Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

RAILROAD RETIREMENT BOARD

20 CFR Parts 355, 356

RIN 3220–AB24

Adjustment of Civil Monetary Penalties

AGENCY: Railroad Retirement Board.

ACTION: Proposed rule.

SUMMARY: As required by subsection(s) of the Debt Collection Improvement Act of 1996, the Railroad Retirement Board (Board) hereby proposes to amend its regulations to provide for adjustments in the amount of civil monetary penalties. The amendment will increase the amount of penalties under the jurisdiction of the Board to keep pace with inflation.

DATES: Comments shall be submitted on or before November 21, 1996.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Michael C. Litt, General Attorney, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611, (312) 751–4929, TDD (312) 751–4701.

SUPPLEMENTARY INFORMATION: Subsection (s) of the Debt Collection Improvement Act of 1996, Public Law 104–134, amended the Federal Civil Penalties Inflation Adjustment Act of 1990 to require agencies to publish regulations within 180 days of enactment of the amendment, April 26, 1996, providing for the adjustment of civil monetary penalties provided by law within the jurisdiction of the agency.

The penalties authorized in the Program Fraud Civil Remedies Act and under the false claims provisions at 31 U.S.C. 3729(a) are within the jurisdiction of the Railroad Retirement Board and, therefore, the Board is required to publish regulations providing for the adjustment of the monetary penalties.

The Federal Civil Penalties Inflation Adjustment Act requires that civil monetary penalties be adjusted by the percentage by which the Consumer Price Index for the month of June of the calendar year preceding the adjustment exceeds the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted. That Act also mandates rounding of the adjustment, depending on the amount of the maximum penalty: any adjustment must be rounded to the nearest $1,000 for maximum penalties greater than $1,000 and less than or equal to $10,000. However, the amendment limits the initial increase to ten percent of the amount of the maximum penalty.

In both instances the ratio of the Consumer Price Index for the month of June of the calendar year preceding the adjustment to the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted is 456.7/327.9, which would produce an increase considerably in excess of ten percent of the penalties. Under the Program Fraud Civil Remedies Act the maximum penalty is $5,000 (there is no minimum penalty); accordingly, the Board proposes to increase the maximum penalty by $500. The minimum and maximum penalties under 31 U.S.C. 3729(a) are $5,000 and $10,000 respectively; accordingly, the Board proposes to increase the minimum penalty by $500 and the maximum penalty by $1,000.

The amendment also restricts application of the adjustments to violations which occur after the date the increase takes effect. Therefore, the increases would not apply in the case of any violation occurring before the effective date of these regulations.

The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action for purposes of Executive Order 12866. Therefore, no regulatory impact analysis is required. There are no information collections associated with this rule.

List of Subjects in 20 CFR Parts 355 and 356

Railroad employees, Railroad retirement.

For the reasons set forth in the preamble, title 20, chapter II, subchapter E, is proposed to be amended as follows:

PART 355—REGULATIONS UNDER THE PROGRAM FRAUD CIVIL REMEDIES ACT OF 1986

1. The authority citation for part 355 continues to read as follows:

Authority: 31 U.S.C. 3809.

§ 355.3 Basis for civil penalties and assessments.

2. Section 355.3(a)(1)(iv) is amended by adding at the end thereof a new sentence to read as follows: This penalty is subject to adjustment in accord with part 356 of this chapter.

3. Section 355.3(b)(1)(ii) is amended by adding at the end thereof a new sentence to read as follows: This penalty is subject to adjustment in accordance with part 356 of this chapter.

4. A new part 356 is added to subchapter E to read as follows:

PART 356—CIVIL MONETARY PENALTY INFLATION ADJUSTMENT

Sec.
356.1 Introduction.
356.2 Program Fraud Civil Remedies Act of 1986.
356.3 False claims.

Authority: 28 U.S.C. 2461; 31 U.S.C. 3729; 31 U.S.C. 3809.

§ 356.1 Introduction.

(a) The Federal Civil Penalties Inflation Adjustment Act requires that civil monetary penalties be adjusted by the percentage by which the Consumer Price Index for the month of June of the calendar year preceding the adjustment exceeds the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted. That Act also mandates rounding of the adjustment, depending on the amount of the maximum penalty.

(b) The ratio in of the Consumer Price Index for the month of June of the calendar year preceding this adjustment to the Consumer Price Index for the month of June of the calendar year in which the amount of civil monetary penalties provided for under the Program Fraud Civil Remedies Act (31 U.S.C. 3801–3812) and the false claims provisions at 31 U.S.C. 3729(a) was last set or adjusted, 1986, is 456.7/327.9, which produces the following increases in the penalties after applicable rounding:

(1) The maximum penalty under Program Fraud Civil Remedies Act for a

false claim or statement would be increased from $5,000 to $7,000.

