Rules and Regulations

Federal Register
Vol. 82, No. 248
Thursday, December 28, 2017

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 324, 329, and 382

RIN 3064–AE46

Restrictions on Qualified Financial Contracts of Certain FDIC-Supervised Institutions; Revisions to the Definition of Qualifying Master Netting Agreement and Related Definitions

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Final rule; technical correction; confirmation of effective date.

SUMMARY: This document makes technical corrections to regulations that were published in the **Federal Register** on October 30, 2017. The FDIC added Part 382 to its regulations to improve the resolvability of systemically important U.S. banking organizations and systemically important foreign banking organizations and enhance the resilience and the safety and soundness of certain State savings associations and State-chartered banks and made certain conforming changes to Part 329. This document is being published to make technical corrections to certain rules under Parts 329 and 382 and make effective amendatory instruction 6 in the previously published regulation.

DATES: Effective January 1, 2018. Amendatory instruction 6 in the final rule published October 30, 2017, at 82 FR 50228, is effective January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Ryan Billingsley, Acting Associate Director, Capital Markets Branch, Division of Risk Management and Supervision, *rbillingsley@fdic.gov;* Alexandra Steinberg Barrage, Senior Resolution Policy Specialist, Office of Complex Financial Institutions, *abarrage@fdic.gov;* David N. Wall, Assistant General Counsel, *dwall@fdic.gov,* Cristina Regojo, Counsel, *cregojo@fdic.gov,* Phillip Sloan, Counsel, *psloan@fdic.gov,* Michael Phillips, Counsel, *mphillips@fdic.gov,* Greg Feder, Counsel, *gfeder@fdic.gov,* or Francis Kuo, Counsel, *fkuo@fdic.gov,* Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: We are making technical corrections to 12 CFR 329.3 and 382.2. We are also making effective amendatory instruction #6, published in the final rule on October 30, 2017, at 82 FR 50228.

List of Subjects

12 CFR Part 329

Administrative practice and procedure, Banks, banking, Federal Deposit Insurance Corporation, FDIC, Liquidity, Reporting and recordkeeping requirements.

12 CFR Part 382

Administrative practice and procedure, Banks, banking, Federal Deposit Insurance Corporation, FDIC, Qualified financial contracts, Reporting and recordkeeping requirements, State savings associations, State non-member banks.

For the reasons stated in the supplementary information, the Federal Deposit Insurance Corporation amends 12 CFR chapter III as follows:

PART 329—LIQUIDITY RISK MEASUREMENT STANDARDS

■ 1. The authority citation for part 329 continues to read as follows:

Authority: 12 U.S.C. 1815, 1816, 1818, 1819, 1828, 1831p–1, 5412.

§ 329.3 [Amended]

■ 2. In § 329.3, amend paragraph (2)(i)(A) of the definition of ''Qualifying master netting agreement'' by adding ''or'' following the semi-colon.

PART 382—RESTRICTIONS ON QUALIFIED FINANCIAL CONTRACTS

■ 3. The authority citation for part 382 continues to read as follows:

Authority: 12 U.S.C. 1816, 1818, 1819, 1820(g), 1828, 1828(m), 1831n, 1831o, 1831p–l, 1831(u), 1831w.

§ 382.1 [Amended]

■ 4. As of January 1, 2018, make effective amendatory instruction #6 as published October 30, 2017, at 82 FR 50228.

§ 382.2 [Amended]

■ 5. In § 382.2, amend paragraph (c)(1)(ii) by removing ''January 19, 2019'' and adding ''January 1, 2019'' in its place.

Dated at Washington, DC, on December 21, 2017.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2017–27971 Filed 12–27–17; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 511

[Docket No. FDA–2011–N–0079]

RIN 0910–AH64

New Animal Drugs for Investigational Use; Disqualification of a Clinical Investigator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule amending the regulations for new animal drugs for investigational use to expand the scope of clinical investigator disqualification to include ineligibility to conduct nonclinical laboratory studies. Under this final rule, when the Commissioner of Food and Drugs (the Commissioner) determines that an investigator is ineligible to receive a new animal drug for investigational use, the investigator also will be ineligible to conduct any nonclinical study intended to support an application for a research or marketing permit for a new animal drug. This final rule will help ensure adequate protection of animal research subjects and the quality and integrity of data submitted to FDA.

