approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning August 4, 1995, because the supplemental NADA contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the use for which the supplemental NADA is approved.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d) in the ''Category II'' table in the entry for ''Ivermectin'' under the third column by removing ''182 g/ton (0.02%)'' and adding in its place ''1,180 g/ton (0.13%)''.

3. Section 558.300 is amended by revising paragraphs (c)(1)(i) and (iii) to read as follows:

§ 558.300 Ivermectin.

* * * * *

(c) * * *

(1) * * *

(i) *Amount.* For growing-finishing swine feed 1.8 grams of ivermectin per ton (to provide 0.1 milligram per kilogram of body weight per day). For mature and breeding swine feed 1.8 to 11.8 grams of ivermectin per ton (to provide 0.1 milligram per kilogram of body weight per day).

* * * * *

(iii) *Limitations.* Feed as the only feed for 7 consecutive days. For use in swine only. Withdraw 5 days before slaughter.

* * * * *

Dated: July 26, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95–19281 Filed 8–3–95; 8:45 am]

BILLING CODE 4160–01–F

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 2606 and 2609

RIN 1212–AA72

Debt Collection Procedures—Tax Refund Offset

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation is adopting, as a final rule with change, amendments that it previously issued as an interim final rule. The procedures in this rule enable the PBGC to refer past-due, legally enforceable debts to the internal Revenue Service to be offset against federal tax refunds.

EFFECTIVE DATE: This rule is effective August 4, 1995.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Attorney, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026, 202–326–4024 (202–326–4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION: On December 6, 1994 (59 FR 62571), the Pension Benefit Guaranty Corporation published an interim final rule that amended its administrative review and debt collection regulations (29 CFR parts 2606 and 2609). As amended, the PBGC's regulations include the procedures required for participation in the federal tax refund offset program authorized by 31 U.S.C. 3720A. Section 3720A, and Internal Revenue Service regulations thereunder (26 CFR 301.6402–6), include requirements to ensure that debts referred for offset against amounts otherwise payable as tax refunds are past-due and legally enforceable and that the agency has made reasonable efforts (pursuant to regulations) to obtain payment.

The one comment on the interim final rule expressed concern about its effects on due process of law requirements under the Fifth Amendment to the United States Constitution. The PBGC believes that the commenter's concern is unwarranted. As noted above, the pre-referral procedures required by IRS regulations, which are included in the interim final rule, provide due process protections. Among other things, before the PBGC refers a debt for tax refund offset, the debtor has at least 60 days to present evidence that all or part of the debt is not past-due or not legally enforceable (§ 2609.33(b)(2)).

This final rule makes no changes in the rules of agency organization and procedure that wee prescribed by the interim final rule and have been in effect since January 5, 1995. Therefore, the Administrative Procedure Act does not require further notice and public procedure or a delayed effective date, and the PBGC for good cause finds that both such actions are unnecessary (5 U.S.C. 553 (b) and (d)).

E.O. 12866

The PBGC previously determined that the interim final rule was not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

List of Subjects

29 CFR Part 2606

Administrative practice and procedure, Organization and functions (Government agencies), Pension insurance, Pensions.

29 CFR Part 2609

Administrative practice and procedure, Claims.

Accordingly, the interim final rule amending 29 CFR parts 2606 and 2609 that was published at 59 FR 62571 on December 6, 1994, is adopted as a final rule without change.

Issued in Washington, DC this 31st day of July, 1995.

Martin Slate,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 95–19175 Filed 8–3–95; 8:45 am]

BILLING CODE 7708–01–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

33 CFR Part 137

[Docket 50112]

RIN 2105–AC01

Limit of Liability for Deepwater Ports

AGENCY: Office of Secretary, Department of Transportation.

ACTION: Final rule.

