
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 parenteral solutions 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 lyophilized 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 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 (FOGRMA) was passed in January 1983.

In our Federal Register Notice dated October 30, 1996 (61 FR 55941), MMS listed key issues involved in implementing RSFA. This workshop will focus on assessing for chronic erroneous reporting and will follow and
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
can 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.

FOR FURTHER INFORMATION CONTACT: John
A. Mills, Telephone: (202) 634-6441,
Facsimile: (202) 634-6439, E-mail:
pancanalwo@aol.com; or Department of
Financial Management, Telephone: 011
(507) 272-3137, Facsimile: 011 (507)
272-3040, E-mail: fmfp@pancanal.com.

SUPPLEMENTARY INFORMATION: Section
1604 of the Panama Canal Act of 1979,
as amended, 22 U.S.C. 3794, establishes
procedures for proposing toll rate
increases and changes in the rules for
measurement of vessels. Those
procedures have been supplemented by
regulations in 35 CFR part 70, which
also provides interested parties with
instructions for participating in the
process governing changes in toll rates
and measurement rules. The
Commission strongly encourages all
interested parties present to present oral,
written comments at the hearing, per
Written Data, Views or
arguments along with other
relevant information. Oral presentations
should be limited to 20 minutes. Further
information governing the content of the
notice of appearance or intention to
present supplementary data at the
hearing appear at 35 CFR 70.8 and
70.10.

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 sufficient to cover Canal costs of
operation and maintenance, including capital for plant
replacement, expansion and
improvements, and working capital.

This notice of proposed rulemaking
also announces the availability from the
Commission of an analysis showing the
basis and justification for the proposed
change, solicits written data, views or
arguments from interested parties, and
sets the time and place for a public
hearing.

DATES: The agency must receive written
comments and requests to present oral
testimony on or before February 6, 1998.
A public hearing will be held at 9 a.m.,
February 13, 1998, in the Republic of
Panama.

ADDRESSES: Mail comments and
requests to testify at the hearing to: John
A. Mills, Secretary, Panama Canal
Commission, 1825 I Street NW., Suite
1050, Washington, DC 20006-5402; or
Department of Financial Management,
Panama Canal Commission, Balboa,
Ancon, Republic of Panama.

The hearing location is at the
Miraflores Visitors Pavilion Theater,
Building 6-A, Miraflores Locks,
Republic of Panama (accessible from
Gaillard Highway).

The hearing will be held from 9 a.m.
to 5 p.m., Monday, February 16, 1998,
and Tuesday, February 17, 1998, to hear
testimony on or before February 6, 1998.

The Secretary of the Commission
requests to testify at the hearing to:

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
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.