DATES: This rule is effective January 29, 2018.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts,

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vernon Toelle, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5637, *vernon.toelle@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

The regulations in § 511.1(c) (21 CFR 511.1(c)) provide that a disqualified clinical investigator is ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. However, the animal drug regulations permit the same clinical investigator to conduct both nonclinical laboratory studies as well as clinical investigations. We have proposed changes to these regulations (81 FR 57812, August 24, 2016) that would prevent disqualified clinical investigators from conducting nonclinical laboratory studies intended to support an application for a research or marketing permit for a new animal drug, thus enhancing protection of animal research subjects and ensuring the quality and integrity of data submitted to FDA in support of a new animal drug approval.

B. Summary of the Major Provisions of the Final Rule

This final rule expands the clinical investigator disqualification regulations in § 511.1(c) to include the ineligibility of a disqualified investigator to conduct any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug. We received one comment, and it supported the proposed amendment.

C. Legal Authority

FDA is issuing these regulations based on its authority under the new animal drug provisions in section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b) and under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which gives the Agency general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

FDA believes this final rule is not a significant regulatory action as defined by Executive Order 12866 and certifies that it will not have a significant economic impact on a substantial number of small entities. FDA and applicants will not incur additional costs by expanding the scope in part 511 for disqualification of a clinical investigator. The benefit of preventing a disqualified clinical investigator from performing both nonclinical laboratory studies as well as clinical investigations will be enhanced protection of animal research subjects and data integrity submitted to FDA in support of a new animal drug approval.

II. Background

FDA may consider disqualification of a clinical investigator when FDA has information that an investigator has repeatedly or deliberately failed to comply with applicable requirements for the conduct of clinical investigations, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report. Disqualification of an investigator is initiated by the appropriate FDA center depending upon the particular type of test article (*e.g.,* new animal drug for investigational use) under study by the investigator in the clinical investigation. For example, the Center for Veterinary Medicine (CVM or the Center) may pursue disqualification of a clinical investigator who conducted a new animal drug clinical investigation and allegedly submitted to FDA or the sponsor false information in a required report.

The regulations provide the investigator who is subject to disqualification an opportunity to be heard and explain the matter complained of, *i.e.,* explain the alleged violations. If the explanation offered is not accepted by the Center, the investigator will be given an opportunity for an informal regulatory hearing under part 16 (21 CFR part 16). After evaluating all available information, including any explanation presented by the investigator, the Commissioner issues a Commissioner's decision regarding the eligibility of the investigator to receive a particular type of test article (*e.g.,* a new animal drug for investigational use). When disqualified by a Commissioner's decision, the investigator is no longer eligible to receive the particular type of test article under study when the violations occurred (*e.g.,* new animal drugs). Also, an investigator disqualified by a Commissioner's decision is ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

Because CVM regulates drugs for animal use, the study subjects are animals in both clinical investigations and nonclinical laboratory studies intended to support the approval of a new animal drug. Nonclinical laboratory studies such as those for target animal safety and human food safety may be essential in determining whether to approve an application for a research or marketing permit for a new animal drug. For animal drug products regulated by CVM, the same investigator may conduct both clinical investigations and nonclinical laboratory studies. For example, CVM's two most recent clinical investigator disqualification matters involved investigators who were also study directors on nonclinical laboratory studies submitted to CVM in support of applications for a new animal drug. In addition, CVM is aware of multiple persons who conduct both clinical investigations and nonclinical laboratory studies intended to support an application for a research or marketing permit for a new animal drug. Therefore, CVM proposed (81 FR 57812) that it have authority to disqualify an investigator from conducting nonclinical laboratory studies intended to support an application for a research or marketing permit for a new animal drug when that same investigator is disqualified from conducting clinical investigations.

A. Need for the Regulation

Expanding the regulations to include that a disqualified investigator is ineligible to conduct any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug helps to ensure adequate protection of animal research subjects and data integrity. This action also leads to improved public confidence in the nonclinical and clinical data supporting FDA decisions for new animal drug approvals.

B. Summary of Comments to the Proposed Rule

We received one comment to the proposed rule. The comment supports the proposal. Therefore, we are finalizing the proposal without revision.