SUMMARY: This rule establishes a $62 million limit of liability for the Louisiana Offshore Oil Port (LOOP) deepwater port. This limit applies only to those oil spills where LOOP would be entitled to limit its liability in accordance with the Oil Pollution Act of 1990. This action does not alter LOOP's unlimited liability for spills caused by gross negligence, willful misconduct, or violation of certain Federal regulations. LOOP is the only U.S. deepwater port in operation at this time; specific liability limits for other, future deepwater ports will be established through separate rulemakings as appropriate.

EFFECTIVE DATE: August 4, 1995.

ADDRESSES: Unless otherwise indicated, documents referenced in this preamble are available for inspection or copying in Docket 50112, Office of Documentary Services (C–55), U.S. Department of Transportation, room PL 401 (Plaza level), 400 Seventh St., SW., Washington, DC. 20590–0001. Certain studies referenced in this notice may be ordered from the National Technical Information Service (NTIS), Springfield, VA 22161; phone orders (703) 487–4650 (Visa, Mastercard and American Express accepted).

FOR FURTHER INFORMATION CONTACT: Mr. Robert I. Stein, Office of Environment, Energy and Safety, at (202) 366–4846, or Mr. Paul B. Larsen, Office of the Assistant General Counsel for Environmental, Civil Rights, and General Law, at (202) 366–9161.

SUPPLEMENTARY INFORMATION:

Regulatory History

On February 8, 1995, the Department of Transportation published a notice of proposed rulemaking (NPRM) entitled Limit of Liability for Deepwater Ports. The Department received 12 letters commenting on this proposal. No public hearings were requested or held. A request for an extension of the comment period was received, but decided against (this is further discussed in paragraph (5) below).

Statutory Basis and Purpose

The purpose of this regulatory action is to establish an appropriate limit of liability for deepwater ports in accordance with section 1004 of OPA 90 (Public Law 101–380).

Section 1004 originally set the limit of liability for deepwater ports at $350 million. However, it also allows the limit to be adjusted to a lower amount as appropriate (but not less than $50 million), subject to a study of the relative operational and environmental risks of transporting oil to the United States by deepwater ports compared to other ports.

The relative risk study, entitled the "Deepwater Ports Study," has been completed and forwarded to Congress. The study concluded that deepwater ports represent a lower operational and environmental risk for delivering crude oil to the United States than the three other common modes of crude oil delivery (direct vessel deliveries, lightering, and offshore mooring stations). Copies of the Deepwater Port Study may be ordered from NTIS (publication number PB94–124054).

At present, the only deepwater port in operation in the United States is LOOP. However, other deepwater ports may be built in the future. Because there may be significant engineering and environmental differences between different deepwater ports, the Department has determined that it is necessary to review any deepwater port individually before setting its limit of liability within the statutory limits of $50 million and $350 million. Limits for other deepwater ports may be different from LOOP's limit.

Therefore, in accordance with its authority under section 1004(d)(2)(C) of OPA 90 (33 U.S.C. 2704), and for reasons explained in the NPRM and this preamble, the Department is establishing a $62 million limit of liability for the LOOP deepwater port.

Discussion of Comments and Changes

Twelve responses were received which commented on several issues in the NPRM. These comments, and the Department's deliberations, are discussed below.

1. Limit of Liability

Ten comments addressed the limit of liability issue, seven of which supported a $58 million limit and one which supported a $50 million limit. These comments stated that the present $350 million limit of liability is inequitable to deepwater ports, particularly when compared to the limits of liability allowed for tank vessels. The comments pointed out the results of the "Deepwater Ports Study" (which determined that delivery of oil via deepwater ports represented a lower environmental risk than delivery by tankers, lightering, or offshore mooring station) and the Coast Guard's risk analysis of LOOP (which determined the maximum credible pipeline spill to be 5,194 barrels), and argued that the limit of liability should reflect the lower risks and smaller credible spill sizes of deepwater ports.

One comment supported an unspecified limit between $58 million and $150 million. Another comment alternatively suggested that it would be more equitable for the deepwater port limit of liability to be the same as for other offshore facilities: $75 million plus cleanup costs, with a requirement for demonstrated financial responsibility of $150 million.

The Department has determined that it is appropriate national policy that a deepwater port should be liable for the cost of its maximum credible spill (assuming no gross negligence or other acts that would disqualify it from limiting its liability). Further, since Congress has directed that the liability limit should be based on the study of the risk of deepwater ports relative to the risk of other means of transporting oil by vessel, it is inappropriate to base a deepwater port limit of liability on that for other offshore facilities.

The NPRM discussed a worst-case unit spill cost of $11,088 per barrel for crude oil, which was based upon national historical spill costs up to 1992. Although it is appropriate to revise the unit cost to a more-current amount, at this time no new historical cost data is available and the Department has decided to use the Consumer Price Index (CPI) as a basis for revision. The national average CPI for 1992 was 140.3 and the most current CPI (March 1995) is 151.4, an increase of 7.9 percent. Therefore, the new unit spill cost is $11,965 per barrel. Applying this to LOOP's maximum credible spill of 5,194 barrels yields $62,146,210. Accordingly, the Department is setting the limit of liability for LOOP at $62 million.

The CPI does not specifically track oil spill costs in its analysis. However, Section 1004 (d)(4) of OPA 90 requires adjustment of the liability limit reflecting significant increases in the CPI.

2. Periodic Review of Limits of Liability

The NPRM requested comments on whether the Department should reassess limits of liability at fixed time intervals. Two comments addressed this issue.

One comment suggested 3-year intervals (in order to be consistent with other periodic review requirements in OPA 90) and the other comment suggested 10 years. DOT will issue a separate CPI adjustment regulation as required by law.

3. Universal Versus Port-by-Port Limit of Liability

One comment called for a single (universal) limit of liability for all deepwater ports instead of the NPRM's proposed port-by-port limit for each individual deepwater port. The comment argued that, by virtue of the Federal licensing process, all deepwater ports would be designed and operated at the same level of safety. Therefore, it is not necessary to establish individual limits.

The Department disagrees that there is no basis for setting individual limits of liability for different deepwater ports. This is because, although all deepwater ports will be designed and operated to the same high safety standards, the worst-case spill can still differ substantially from port to port. LOOP's maximum credible pipeline spill of 5,194 barrels is directly governed by its distance offshore (18 miles), its design flow rate (100,000 barrels per hour), and the size of its pipeline (48 inches). Even when designed and operated to the same safety standards, these parameters may be significantly different for another deepwater port, resulting in a different maximum credible spill.

The same commenter also discussed some economic issues; these are addressed in the ''Assessment'' section of this preamble.

4. Consistency Determination

The state of Louisiana requested submittal of a Consistency Determination with respect to its Coastal Zone Management Plan in accordance with 15 CFR part 930 subpart C. Such determinations are required whenever any action by a Federal agency affects land or water uses with a state's coastal zone.

The Department has determined that a Consistency Determination is not necessary because this action is administrative in nature and does not affect either land or water usage.

5. Extension of Comment Period

One commenter has recently acquired an interest in a planned deepwater port project off the coast of Texas and requested an extension of the comment period to respond to the NPRM.

The Department has determined that extending the comment period for this reason would not materially benefit the rulemaking. This is because this final rule only directly affects the LOOP deepwater port; other deepwater ports will be separately and individually evaluated for their own limit of liability when appropriate.

6. Basis for Regulatory Action

One comment disagreed that the findings of the ''Deepwater Ports Study'' form a sufficient basis for this regulatory action (to reduce the limit of liability for deepwater ports) because the Study did not include relative risks of other onshore and offshore facilities. The comment stated that many onshore facilities pose less risks than deepwater ports and, therefore, adjusting limits of liability for deepwater ports should not be undertaken without also adjusting limits of liability for onshore and offshore facilities.

