

animal drugs, the sponsor shall demonstrate by substantial evidence, as defined in this section, that the combination new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling and that each active ingredient or animal drug contributes to the effectiveness of the combination new animal drug.

4. Section 514.111 is amended by revising paragraph (a)(5) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(5) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence as defined in § 514.4.

* * * * *

Dated: October 30, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97-29275 Filed 10-31-97; 2:48 pm]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 58

[AD-FRL-5903-6]

RIN 2060-AF71

Ambient Air Quality Surveillance for Lead

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Lead air pollution levels measured near the Nation's roadways have decreased 97 percent between 1976 and 1995 with the elimination of lead in gasoline used by on-road mobile sources. Because of this historic decrease, EPA is shifting its ambient air monitoring focus from measuring lead

air pollutant concentrations emanating from mobile source emissions toward a focus on stationary point sources of lead air pollution. Today's action proposes to revise the part 58 lead air monitoring regulations to allow many lead monitoring stations to be discontinued while maintaining a core lead monitoring network in urban areas to track continued compliance with the lead National Ambient Air Quality Standards (NAAQS). This action also requires lead ambient air monitoring around lead stationary sources. This action is being taken at the direct request of numerous State and local agencies whose on-road mobile source-oriented lead monitors have been reporting peak lead air pollution values that are many times less than the quarterly lead NAAQS of 1.5µg/m³ for many years. Approximately 70 of the National Air Monitoring Stations (NAMS) and a number of the State and Local Air Monitoring Stations (SLAMS) could be discontinued with this action, thus making more resources available to those State and local agencies to deploy lead air quality monitors around heretofore unmonitored lead stationary sources.

DATES: Comments must be submitted on or before December 5, 1997.

ADDRESSES: Comments should be submitted (in duplicate, if possible) to: Air Docket (LE-131), US Environmental Protection Agency, Attn. Docket No. A-91-22, 401 M Street, SW, Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Brenda Millar, Emissions, Monitoring, and Analysis Division (MD-14), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Telephone: (919) 541-4036, e-mail: millar.brenda@email.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Authority

Sections 110, 301(a), and 319 of the Clean Air Act as amended 42 U.S.C. 7410, 7601(a), 7619.

II. Background

The current ambient air monitoring regulations that pertain to lead air sampling were written in the 1970's when lead emissions from on-road mobile sources (e.g., automobiles, trucks) were the predominant lead air emission source affecting our communities. As such, the current lead monitoring requirements focus primarily upon the idea of determining the air quality impacts from major roadways and urban traffic arterial highways. Since the 1970's, lead has been removed from gasoline sources for on-road vehicles (on-road vehicles now account for less than 1 percent of total lead emissions), and a 97 percent decrease in lead air pollution levels measured in our neighborhoods and near roadways has occurred nationwide. Because of this historic decrease, EPA is reducing its requirements for measuring lead air pollutant concentrations near major highways, and is focusing on stationary point sources and their impacts on neighboring populations.

The current lead air monitoring regulations require that each urbanized area with a population of 500,000 or more operate at least two lead NAMS, one of which must be a roadway-oriented site and the second must be a neighborhood site with nearby traffic arteries or other major roadways. There are approximately 85 NAMS in operation and reporting data for 1996. This action would reduce this NAMS requirement to include one NAMS site in one of the two largest Metropolitan Statistical Areas (MSA/CMSA) within each of the ten EPA Regions, and one NAMS population-oriented site in each populated area (either a MSA/CMSA, town, or county) where lead violations have been measured over the most recent 8 calendar quarters. This latter requirement is designed to provide information to citizens living in areas that have one or more lead stationary sources that are causing recent air quality violations. At present, the MSA/CMSAs, cities, or counties that have one or more quarterly Pb NAAQS violations that would be subject to this requirement include:

TABLE 1.—CMSA/MSA'S OR COUNTIES WITH ONE OR MORE LEAD NAAQS VIOLATIONS IN 1995-1996

CMSA/MSA or county	Contributing lead source(s)
Philadelphia-Wilmington-Atlantic City CMSA	Franklin Smelter in Philadelphia County, PA.
Tampa-St. Petersburg-Clearwater MSA	Gulf Coast Lead in Hillsborough County, FL.
Memphis MSA	Refined Metals in Shelby County, TN.
Nashville MSA	General Smelting in Williamson County, TN.
St. Louis MSA	Chemmetco in Madison County, IL, and Doe Run in Jefferson County, MO.
Cleveland-Akron CMSA	Master Metals in Cuyahoga County, OH.
Iron County, MO	ASARCO in/near Hogan, MO.