(2) The maximum and minimum penalties under the false claims provisions at 31 U.S.C. 3729(a) would be increased from $10,000 to $14,000 and $5,000 to $7,000, respectively.

(c) Imposition of the increases are limited to actions occurring after the effective date of the increases.

(d) No increase may exceed ten percent of the penalty or range of penalties, as applicable.

§ 356.2 Program Fraud Civil Remedies Act of 1986.

In the case of penalties assessed under part 355 of this chapter, an additional penalty of $500 may be assessed for claims or statements made after October 23, 1996.

§ 356.3 False claims.

In the case of penalties assessed under 31 U.S.C. 3729 based on actions occurring after October 23, 1996, the minimum penalty is $5,500 and the maximum penalty is $11,000.

Dated: September 19, 1996.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 96–24544 Filed 10–22–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. 96N–0057]

National Environmental Policy Act; Proposed Revision of Policies and Procedures; Reopening of Comment Period as to Specific Documents

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to November 22, 1996, the comment period on specific information that supports certain categorical exclusions proposed by FDA in the proposed rule entitled ''National Environmental Policy Act; Proposed Revision of Policies and Procedures.'' The proposal was published in the Federal Register of April 3, 1996 (61 FR 14922) (republished on May 1, 1996 (61 FR 19476)). FDA is reopening the comment period for 30 days for the sole purpose of inviting public comments on those categorical exclusions for which information has been added to the administrative record.

DATES: Written comments must be received by or postmarked on or before November 21, 1996. Comments postmarked after such date will not be considered.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For information regarding human drugs: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5721.

For information regarding biologics: Nancy A. Roscioli, Center for Biologics Evaluation and Research (HFM–205), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3031.

For information regarding veterinary medicines: Charles E. Eirkson, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1683.

For information regarding foods: Buzz L. Hoffmann, Center for Food Safety and Applied Nutrition (HFS–246), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3005.

For information regarding medical devices and radiological health: Mervin O. Parker, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 3, 1996 (61 FR 14922) (republished on May 1, 1996 (61 FR 19476)), FDA published a proposed rule to amend its regulations governing compliance with the National Environmental Policy Act of 1969 (NEPA) as implemented by the regulations of the Council on Environmental Quality. The primary purpose of the proposed rule is to increase the efficiency of FDA's implementation of NEPA and reduce the number of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an environmental impact statement nor an environmental assessment (EA) is required. The proposed rule was issued in response to an initiative announced in the President's National Performance Reports, ''Reinventing Drug and Medical Device Regulations,'' April 1995, and ''Reinventing Food Regulations,'' January 1996. The proposal gave interested persons the opportunity to submit written comments until July 2, 1996.

One of the categorical exclusions included in the proposed rule is a categorical exclusion for an ''[a]ction on an NDA [new drug application], abbreviated application, or a supplement to such application, or action on an OTC [over-the-counter] monograph, if the action increases the use of the active moiety, but the concentration of the substance in the environment will be below 1 part per billion [ppb].'' (See proposed § 25.31(b) (61 FR 19476 at 19492).) The agency proposed this categorical exclusion because FDA has determined that such actions for which concentrations of the substance in the environment from use and disposal will be below 1 ppb ordinarily do not have a significant effect on the environment. If there are specific environmental concerns beyond those relating to use and disposal, for example sourcing, FDA may give a specific action further environmental consideration.

On July 2, 1996, FDA received a request from Edward Lee Rogers, on behalf of the Oregon Natural Resources Council Fund and the Oregon Natural Resources Council Action, to extend the comment period to permit comment on the ''underlying data upon which FDA relies for the claimed adequacy and appropriateness of that [1 ppb] criteria.''

FDA considered this request and has decided to add information to the administrative record and reopen the comment period. FDA has added to the administrative record a report on the ''Retrospective Review of Ecotoxicity Data Submitted in Environmental Assessments.'' This report summarizes the ecotoxicity data that supports the Center for Drug Evaluation and Research's (CDER's) proposal to categorically exclude actions on an NDA, abbreviated application, or a supplement to such application, or action on an OTC monograph, if the action increases the use of the active moiety, but the concentration of the substance in the environment will be below 1 ppb. FDA has also added to the administrative record an index of the petitions and actions that support certain categorical exclusions for foods,