The ''Deepwater Ports Study'' did not include relative risk analyses of onshore and offshore facilities because these are not alternative modes for the transportation of oil by vessel to the United States. The Department has determined that the Study's findings are a sufficient basis for this action. Further, although OPA 90 does give the Department discretion to also adjust limits of liability for transportation-related onshore facilities, such action would be a separate rulemaking.

7. Joint Liability Scenarios

The NPRM discussed several scenarios in which LOOP might be liable (solely or jointly) for a tanker spill. LOOP's comment on this issue took exception to these scenarios, stating that OPA 90 does not provide for joint liability: the source of the spill is considered the responsible party except where a third party was solely responsible for the spill. LOOP stated that in cases where responsibility for a spill may be shared, liability under such a spill would not be created by OPA 90 and therefore such scenarios are outside the scope of this rulemaking.

Although OPA 90 does not recognize joint responsible parties other than between the owner, operator, or demise charterer of a vessel, it does recognize (in section 1002(d)(2)(A)) that third parties might cause an incident, and makes them liable up to their limit as if they were the responsible party. In addition, liability under OPA 90 is defined to be the standard of liability which obtains under 33 U.S.C. 1321. As noted in the conference report, this has been construed as joint and several liability. The Department has determined that the existence of potential liability for a tanker spill, under limited circumstances, was not a determinative factor in setting the liability limits in this rule.

8. Unlimited Liability Provisions of OPA 90

The $62 million limit of liability herein applies only to spills at LOOP that are not caused by gross negligence, willful misconduct, or violation of certain Federal regulations in accordance with section 1004 of OPA 90 (33 U.S.C. 2704). The unlimited liability provisions of OPA 90 are not affected by this rulemaking.

Regulatory Analyses and Notice

DOT Regulatory Policies and Procedures

This final rule is considered to be a significant rulemaking under DOT Regulatory Policies and Procedures, 44 FR 11040, because of substantial industry interest.

Executive Order 12866

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12866, and it has been determined that it is not an economically significant rulemaking.

Executive Order 12612

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that it does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Department must consider whether this regulation will have a significant impact on a substantial number of small entities.

The NPRM stated that the proposed action only directly affected a single company, Louisiana Offshore Oil Port (LOOP), Inc., which owns and operates the only deepwater port in the United States at present. The NPRM also stated that neither LOOP specifically, nor deepwater ports in general, qualify as small business concerns. The NPRM specifically requested comments from small companies affected by the proposed action; however, no comments were received.

Therefore, the Department concludes that this action does not affect any small business entities.

Paperwork Reduction Act

This final rule contains no collection of information requirements under the Paperwork Reduction Act.

Assessment

The regulatory evaluation in the NPRM stated that the proposed action might have an economic effect on LOOP (depending upon what final limit of liability was established), but that no effect was anticipated on the general private sector, consumers, or Federal, state or local governments. Only two comments were received that addressed the economic effects of this action.

The first comment was from LOOP, Inc., which stated: ''OPA's liability limit plays an important part in LOOP's insurance costs. When the OPA limit is reduced, it will most probably result in a lowering of the total insurance premiums paid by LOOP. These reduced costs will enable LOOP to be more competitive and could be reflected in lower rates for service, thus benefiting oil importers and, ultimately, American consumers of oil products such as gasoline.''

The Department recognizes that LOOP's business activity is to receive crude oil cargoes from offshore VLCC and ULCC tankers and transfer those cargoes ashore (via seafloor pipeline), an activity in which it competes with local lightering companies that provide a similar transfer service using small tankers (typically 80,000 deadweight tons or smaller). LOOP's original limit of liability under the Deepwater Ports Act was $50 million; in 1980 the liability limit was established at $150 million. OPA 90's default limit of liability of $350 million raised LOOP's insurance costs. This rulemaking establishes $62 million as the appropriate limit of liability for LOOP. It is noted that the limit of liability of typical lightering vessels (against which LOOP competes) is less than $40 million.

