Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis and the interarticular disc prosthesis (interpositional implant) have been classified into class III since December 12, 1994, and manufacturers of such TMJ prostheses legally in commercial distribution before May 28, 1976, or found by FDA to be substantially equivalent to such devices, will be permitted to continue marketing during FDA's review of the PMA or notice of completion of the PDP, the Commissioner of Food and Drugs certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Comments

Interested persons may, on or before October 15, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Interested persons may, on or before August 1, 1997, submit to the Dockets Management Branch a written request to change the classification of the total TMJ prosthesis, glenoid fossa prosthesis, mandibular condyle prosthesis, or the interarticular disc prosthesis (interpositional implant). Two copies of any request are to be submitted, except that individuals may submit one copy. Comments or requests are to be identified with the docket number found in brackets in the heading of this document. Received comments and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 be amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 872.3940 is amended by revising paragraph (c) to read as follows:

§ 872.3940 Total temporomandibular joint prosthesis.

* * * * *

(c) Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required. A PMA or a notice of completion of a PDP is required to be filed on or before (date 90 days after the effective date of a final rule based on this proposed rule), for any total temporomandibular joint (TMJ) prosthesis that was in commercial distribution before May 28, 1976, or that has on or before (date 90 days after the effective date of a final rule), been found to be substantially equivalent to a total TMJ prosthesis that was in commercial distribution before May 28, 1976. Any other total TMJ prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

3. Section 872.3950 is amended by revising paragraph (c) to read as follows:

§ 872.3950 Glenoid fossa prosthesis.

* * * * *

(c) Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required. A PMA or a notice of completion of a PDP is required to be filed on or before (date 90 days after the effective date of a final rule based on this proposed rule), for any glenoid fossa prosthesis that was in commercial distribution before May 28, 1976, or that has on or before (date 90 days after the effective date of a final rule), been found to be substantially equivalent to a glenoid fossa prosthesis that was in commercial distribution before May 28, 1976. Any other glenoid fossa prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

4. Section 872.3960 is amended by revising paragraph (c) to read as follows:

§ 872.3960 Mandibular condyle prosthesis.

* * * * *

(c) Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required. A PMA or a notice of completion of a PDP is required to be filed on or before (date 90 days after the effective date of a final rule based on this proposed rule), for any mandibular condyle prosthesis that was in commercial distribution before May 28, 1976, or that has on or before (date 90 days after the effective date of a final rule), been found to be substantially equivalent to a mandibular condyle prosthesis that was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

5. Section 872.3970 is amended by revising paragraph (c) to read as follows:

§ 872.3970 Interarticular disc prosthesis (interpositional implant).

* * * * *

(c) Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required. A PMA or a notice of completion of a PDP is required to be filed on or before (date 90 days after the effective date of a final rule based on this proposed rule), for any interarticular disc prosthesis (interpositional implant) that was in commercial distribution before May 28, 1976, or that has on or before (date 90 days after the effective date of a final rule), been found to be substantially equivalent to an interarticular disc prosthesis (interpositional implant) that was in commercial distribution before May 28, 1976. Any other interarticular disc prosthesis (interpositional implant) shall have a PMA or a declared PDP in effect before being placed in commercial distribution.

Dated: July 3, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–18831 Filed 7–16–97; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[LA–41–1–7342, FRL–5859–3]

Designation of Areas for Air Quality Planning Purposes; State of Louisiana; Correction of the Designation for Lafourche Parish

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed correction.

SUMMARY: This document announces EPA's proposal to correct the designation of Lafourche Parish, Louisiana, to nonattainment for ozone. Subsequent to publication, but prior to the effective date of the approval action in this matter, Lafourche Parish violated the ozone standard. Pursuant to the Clean Air Act (the Act), which allows

EPA to correct its actions, EPA is today proposing to correct the designation of Lafourche Parish to nonattainment for ozone.

DATES: Comments on this proposed action must be received by August 18, 1997.

ADDRESSES: Comments should be mailed to Thomas H. Diggs, Chief, Air Planning Section (6PD–L), EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733. Copies of information relevant to this action are available for inspection during normal hours at the following locations: Environmental Protection Agency, Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733.

Anyone wishing to review this proposal at the Region 6 EPA office is asked to contact the person below to schedule an appointment 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Lt. Mick Cote, Air Planning Section (6PD–L), Environmental Protection Agency, Region VI, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7219.

