20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2220a [Amended]

■ 2. In § 520.2220a, in paragraph (a)(2), add in numerical sequence ''058829''.

Dated: November 16, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

FR Doc. E9–27885 Filed 11–19–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR 2550

RIN 1210–AB13

Investment Advice—Participants and Beneficiaries

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Withdrawal of final rule.

SUMMARY: This document withdraws final rules under the Employee Retirement Income Security Act, and parallel provisions of the Internal Revenue Code of 1986, relating to the provision of investment advice to participants and beneficiaries in individual account plans, such as 401(k) plans, and beneficiaries of individual retirement accounts (and certain similar plans). Final rules were published in the **Federal Register** on January 21, 2009 (74 FR 3822). The effective and applicability dates of the final rules had been deferred until May 17, 2010, in order to permit a review of policy and legal issues raised with respect to the rules. As discussed in this Notice, the Department has determined to withdraw the final rules. The Department also intends to soon propose a revised rule limited to the application of the statutory exemption relating to investment advice.

DATES: Effective January 19, 2010, the final rule published January 21, 2009 amending 29 CFR Part 2550 (74 FR 3822), for which the effective and applicability date was delayed on March 20, 2009 (74 FR 11847), May 22, 2009 (74 FR 23951) and November 17, 2009 (74 FR 59092), is withdrawn.

FOR FURTHER INFORMATION CONTACT: Fred Wong, Office of Regulations and Interpretations, Employee Benefits Security Administration (EBSA), (202) 693–8500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

A. Background

On January 21, 2009, the Department of Labor published final rules on the provision of investment advice to participants and beneficiaries of participant-directed individual account plans and to beneficiaries of individual retirement accounts and certain similar plans (IRAs) (74 FR 3822). The rules implement a statutory prohibited transaction exemption under ERISA Section 408(b)(14) and Sec. 408(g), and under section 4975 of the Internal Revenue Code of 1986 (Code),[1] and also contain an administrative class exemption granting additional relief. As published, these rules were to be effective on March 23, 2009. On February 4, 2009, the Department published in the **Federal Register** (74 FR 6007) an invitation for public comment on a proposed 60-day extension for the effective dates of the final rules until May 22, 2009, and a proposed conforming amendment to the applicability date of Section 2550.408g–1, in order to afford the Agency the opportunity to review legal and policy issues relating to the final rules. The Department also invited public comments on the provisions of those rules and on the merits of rescinding, modifying or retaining the rules. In response to this invitation, the Department received 28 comment letters.[2] On March 20, 2009, the Department adopted the 60-day extension of the final rule's effective and applicability date. (See 74 FR 11847). In order to afford the Department additional time to consider the issues raised by commenters, the effective and applicability dates were further delayed until November 18, 2009 (74 FR 23951), and then until May 17, 2010.

B. Comments Received

A number of the commenters expressed the view that the final rule raises significant issues of law and policy, and should be withdrawn. Several of these commenters argued that the class exemption contained in the final rule permits financial interests that would cause a fiduciary adviser, and individuals providing investment advice on behalf of a fiduciary adviser, to have conflicts of interest, but does not contain conditions that would adequately mitigate such conflicts. They asserted that investment advice provided under the class exemption therefore might be tainted by the fiduciary adviser's conflicts. Other commenters expressed concerns about those provisions of the rule relating to the ''fee-leveling'' requirement under the statutory exemption. In particular, some opined that the Department's interpretation of the statutory exemption's fee-leveling requirement is incorrect for permitting the receipt of varying fees by an affiliate of a fiduciary adviser. As a result, they argued, a fiduciary adviser under such a fee-leveling arrangement has a conflict of interest, and the final rule does not adequately protect against investment advice that is influenced by the financial interests of the fiduciary adviser's affiliates. Commenters who advocated retention of the final rule argued that it contains strong safeguards that would protect the interests of plan participants and beneficiaries.

C. Analysis and Determination

As documented in the Department's regulatory impact analysis (RIA) of the January 2009 final regulation and class exemption, defined contribution (DC) plan participants and IRA beneficiaries

[1] These provisions were added to ERISA and the Code by the Pension Protection Act of 2006 (PPA), Public Law 109–280, 120 Stat. 780 (Aug. 17, 2006).