III. Legal Authority

We are issuing this final rule under section 512(j) of the FD&C Act, which authorizes FDA to issue regulations for exempting from the operation of section 512 of the FD&C Act new animal drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs, and section 701(a) of the FD&C Act, which authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act. An investigator who repeatedly or deliberately submits to FDA or the sponsor false information in a required report would not be considered a qualified expert with the experience required to conduct nonclinical laboratory studies intended to support an application for a research or marketing permit for a new animal drug. FDA therefore concludes that legal authority to promulgate this rule exists under sections 512(j) and 701(a) of the FD&C Act, as essential to protection of the public health and safety and to enforcement of the Agency's responsibilities under sections 201, 501, 502, 503, 512, and 701 of the FD&C Act (21 U.S.C. 321, 351, 352, 353, 360b, and 371).

IV. Comments on the Proposed Rule and FDA Response

We received no adverse or substantive comment and are finalizing without change.

V. Effective Date

This rule is effective January 29, 2018.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule does not impose new requirements on any entity and therefore has no associated compliance costs, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

This rule expands the scope in part 511 of disqualification of a clinical investigator to include ineligibility to conduct nonclinical laboratory studies intended to support an application for a research or marketing permit for a new animal drug. A final rule published on April 30, 2012 (77 FR 25353), prevents a disqualified investigator from conducting any clinical investigation, and therefore applies explicitly to clinical investigations. However, that rule was silent on nonclinical laboratory studies. Thus, before this final rule, a disqualified investigator could conduct a nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug. Because the reason for disqualification in part 511 is typically the repeated or deliberate submission of false information to us or to sponsors in a required report, preventing a disqualified clinical investigator from performing both nonclinical laboratory studies and clinical investigations is essential to adequate protection of animal research subjects and data integrity.

We will not incur additional costs by expanding the scope in part 511 for disqualification of a clinical investigator because we already post the names of any disqualified investigator on FDA's internet site at *https://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true.* Similarly, industry will not incur additional costs because the rule does not require applicants to perform additional tasks. For instance, upon disqualification, we post the respective investigator's name on FDA's internet site, which helps mitigate the employment of a disqualified investigator for clinical investigations or nonclinical laboratory studies intended to support an application for a research or marketing permit for a new animal drug. The benefit of preventing a disqualified clinical investigator from performing both nonclinical laboratory studies and clinical investigations will be enhanced protection of animal research subjects and data integrity.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 511

Animal drugs, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16 and 511 are amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. In § 16.1, in paragraph (b)(2), revise the numerically sequenced entry for § 511.1(c)(1) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

(c)(1), relating to whether an investigator is eligible to receive test articles under part 511 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products; and any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

* * * * *

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

■ 3. The authority citation for part 511 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 360b, 371.

■ 4. In § 511.1:

■ a. Revise the section heading;

■ b. Revise the last sentence in paragraph (c)(1);

■ c. Add paragraphs (c)(1)(i) and (ii);

■ d. Revise the last sentence in paragraph (c)(2);

■ e. Add paragraphs (c)(2)(i) and (ii); and

■ f. Revise paragraph (c)(6).

The revisions and additions read as follows:

§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

(c) * * *

(1) * * * If an explanation is offered but not accepted by the Center for Veterinary Medicine, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the question of whether the investigator is eligible to receive test articles under this part and eligible to conduct:

(i) Any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA; and

(ii) Any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

(2) * * * The notification also will explain that an investigator determined to be ineligible to receive test articles under this part will be ineligible to conduct:

(i) Any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products; and

(ii) Any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug.

* * * * *

(6) An investigator who has been determined to be ineligible under paragraph (c)(2) of this section may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ all test articles, and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA and any nonclinical laboratory study intended to support an application for a research or marketing permit for a new animal drug, solely in compliance with the applicable provisions of this chapter.

* * * * *

Dated: December 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27973 Filed 12–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2017–N–6842]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Pressure Wedge for the Reduction of Cesarean Delivery

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the pressure wedge for the reduction of cesarean delivery into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the pressure wedge for the reduction of cesarean delivery's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective December 28, 2017. The classification was applicable on December 19, 2016.

FOR FURTHER INFORMATION CONTACT: Mack Hall III, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3572, Silver Spring, MD 20993–0002, 301–796–5621, *mack.hall@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the pressure wedge for the reduction of cesarean delivery as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket