
List of Subjects in 21 CFR Part 201
Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 201 be amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:


2. New §201.323 is added to subpart G to read as follows:

§201.323 Aluminum in large and small volume parenterals used in total parenteral nutrition.

(a) The aluminum content of all large volume parenteral (LVP) drug products used in total parenteral nutrition (TPN) therapy shall not exceed 25 micrograms per liter (µg/L).

(b) The package insert of all LVP’s used in TPN therapy shall state that the drug product contains no more than 25 µg/L. This information shall be contained in the “Precautions” section of the labeling of all LVP’s used in TPN therapy.

(c) The maximum level of aluminum present at expiry shall be stated on the immediate container label of all small volume parenteral (SVP) drug products and pharmacy bulk packages used in the preparation of TPN solutions. The aluminum content shall be stated as follows: “Contains no more than µg/L.” The immediate container label of all SVP drug products and pharmacy bulk packages that are lypohylized powders used in the preparation of TPN solutions shall contain the following statement: “When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than µg/L.” This maximum level of aluminum shall be stated as the highest of:

(1) The highest level for the batches produced during the last 3 years;

(2) The highest level for the latest five batches; or

(3) The maximum historical level, but only until completion of production of the first five batches after this rule takes effect.

(d) The package insert for all LVP’s, SVP’s, and pharmacy bulk packages shall contain the following warning statement, intended for patients with impaired kidney function and for neonates receiving TPN therapy. This information shall be contained in the “Warnings” section of the labeling of all SVP’s and LVP’s as follows:

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature and they require large amounts of calcium and phosphate solutions, which contain aluminum.

(e) Applicants and manufacturers shall develop validated assay methods to determine the aluminum content in parenteral drug products. The assay methods shall comply with current good manufacturing practice requirements. Applicants shall submit to the Food and Drug Administration (FDA) both validation of the method used and release data for several batches. Manufacturers of parenteral drug products not subject to an approved application shall make assay methodology available to FDA during inspections. Holders of pending applications shall submit an amendment under §§314.60 or §314.96 of this chapter.

Dated: December 5, 1997.
William K. Hubbard,
Associate Commissioner for Policy Coordination.
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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Chapter II

Workshops on The Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 (RSFA)

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of workshop.

SUMMARY: The Minerals Management Service (MMS), Royalty Management Program, is implementing the requirements of the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996. The purpose of this notice is to inform the public of a public workshop session on assessing for chronic erroneous reporting.

DATES: The workshop will be held on Tuesday, January 27, 1998, from 2 p.m. until 4 p.m., Mountain time.

ADDRESSES: The workshop will be held at the Embassy Suites Denver Southeast, 7525 East Hampden Avenue, Denver, Colorado 80231, telephone (303) 696-6644. Mail all comments to: David S. Guzy, Chief, Rules and Publications Staff, Royalty Management Program, Minerals Management Service, P.O. Box 25165, MS 3021, Denver, Colorado 80225-0165; courier delivery to building 85, Denver Federal Center, Denver, Colorado 80225; or e-mail: David_Guzy@mms.gov.

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Publications Staff, telephone (303) 231-3432; Fax (303) 231-3385; e-mail: David_Guzy@mms.gov.

SUPPLEMENTARY INFORMATION: President Clinton signed the Federal Oil and Gas Royalty Simplification and Fairness Act (RSFA) on August 13, 1996, to improve the management of royalties from Federal oil and gas leases. This is the first major legislation affecting royalty management since the Federal Oil and Gas Royalty Management Act of 1982 (FOGORMA) was passed in January 1983.

In our Federal Register Notice dated October 30, 1996 (61 FR 59541), MMS listed key issues involved in implementing RSFA. This workshop will focus on assessing for chronic erroneous reporting and will follow
be held at the same location as the
appeals workshop.

In order to accomplish a broad based
fact finding on how the requirements of
RSFA affect our customers and
stakeholders, comments from the public
are encouraged. In addition to
attendance at this meeting, comments
may be made in writing and sent directly
to MMS using instructions in the
ADDRESSES

part of this notice.


Lucy Querques Denett,
Associate Director for Royalty Management.

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PANAMA CANAL COMMISSION

35 CFR Parts 133 and 135

RIN 3207-AA45

Tolls for Use of Canal; Rules for
Measurement of Vessels

AGENCY: Panama Canal Commission.

ACTION: Notice of proposed rulemaking;
request for comments; notice of hearing.

SUMMARY: The Panama Canal Commission (Commission) proposes
to set a fixed, minimum toll rate for certain small vessels transiting
the Panama Canal. The Commission has determined an
efficient use of existing Canal capacity and resources requires a
change in the method of calculating tolls used to meet the transit needs
of certain small vessels. A minimum toll for small vessels will ensure
the Commission can recover at least part of the resources it expends on
the type of transits. The proposed increase complies with
the statutory requirement tolls be set at
35 CFR Part 133 for yachts and other small vessels transiting the Canal
based on other than net vessel tons of earning capacity.

Section 1602(b) of the Panama Canal Act of
1979, as amended, 22 U.S.C. 3792(b), requires Canal tolls be
prescribed at rates calculated to produce
revenues to cover as nearly as practicable all costs of maintaining and
operating the Panama Canal and the facilities and appurtenances related
thereto. In analyzing the issue of tolls for certain small vessels, it is recognized
the primary purpose of the Commission is to provide a safe and efficient transit
service to the oceangoing vessels of the world, primarily those engaged in
commerce. The waterway, however, also
attracts a considerable number of small vessels, such as yachts, fishing craft,
and tugboats. Such small vessel transits are incidental to the primary mission of
the Canal. They also consume a disproportionately large share of available Canal
capacity and resources, creating costly inefficiencies in Canal operations. In addition, and perhaps more importantly, small vessels (especially yachts), impose
administrative costs and logistical problems which currently are not offset
by the tolls they pay. Consequently, last
November, Congress amended section
1602(a) of the Panama Canal Act of
1979, 22 U.S.C. 3792(a) by Pub. L. 105-
85 to allow the Commission to set tolls
for yachts and other small vessels
transiting the Canal based on other than net vessel tons of earning capacity.

The Commission is attempting to
reduce the administrative costs and
logistical requirements of small vessel
transits. It is also trying to improve the
scheduling options available for these vessels with the goal of minimizing the
negative impact on the Commission’s
resources and capacity, and, wherever
possible, reduce the expenses associated
with the transit of these small vessels.

All of these steps are taken in order to maintain the transit service offered to
these vessels. Even with these measures, however, the Commission’s analysis of
small vessel transits indicates the cost of
providing the service far exceeds the toll charged for the service. To address
this issue, the Commission’s Board of
Directors approved a recommendation to set a fixed, minimum toll for certain
small vessels to recover these expenses in a proportionate manner.

The Commission will consider all
submissions before publishing the final
rule in the Federal Register. The final
rule, as approved and published by the
Commission, will be effective no earlier
than 30 days after the date of its
publication as final in the Federal Register.

The Commission is exempt from
Executive Order 12866. Accordingly,
provisions of that directive do not apply
to this rule. Even if the Order were
applicable, this change would not
constitute a “rule” as that term is
defined in the Regulatory Flexibility Act
(5 U.S.C. 601(2)) because it concerns
“rates” and “practices relating” thereto.

Furthermore, the Commission has
determined implementation of this rule
will have no adverse effect on
competition, employment, investment,
productivity, innovation, or on the
ability of the United States based
to compete with foreign
based enterprises in domestic or export
markets.

The Secretary of the Commission
certifies these proposed regulatory
changes meet the applicable standards of
sections 3(a) and 3(b)(2) of Executive
Order No. 12988 of February 7, 1996.

List of Subjects

35 CFR Part 133
Navigation, Panama Canal, Tolls,
Vessels.
35 CFR Part 135
Measurement, Vessels.