[2] These comments are available on the Department's Web site at: *http://www.dol.gov/ebsa/regs/cmt-investmentadvicefinalrule.html.*

often make costly investment errors. Those who receive and follow quality investment advice can reduce such errors and thereby reap substantial financial benefit. The Department estimated that the PPA statutory exemption as implemented by the final regulation, together with the final class exemption, would extend investment advice to 21 million previously unadvised participants and beneficiaries, generating $13 billion in annual financial benefits at a cost of $5 billion, for a net annual financial benefit of $8 billion.

In arriving at its estimates, the Department assumed that on average participants and beneficiaries who are advised make investment errors at one-half the rate of those who are not. The Department further assumed that different types of investment advice arrangements on average would be equally effective: Arrangements operating without need for exemptive relief, those operating pursuant to the PPA, and those operating pursuant to the class exemption all would reduce investment errors by one-half on average.

The Department's assumptions regarding the effectiveness of different advice arrangements were subject to uncertainty, particularly as applied to its assessment of the final class exemption's effects. In the preamble to the January 2009 final regulation and class exemption the Department noted evidence that conflicts of interest, such as those that might be attendant to advice arrangements operating pursuant to the class exemption, can sometimes taint advice. Conflicted advisers pursuing their own interests, and the investment managers who compensate them, may profit at the expense of participants and beneficiaries. The conditions attached to the class exemption were intended to ensure that advisers operating pursuant to the class exemption would honor the interests of participants and beneficiaries.

As discussed earlier, a number of commenters raised legal and policy issues concerning the exemption and, in particular, questioned the adequacy of the final class exemption's conditions to mitigate the potential for investment adviser self-dealing. The Department believes that the questions raised in these comments are sufficient to cast doubt on the conditions' adequacy to mitigate advisers' conflicts. If conflicts are not mitigated advice might be tainted. Therefore the Department has set aside its previous assumption that participants and beneficiaries who follow advice delivered pursuant to the final class exemption will commit investment errors at one-half the rate of those who are unadvised, together with its previous conclusion that the final class exemption's benefits justify its cost. Instead the Department believes that doubts as to whether the final class exemption's conditions are adequate to mitigate conflicts justify withdrawal of the final class exemption. Accordingly, the Department is withdrawing the January 2009 final rule. With regard to the statutory prohibited transaction exemption under ERISA Section 408(b)(14) and Section 408(g), and Code Section 4975, in order to address the absence of regulatory guidance that results from withdrawal of the January 2009 final rule, the Department intends to propose regulations that, upon adoption, implement those provisions. Work is currently being completed on those proposed regulations, and the Department anticipates that they will be published in the **Federal Register** shortly.

For the reasons set forth above, the publication on January 21, 2009 (74 FR 3822), of the final rule amending 29 CFR Part 2550, for which the effective and applicability date was delayed on March 20, 2009 (74 FR 11847), May 22, 2009 (74 FR 23951) and November 17, 2009, is withdrawn.

Signed at Washington, DC, this 16th day of November 2009.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

[FR Doc. E9–27889 Filed 11–19–09; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–0946]

RIN 1625–AA00

Safety Zones; Blasting and Dredging Operations and Movement of Explosives, Columbia River, Portland to St. Helens, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing two temporary safety zones on the Columbia River to help ensure the safety of the maritime public during blasting and dredging operations taking place near St. Helens, Oregon as well as the movement of explosives for those operations from Portland, Oregon to the work site. The first temporary safety zone is a fixed zone around the area where the blasting and dredging operations will be taking place near St. Helens, Oregon. The second temporary safety zone is a moving zone around the barge KRS 200–6 at any time that it has explosives onboard.

DATES: This rule is effective from 12:01 a.m. on November 20, 2009 through 11:59 p.m. on February 28, 2010.

The safety zone has been enforced with actual notice since October 30, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2009–0946 and are available online by going to *http://www.regulations.gov*, inserting USCG–2009–0946 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail MST1 Jaime Sayers, Waterways Management Division, U.S. Coast Guard Sector Portland; telephone 503–240–9319, e-mail *Jaime.A.Sayers@uscg.mil*. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) because the publishing of an NPRM would be impracticable and contrary to public interest since immediate action is needed to ensure the public's safety during blasting and dredging operations. Delaying the implementation of the safety zone would subject the public to the hazards associated with blasting and dredging operations and the movement of explosives for those operations. The