liquidation process, which applies to financial companies that are in default or in danger of default under Section 203(b)(1) of the Dodd-Frank Act.

The second proviso requires that the mutual insurance holding company is not subject to bankruptcy proceedings under Title 11 of the United States Code and is included to make clear that the mutual insurance holding company must not only be subject to the applicable state insurance law but must also be resolved under the applicable state insurance law. Thus, the Final Rule does not delete this requirement as some public comments suggested, but rather retains it to ensure that there is no ambiguity or conflict with respect to the determination of which insolvency regime is applicable to a mutual insurance holding company. To the extent that any such ambiguity or conflict exists, it is the intent of the Final Rule that the ambiguity be resolved in favor of allowing resolution under Title II of the Dodd-Frank Act even if the mutual insurance holding company may be an eligible debtor under Title 11 of the United States Code.

The third proviso, which requires that the mutual insurance holding company’s largest United States subsidiary (as measured by total assets as of the end of the previous calendar quarter) is an insurance company or an intermediate insurance stock holding company, is included to ensure that, if a mutual insurance holding company covered by the Final Rule is placed in orderly liquidation under Title II of the Dodd-Frank Act, the Director of the Federal Insurance Office would participate in making the recommendation to take such action in accordance with the provisions of Section 203(a)(1)(C) of the Dodd-Frank Act. In addition, this requirement is intended to make clear that an insurance company subsidiary of the mutual insurance holding company

must be its most significant subsidiary by asset size.

The final proviso requires the mutual insurance holding company to limit its investments to the securities of the intermediate insurance stock holding company, the securities of the converted mutual insurance company and other assets and securities of the type authorized for holding and investment by an insurance company domiciled in its state of incorporation. The FDIC rejected a public comment to alter these investment requirements because the FDIC believes that this proviso ensures that the mutual insurance holding company is operating purely as a holding company and is not itself actively engaged in operating non-insurance businesses.¹²

IV. Regulatory Analysis and Procedure

A. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) (“PRA”), the FDIC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The Final Rule would not involve any new collections of information pursuant to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Consequently, no information will be submitted to the Office of Management and Budget for review.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act 5 U.S.C. 601 *et seq.* (RFA) requires each federal agency to prepare a final regulatory flexibility analysis in connection with the promulgation of a final rule, or certify that the final rule will not have a significant economic impact on a substantial number of small entities.¹³ Pursuant to Section 605(b) of the Regulatory Flexibility Act, the FDIC certifies that the Final Rule will not have a significant economic impact on a substantial number of small entities.

Under regulations issued by the Small Business Administration (“SBA”), a “small entity” includes those firms within the “Finance and Insurance” sector with asset sizes that vary from \$7 million or less in assets to \$175 million or less in assets.¹⁴ The Final Rule clarifies that a mutual insurance holding

company that is a covered financial company will be treated as an insurance company for the purpose of Section 203(e) of the Dodd-Frank Act. The Final Rule provides internal guidance to FDIC personnel in such an event and will address an uncertainty in the financial system as to how such a company would be treated for purposes of Section 203(e) of the Dodd-Frank Act. For a mutual insurance holding company to be determined to be a covered financial company under Section 203(b) of the Dodd-Frank Act, its failure must have serious adverse effects on the financial stability of the United States. The Final Rule would apply to a mutual insurance holding company regardless of such company’s size. Although the asset size of a company may not be the determinative factor of whether such company may pose a systemic risk to the financial stability of the United States, it is an important consideration. It is unlikely that the failure of a mutual insurance holding company that is at or below the \$175 million asset threshold, or the nature, scope, size, scale, concentration, interconnectedness, or mix of its activities, would pose a threat to the financial stability of the United States. As such, the Final Rule will not have a significant economic impact on small entities.

C. Small Business Regulatory Enforcement Fairness Act

The Office of Management and Budget has determined that the Final Rule is not a “major rule” within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996 (“SBREFA”) (5 U.S.C. 801 *et seq.*). As required by SBREFA, the FDIC will file the appropriate reports with Congress and the General Accounting Office so that the Final Rule may be reviewed.

D. The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The FDIC has determined that the Final Rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, 112 Stat. 2681).

E. Plain Language

Section 722 of the Gramm-Leach-Bliley Act (Pub. L. 106–102, 113 Stat. 1338, 1471), requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The

¹² The investments of the intermediate insurance stock holding company, however, are not restricted in this manner because, under the Final Rule, the intermediate insurance stock holding company is not treated as an insurance company for the purpose of Section 203(e) of the Dodd-Frank Act.

¹³ See 5 U.S.C. 603, 604 and 605.

