

of 1935 set forth in Holding Company Act Release No. 35-23049, if adopted, will not have a significant economic impact on a substantial number of small entities. The amendments deal with the preservation of records by public-utility holding companies registered under the Holding Company Act and their service company subsidiaries. The reason for this certification is that the proposed amendments will not affect a substantial number of small entities. There are presently 12 registered holding companies and 12 service company subsidiaries of such holding companies to which the rules would apply. None of these companies is a small entity as defined in Rule 110 under the Holding Company Act (17 CFR § 250.110). Thus the proposal will not affect any small entities.

Dated: September 7, 1983.

John S.R. Shad,
Chairman.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 76N-052B]

Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for OTC Bronchodilator Drug Products; and Reopening of Administrative Record

Correction

In FR Doc. 83-23706 beginning on page 39242 in the issue of Tuesday, August 30, 1983, make the following correction. On page 39242, third column, in the "ADDRESS" section "(HFA-205)" should read "(HFA-305)".

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[A-5-FRL 2433-2]

Designation of Areas for Air Quality Planning Purposes; Attainment Status Designations: Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: EPA proposes to change the designation for Allen County, Indiana

from nonattainment to attainment for air quality attainment relative to ozone. This revision is based on a request from the State of Indiana to redesignate this area and on the supporting data the State submitted. Under the Clean Air Act, designations can be changed if sufficient data are available to warrant such change.

DATE: All comments must be received by October 19, 1983.

ADDRESSES: Copies of the redesignation request, technical support documents and the supporting air quality data are available at the following addresses:

U.S. Environmental Protection Agency,
Region V, Air and Radiation Branch,
230 S. Dearborn Street, Chicago,
Illinois 60604

Indiana Air Pollution Control Division,
Indiana State Board of Health, 1330
West Michigan Street, Indianapolis,
Indiana 46206

Comments on this proposed rule should be addressed to: (Please submit an original and five copies if possible.)

Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR-26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604

FOR FURTHER INFORMATION CONTACT:
Anne E. Tenner, (312) 886-6036.

SUPPLEMENTARY INFORMATION: On March 3, 1978 (43 FR 8962), pursuant to Section 107 of the Act, EPA designated Allen County, Indiana as nonattainment for ozone. In the February 3, 1982, *Federal Register* (47 FR 5440), EPA proposed to redesignate Allen County, Indiana from nonattainment to attainment/unclassifiable for ozone based upon monitored data from 1980. A discussion of the basis of EPA's action can be found in that Notice of Proposed Rulemaking.

Two comments were received by the Agency during the public comment period. The Northwestern Indiana Regional Coordinating Council supported the redesignation while the State of Connecticut opposed the redesignation based on the fact that the second highest ozone reading in 1980 was in excess of that allowable under the National Ambient Air Quality Standards (NAAQS). As a result of this public comment, EPA deferred rulemaking until new ozone data was received by the Agency. On March 31, 1983, the State of Indiana submitted new information to EPA and again requested redesignation of Allen County, Indiana from nonattainment to attainment for ozone. This request was based on

monitored ozone concentrations during the period of 1980 through 1982.

When considering a redesignation request for ozone, a number of criteria must be considered. The most important is the ozone NAAQS which is specified in 40 CFR Part 50. The NAAQS for ozone is defined to be violated when the annual average expected number of daily exceedances of the standard (0.12 parts per million (ppm), one hour average) is greater than one (1.0). A daily exceedance occurs when the maximum hourly ozone concentration during a given day exceeds 0.124 ppm ("Guideline for the Interpretation of Ozone Air Quality Standards," EPA-450/4-79-003). The expected number of daily exceedances is calculated from the observed number of exceedances by making the assumption that the non-monitored days (invalid, missing, or incomplete) have the same fraction of daily exceedances as observed on monitored days (EPA-450/4-7-003).

EPA's policy on redesignations for ozone is discussed in memoranda from EPA's Office Air Quality Planning and Standards (OAQPS), dated December 7, 1979 and April 21, 1983. In keeping with the ozone NAAQS and with additional guidance provided in the "Guideline for the Interpretation of Ozone Air Quality Standards" (EPA-450/4-79-003), these memoranda recommend that the three most recent years of ozone monitoring data be considered. An area cannot be redesignated to attainment if the ozone NAAQS is violated at any site in the area.

During the 1980-1982 period, ozone was monitored at sites located at 17215 Woodburn and 2022 North Beacon. There were no exceedances recorded at the 17215 Woodburn monitor. The maximum highest ozone concentration recorded at the site was 0.116 ppm, which occurred in 1980. The second highest maximum ozone concentration was 0.108 ppm, which occurred in 1981.

Two exceedances of the ozone standard were recorded at the 2022 North Beacon site in 1980. Following procedures given in the "Guidelines for Interpretation of the Ozone Air Quality Standards", the expected exceedance was calculated to be 2.4 in 1980.

No exceedances of the ozone standard were recorded at this site in 1981 and 1982. Therefore, the average number of expected daily exceedances for 1980 through 1982 is 0.8. These data, in addition to the 17215 Woodburn data, demonstrate that no violations of the ozone NAAQS were observed in Allen County, Indiana during the period of 1980 through 1982.