SUPPLEMENTARY INFORMATION:

I. Background

Lafourche Parish was originally designated as nonattainment for ozone on September 11, 1978 (40 CFR 81.319). Under the Act, as amended in 1990, the area retained its designation of nonattainment and was classified as an incomplete data area by operation of law pursuant to sections 107(d) and 181(a) of the Act (56 FR 56694).

On November 18, 1994, the State of Louisiana submitted a maintenance plan and redesignation request for Lafourche Parish to EPA for approval. On August 18, 1995, EPA issued a direct final notice approving Louisiana's redesignation request (60 FR 43020), because it met the maintenance plan and redesignation requirements set forth in the Act. Section 107(d)(1)(A)(ii) of the Act, 42 U.S.C. 7407(d)(1)(A)(ii), provides that an attainment area is one that ''meets'' the National Ambient Air Quality Standards (NAAQS). Section 107(d)(3)(E)(i) of the Act, 42 U.S.C. 7407(d)(3)(E)(i), prohibits EPA from redesignating an area to attainment unless EPA determines that the area ''has attained'' the NAAQS. The EPA's redesignation policy includes language to address how EPA will respond to a monitored violation of the NAAQS prior to the effective date of a redesignation action.

The EPA's redesignation policy is discussed in a guidance memorandum dated September 4, 1992, entitled *Procedures for Processing Requests to Redesignate Areas to Attainment.* This policy memorandum provides that if monitoring data indicates a violation of the NAAQS before the redesignation action is effective, the approval of the redesignation action should be withdrawn or disapproved.

Language in the direct final notice of August 18, 1995, restates this policy as follows: ''If the monitoring data records a violation of the NAAQS before the direct final action is effective, the direct final approval of the redesignation will be withdrawn and a proposed disapproval substituted for the direct final approval'' (60 FR 43021–43022). The ozone monitor in Lafourche Parish recorded a violation (a fourth exceedance of the ozone standard in three years) on August 27, 1995, during the 30-day comment period of EPA's approval action on the redesignation request. The EPA did not withdraw its approval of the redesignation action, and it took effect on October 18, 1995. The fourth exceedance was validated on January 10, 1996.

II. Correction of Error Under Section 110(k)(6)

Section 110(k)(6) of the Act provides that whenever the Regional Administrator determines that the Regional Administrator's action approving, disapproving, or promulgating any plan or plan revision (or part thereof), area designation, redesignation, classification, or reclassification was in error, the Regional Administrator may in the same manner as the approval, disapproval, or promulgation revise such action as appropriate without requiring any further submission from the State. Such determination and the basis thereof shall be provided to the State and public. The EPA interprets this provision to authorize the Agency to make corrections to a promulgation when it is shown to EPA's satisfaction that an error occurred in failing to consider or inappropriately considering information available to EPA at the time of the promulgation, or the information made available at the time of promulgation is subsequently demonstrated to have been clearly inadequate.

The EPA's initial action to redesignate Lafourche Parish to attainment (60 FR 43020), was based on a demonstration that the area met the NAAQS for ozone. Monitoring data recorded during the comment period on the initial action indicate that the area was in violation of the ozone standard, and EPA's action to allow the redesignation to become effective in light of the violation was in conflict with the statute, EPA policy, language contained in the Lafourche approval, and other notices of disapproval published by EPA for areas that had violated the NAAQS while their redesignation requests were pending. These other areas include Richmond, Virginia, (59 FR 22757), the Pittsburgh-Beaver Valley nonattainment area, (61 FR 19193), the Kentucky portion of the Cincinnati-Hamilton nonattainment area, (61 FR 50718), the Ohio portion of the Cincinnati-Hamilton nonattainment area, (62 FR 7194), and Birmingham, Alabama, (62 FR 23421). The EPA is soliciting comment on our proposed correction of this area back to nonattainment for ozone.

III. Proposed Action

In 60 FR 43020, EPA issued a direct final rule promulgating a change to the designation of Lafourche Parish, Louisiana to attainment for ozone, and amended 40 CFR parts 52 and 81 accordingly. In today's action, EPA is proposing to correct an error by changing the designation of Lafourche Parish to an ozone nonattainment area, and classifying it as an ozone nonattainment incomplete data area. Today's action also proposes an amendment to 40 CFR parts 52 and 81 to reflect the change in designation. These actions are proposed in accordance with section 110(k)(6) of the Act.