TABLE 1.—CMSA/MSA'S OR COUNTIES WITH ONE OR MORE LEAD NAAQS VIOLATIONS IN 1995–1996—Continued

CMSA/MSA or county	Contributing lead source(s)
Omaha MSA	ASARCO in Douglas County, NE.
Lewis and Clark County, MT	ASARCO in/near East Helena, MT.

Data from these NAMS will be used to assess national trends in lead ambient air pollution. Figure 1 demonstrates the effect that these monitoring reductions will have on our national lead air pollutant trends.

For other monitoring within the SLAMS network, EPA is proposing to require, State and local agencies to focus their efforts toward establishing air monitoring networks around lead stationary sources which are causing or have a potential to cause exceedances of the quarterly lead NAAQS. Many of these sources have been identified through EPA's ongoing Lead NAAQS Attainment Strategy, and monitoring has already been established. In general, stationary sources emitting five or more tons per year are considered to be candidates for additional lead monitoring, although smaller stationary sources may also be problematic depending upon the facility's size and proximity to neighborhoods. EPA recommends a minimum of two sites per source, one located for stack emission impacts and the other for fugitive emission impacts. Variations of this two-site network are expected as source type, topography, locations of neighboring populations, and other factors play a role in how to most appropriately design such a network. EPA guidance for lead monitoring around point sources has been developed and is available through a variety of sources including the National Technical Information Service (703-487-4650), and electronic forms accessible through EPA's Office of Air Quality Planning & Standards Technology Transfer Network, Ambient Monitoring Technology Information Center (AMTIC) bulletin board system at <http://ttnwww.rtpnc.epa.gov>.

In addition to the changes to the lead monitoring requirements, EPA proposes several minor changes to update and correct regulatory provisions to current practices. Specifically this affects 40 CFR part 58 sections 58.31, 58.34, 58.41, Appendix B, Appendix D sections 3.2 and 3.3, and Appendix G sections 1 and 2b.

III. Administrative Requirements Section

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and to the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations or recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of the Executive Order 12866 and is therefore not subject to formal OMB review.

B. Paperwork Reduction Act

Today's action does not impose any new information collection burden. This action proposes to revise the part 58 air monitoring regulations for lead to allow many monitoring sites to be discontinued. The Office of Management and Budget (OMB) has previously approved the information collection requirements in the part 58 regulation under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060-0084 (EPA ICR No. 0940.13 and revised by 0940.14).

C. Impact on Small Entities

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the

agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions whose jurisdictions are less than 50,000 people. This proposal will not have a significant impact on a substantial number of small entities because it does not impact small entities whose jurisdictions cover less than 50,000 people. Pursuant to the provision of 5 USC 605(b), I certify that this action will not have a significant economic impact on a substantial number of small entities.

Since this modification is classified as minor, no additional reviews are required.

D. Unfunded Mandates Reform Act of 1995

Under section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final standards that include a Federal mandate that may result in estimated costs to State, local, or tribal governments, or to the private sector, of, in the aggregate, \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the standard and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the standards. The EPA has determined that this action does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments. Therefore, the requirements of the Unfunded Mandates Act of 1995 do not apply to this action.

List of Subjects in 40 CFR Part 58

Environmental protection, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Quality assurance requirements.

Carol W. Browner,

Administrator.

[FR Doc. 97-29293 Filed 11-4-97; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 36

[CC Docket No. 80-286; FCC 97-354]

Jurisdictional Separations Reform and Referral to the Federal-State Joint Board

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: On October 2, 1997, the Commission adopted a Notice of Proposed Rulemaking (NPRM), that initiates a proceeding with the goal of reviewing comprehensively the Part 36 jurisdictional separations procedures to ensure that they meet the objectives of the Telecommunication Act of 1996 (1996 Act), and to consider changes that may need to be made to the jurisdictional separations process in light of changes in the law, technology, and market structure of the telecommunications industry. Pursuant to section 410(c) of the Communications Act, the Commission refers the issues raised in the NPRM to the Federal-State Joint Board established in CC Docket No. 80-286 (Separations Joint Board) for preparation of a recommended decision.