The second comment was from Petroport, Inc., which is planning to develop a deepwater port 35 miles offshore of Freeport, Texas. Petroport's comment discussed the economic effect of establishing limits of liability for deepwater ports on a port-by-port basis rather than a single, universal limit for all deepwater ports. This comment stated: ''Petroport is concerned that if the Department establishes a limit only for LOOP at this time and requires separate rulemakings for future deepwater ports, then its own deepwater port, and other such facilities, would be placed at a severe competitive disadvantage. The Department inadvertently would create uncertainty in the market, could possibly discourage, and certainly would delay, other deepwater port ventures through the creation of unnecessary regulatory burdens.''

Petroport, Inc., was also concerned that a new deepwater port would have to operate under OPA 90's default $350 million limit of liability until completion of a rulemaking to establish a lower, more-appropriate limit. Petroport, Inc., was further concerned that the port-by-port approach would impede development of other deepwater ports, thereby creating a noncompetitive monopoly for LOOP.

The Department disagrees that the port-by-port approach for setting individual limits of liability would discourage or delay the overall development of a deepwater port. The deepwater port licensing process (found in 33 CFR Part 148) already requires, among other things, submittal of an environmental analysis which, in turn, must evaluate spill sizes and the possibility of pollution incidents resulting from personnel and equipment failures, natural calamities and casualties, etc. The environmental analysis submittal will allow the Department timely development of an appropriate limit of liability concurrently with the overall processing of the license application. Therefore, this action will not delay development of any new deepwater port project nor does it impose any new or undue regulatory burden on an applicant.

The Department also disagrees that any delays in development of a deepwater port foster a noncompetitive monopoly for LOOP. Even though LOOP is the sole deepwater port in the United States, it does not benefit from a monopolistic position in the market: LOOP's primary competition comes from lightering companies, not from the presence (or absence) of other deepwater ports. Other deepwater ports will be in a similar competitive situation with local lightering companies.

The Department concludes that, although this action may improve LOOP's competitiveness as an individual company, the overall competitiveness of oil transfer business activity will not be significantly affected. Therefore, the anticipated impact of this rulemaking does not warrant a full Regulatory Analysis or Evaluation.

National Environmental Policy Act

The Department has determined that this rulemaking is administrative in nature and therefore is categorically excludable from further environmental assessment.

List of Subjects in 33 CFR Part 137

Claims; Harbors; Insurance; Oil pollution.

For the reasons discussed in the preamble, the Department amends 33 CFR part 137 as follows:

SUBCHAPTER M—MARINE POLLUTION FINANCIAL RESPONSIBILITY AND COMPENSATION

PART 137—DEEPWATER PORT LIABILITY FUND

1. The authority citation for 33 CFR part 137 is revised to read as follows:

Authority: 33 U.S.C. 1509(a), 1512(a), 1517(j)(1)), 2704; 49 CFR 1.46.

2. Subpart G is added as follows:

Subpart G—Limits of Liability

Sec.
137.601 Purpose.
137.603 Limits of Liability.

Subpart G—Limits of Liability

This subpart sets forth the limits of liability for U.S. deepwater ports in accordance with section 1004 of the Oil Pollution Act of 1990 (33 U.S.C. 2704).

§ 137.603 Limits of Liability.

(a) The limits of liability for U.S. deepwater ports will be established by the Secretary of Transportation on a port-by-port basis, after review of the maximum credible spill and associated costs for which the port would be liable. The limit for a deepwater port will not be less than $50 million or more than $350 million.

(1) The limit of liability for the LOOP deepwater port licensed and operated by Louisiana Offshore Oil Port, Inc., is $62,000,000.

(2) [Reserved]

(b) [Reserved]

Dated: July 31, 1995.

Federico Peña,

Secretary of Transportation.

[FR Doc. 95–19212 Filed 8–3–95; 8:45 am]

BILLING CODE 4910–62–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MO–18–1–6024A; FRL–5263–9]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This document takes final action to approve the State