IV. Administrative Requirements

A. Executive Order (E.O.) 12866

The Office of Management and Budget has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 600 *et seq.*, requires any federal agency, when it develops a rule, to identify and address the impact of the rule on the small businesses and other small entities that will be subject to the rule (RFA sections 603 and 604). This requirement applies to 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 (RFA section 605(b)). Besides small businesses, small entities include small governments with jurisdictions of less than 50,000 people and small nonprofit organizations.

Today's action is not subject to notice-and-comment rulemaking requirements. As an action under section 110(k)(6) of the Act, it is governed by section 553 of the Administrative Procedure Act

(APA), 5 U.S.C. 551 *et seq.* That section provides that an agency must provide public notice of, and an opportunity to comment on, a proposed rule unless the agency finds for good cause that providing notice-and-comment procedures for the rule are ''impracticable, unnecessary or contrary to the public interest'' (section 553(b)).

The Agency believes there is good cause for finding public notice and comment procedures unnecessary for this action to correct the designation of Lafourche Parish. As EPA explained in the notice of August 18, 1995, Lafourche Parish could not be designated to attainment if the area experienced a violation of the ozone NAAQS during the period for public comment on the notice. Lafourche Parish in fact experienced a violation during the public comment period, but the Agency did not withdraw its notice approving the redesignation. The Agency is now proposing to correct that error. Since the public had an opportunity to comment on the original notice and the Agency is only correcting a mistake with this action, public notice and comment on today's notice is not legally necessary. The Agency is nonetheless voluntarily using notice-and-comment procedures to make this correction.

As an action not subject to notice-and-comment requirements, this action is also not subject to the RFA requirement to prepare regulatory flexibility analyses. Moreover, this action will not establish any requirements applicable to small entities. It simply corrects the designation of the area by restoring the nonattainment designation that was erroneously changed to attainment. The RFA requires analyses of a rule's requirements as they would apply to small entities. If the rule does not apply to small entities, an RFA analysis is inapplicable.

Further, it is unlikely that this action will result in State imposition of control requirements that are different from those applicable in Lafourche Parish before the erroneous change in designation status. Under Title I of the Act, States are primarily responsible for establishing control requirements needed to attain and the maintain the NAAQS. Louisiana has adopted an implementation plan that includes control requirements that apply to particular sources or categories of sources, depending on a number of factors, including the designation status of the area in which a source is located. As a result of today's action, Louisiana will once again have to apply some of those control programs in Lafourche Parish. Some of those programs may ultimately impose requirements on small entities in the Parish. However, these controls were applicable before the erroneous designation to attainment; correcting that mistake will only put the small entities in that area in the place they were prior to the mistake being made.

Beyond that, the purpose of the RFA is to promote Federal agency efforts to tailor a rule's requirements to the scale of the small entities that will be subject to it. That purpose cannot be served in the case of State control requirements. Some of the control requirements included in States' SIPs are prescribed to some extent by the Act. Even so, the only issue before EPA in actions such as this one is the proper designation of a particular area. The implementation consequences of a designation are beyond the scope of such actions, and indeed, beyond EPA's reach to the extent they are dictated by the Act itself or are left to States' discretion. In light of all the above, if the RFA were applicable to this action, the Agency would certify that it will not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule 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 rule.

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 in the aggregate, or to the private sector. This Federal action simply proposes to correct an error in the designation for the reasons described above and does not, in itself, impose any mandates.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental regulations, Ozone, Reporting and recordkeeping, and volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control, National parks and wilderness areas, Designation of areas for air quality planning purposes.

Authority: 42 U.S.C. 7401–7871q.

Dated: July 8, 1997.

Jerry Clifford,

Acting Regional Administrator.

[FR Doc. 97–18858 Filed 7–16–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL 5857–6]

National Oil and Hazardous Substances Pollution Contingency Plan National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete the Bruin Lagoon Site from the National Priorities List and request for comments.

SUMMARY: The Environmental Protection Agency (EPA) Region III announces its intent to delete the Bruin Lagoon Site (Site) from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended. EPA and the State of Pennsylvania have determined that all appropriate CERCLA response actions have been implemented and that no further cleanup is appropriate. Moreover, EPA and the State have determined that remedial activities conducted at the Site to date have been protective of public health, welfare, and the environment.

DATES: Comments concerning the proposed deletion of this Site from the NPL may be submitted on or before August 18, 1997.

ADDRESSES: Comments may be submitted to Garth Connor, (3HW22), Project Manager, U.S. Environmental Protection Agency, 841 Chestnut Building, Philadelphia, Pennsylvania, 19107, (215) 566–3209.

Comprehensive information on this Site is available through the public docket which is available for viewing at