This NPRM contains proposed or modified information collections subject to the Paperwork Reduction Act of 1995 (PRA). It has been submitted to the Office of Management and Budget (OMB) for review under the PRA. OMB, the general public, and other Federal agencies are invited to comment on the proposed or modified information collections contained in this proceeding.

DATES: Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 1.419, interested parties may file comments on or before December 10, 1997, and reply comments on or before January 26, 1998. Written comments by the public on the proposed and/or modified information collections are due December 10, 1997. Written comments must be submitted by the Office of Management and Budget (OMB) on the proposed and/or modified information collections on or before January 5, 1998.

ADDRESSES: Parties should send their comments or reply comments to Office

of the Secretary, Federal Communications Commission, 1919 M Street, N.W., Room 222, Washington, D.C. 20554. Parties should also send a paper copy, and a copy on 3.5 inch diskette formatted in an IBM compatible form using, if possible, WordPerfect 5.1 for Windows software, to Connie Chapman of the Common Carrier Bureau's Accounting and Audits Division, 2000 L Street, N.W., room 258H, Washington, D.C. 20554. Parties also must serve comments on the Federal-State Joint Board in accordance with the service list (See Attachment). Commenters should also provide one copy of any documents filed in this proceeding to the Commission's copy contractor, International Transcription Service, 1231 20th Street, N.W., Washington, D.C. 20036.

In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 234, 1919 M Street, N.W., Washington, DC 20554, or via the Internet to jboley@fcc.gov, and to Timothy Fain, OMB Desk Officer, 10236 NEOB, 725-17th Street, N.W., Washington, DC 20503 or via the Internet to fain_t@al.eop.gov.

FOR FURTHER INFORMATION CONTACT: Lynn Vermillera, Accounting and Audits Division, Common Carrier Bureau, (202) 418-7120. Alternate contact, Connie Chapman (202) 418-0885. For additional information concerning the information collections contained in this Notice contact Judy Boley at 202-418-0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking adopted October 2, 1997, and released October 7, 1997. The full text of this Commission NPRM is available for inspection and copying during normal business hours in the FCC Public Reference Room (Room 239), 1919 M St., N.W., Washington, D.C. The complete text of this NPRM may also be purchased from the Commission's copy contractor, International Transcription Service, 1231 20th Street, N.W., Washington, D.C. 20036.

Summary of Notice of Proposed Rulemaking

1. The NPRM seeks comment on the changes in law, technology, and market structure of the telecommunications industry that affect the separations process. It then seeks comment on the criteria that should be used to evaluate the existing separations process and

proposals to reform the process in light of the goals of our comprehensive review.

2. In addition, the NPRM seeks comment on whether separations rules are still needed during the transition period from a regulated to a competitive marketplace. In this section, the Commission seeks comment on whether some form of separations must exist under the 1930 *Smith v. Illinois* decision, or whether statutory, regulatory and market changes since that decision have been so pronounced and persuasive as to make its holding inapplicable in the new deregulatory environment.

3. The NPRM then seeks comment on industry proposals to replace the existing Part 36 separations rules. In particular, the NPRM seeks comment on three industry proposals. The NPRM first seeks comment on NYNEX's proposal to separate costs for individual incumbent local exchange carriers (ILECs) in a given study area based on a single, frozen, interstate allocation factor. It then seeks comment on Bell South's proposal to separate costs in each study area based on two factors, one for investment and one for expenses. It then seeks comment on Southwestern Bell's proposal to consolidate the several dozen plant and service categories in the existing separations rules into four cost categories.

4. The NPRM then evaluates the existing separations rules and seeks comment on how various separations reform options would affect prices and revenue requirements. In this section, the NPRM seeks comment on revisions to the definition of "study area." It also seeks comment on whether the existing set of plant, expense, and service categories should be revised. The NPRM also seeks comment on whether there is a need to revise the way in which costs are apportioned to each category and the way in which those costs are then apportioned to the interstate and intrastate jurisdiction.

5. The NPRM also seeks comment on whether and how to separate the costs associated with interconnection. In this section, the Commission proposes two alternatives for allocating the costs of providing interconnection between the state and federal jurisdiction. The first alternative is for the costs, once identified in part 32 as proposed in the companion NPRM on accounting for interconnection, to be removed entirely from the separations process and allocated through a process designed to apply exclusively to these costs. The second alternative is that the costs, once identified in part 32, be separated