¹⁴ 13 CFR 121.201.

FDIC has sought to present the Final Rule in a simple and straightforward manner.

List of Subjects in 12 CFR Part 380

Holding companies, Insurance companies, Mutual insurance holding companies.

For the reasons stated above, the Board of Directors of the Federal Deposit Insurance Corporation amends part 380 of title 12 of the Code of Federal Regulations as follows:

PART 380—ORDERLY LIQUIDATION AUTHORITY

- 1. The authority citation for part 380 is revised to read as follows:

Authority: 12 U.S.C. 5383(e); 12 U.S.C. 5389; 12 U.S.C. 5390(s)(3); 12 U.S.C. 5390(b)(1)(C); 12 U.S.C. 5390(a)(7)(D).

- 2. The heading for subpart A is revised to read as follows:

Subpart A—General and Miscellaneous Provisions

- 3. Amend § 380.1 by adding definitions of *Intermediate insurance stock holding company*, *Mutual insurance company*, and *Mutual insurance holding company* in alphabetical order to read as follows:

§ 380.1 Definitions.

* * * * *

Intermediate insurance stock holding company. The term “*intermediate insurance stock holding company*” means a corporation organized either at the time of, or at any time after, the organization of the mutual insurance holding company that:

- (1) Is a subsidiary of a mutual insurance holding company;
- (2) Holds a majority of the issued and outstanding voting stock of the converted mutual insurance company created at the time of formation of the mutual insurance holding company; and
- (3) Holds, as its largest United States subsidiary (as measured by total assets as of the end of the previous calendar quarter), an insurance company.

Mutual insurance company. The term “*mutual insurance company*” means an insurance company organized under the laws of a State that provides for the formation of such an entity as a non-stock mutual corporation in which the surplus and voting rights are vested in the policyholders.

Mutual insurance holding company. The term “*mutual insurance holding company*” means a corporation that:

- (1) Is lawfully organized under state law authorizing its formation in connection with the reorganization of a

mutual insurance company that converts the mutual insurance company to a stock insurance company, and—

(2) Holds either:

(i) A majority of the issued and outstanding voting stock of the intermediate insurance stock holding company, if any, or

(ii) If there is no intermediate insurance stock holding company, a majority of the issued and outstanding voting stock of the converted mutual insurance company.

* * * * *

- 4. Add § 380.11 to read as follows:

§ 380.11 Treatment of mutual insurance holding companies.

A mutual insurance holding company shall be treated as an insurance company for the purpose of section 203(e) of the Dodd-Frank Act, 12 U.S.C. 5383(e); provided that—

(a) The company is subject to the insurance laws of the state of its domicile, including, specifically and without limitation, a statutory regime for the rehabilitation or liquidation of insurance companies that are in default or in danger of default;

(b) The company is not subject to bankruptcy proceedings under Title 11 of the United States Code;

(c) The largest United States subsidiary of the company (as measured by total assets as of the end of the previous calendar quarter) is an insurance company or an intermediate insurance stock holding company; and

(d) The assets and investments of the company are limited to the securities of an intermediate insurance stock holding company, the securities of the converted mutual insurance company and other assets and securities of the type authorized for holding and investment by an insurance company domiciled in its state of incorporation.

Dated at Washington, DC, this 23rd day of April 2012.

By order of the Board of Directors.
Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2012–10146 Filed 4–27–12; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 312, 511, and 812

[Docket No. FDA–2011–N–0079]

RIN 0910–AG49

Disqualification of a Clinical Investigator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations to expand the scope of clinical investigator disqualification. Under this rulemaking, when the Commissioner of Food and Drugs (the Commissioner) determines that an investigator is ineligible to receive one kind of test article (drugs, devices or new animal drugs), the investigator also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for other kinds of products regulated by FDA. This final rule is based in part upon recommendations from the Government Accountability Office (GAO), and is intended to help ensure adequate protection of research subjects and the quality and integrity of data submitted to FDA. FDA also is amending the list of regulatory provisions under which an informal regulatory hearing is available by changing the scope of certain provisions and adding regulatory provisions that were inadvertently omitted.

DATES: This rule is effective May 30, 2012.

FOR FURTHER INFORMATION CONTACT: Kathleen E. Pfaender, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993, 301–796–8340.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 13, 2011 (76 FR 20575), FDA proposed to amend its regulations to expand the scope of clinical investigator disqualification (the April 2011 proposed rule). As discussed in greater detail in the preamble to the proposed rule (76 FR 20575 at 20576 to 20585), when disqualified by a Commissioner's decision under one part of the former regulations a clinical investigator continued to be eligible to receive other types of test articles and conduct