

PDP, the agency 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.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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 is revised to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

2. Section 872.6730 is amended by revising paragraph (c) to read as follows:

§ 872.6730 Endodontic dry heat sterilizer.

* * * * *

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

Dated: May 24, 1995.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95-13831 Filed 6-6-95; 8:45 am]

BILLING CODE 4160-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[TX-001; FRL-5217-7]

Clean Air Act Proposed Interim Approval Operating Permits Program for the State of Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed interim approval.

SUMMARY: The EPA proposes source category-limited interim approval of the operating permits program submitted by the Governor of Texas for the State of Texas for the purpose of complying with Federal requirements which mandate that States develop and submit to EPA programs for issuing operating permits to all major stationary sources, with the exception of sources on Indian Lands. Source category-limited interim approval was specifically requested by the Governor for this submission.

DATES: Comments on this proposed action must be received in writing by July 7, 1995.

ADDRESSES: Written comments on this action should be addressed to Ms. Jole C. Luehrs, Chief, New Source Review (NSR) Section, at the EPA Region 6 Office listed below. Copies of the State's submittal and other supporting information used in developing the proposed interim approval are available for inspection during normal business hours at the following locations. Interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before visiting day.

Environmental Protection Agency,
Region 6, Air Programs Branch (6T-AN), 1445 Ross Avenue, Suite 700,
Dallas, Texas 75202-2733.
Texas Natural Resource Conservation
Commission, Office of Air Quality,
12124 Park 35 Circle, Austin, Texas
78753.

FOR FURTHER INFORMATION CONTACT: David F. Garcia, New Source Review Section, Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733, telephone 214-665-7217.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

A. Introduction

As required under title V of the Clean Air Act, as amended on November 15, 1990 ("the Act"), the EPA has promulgated rules which define the minimum elements of an approvable

State operating permits program and the corresponding standards and procedures by which the EPA will approve, oversee, and withdraw approval of a State operating permits program (see 57 **Federal Register** 32250, July 21, 1992). These rules are codified at 40 Code of Federal Regulations (CFR) part 70 ("the part 70 regulation"). Title V requires States to develop, and submit to the EPA, programs for issuing these operating permits to all major stationary sources and to certain other sources.

The Act requires that States develop and submit these programs to the EPA by November 15, 1993, and that the EPA act to approve or disapprove each program within one year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the Act and the part 70 regulation which together outline criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of part 70, the EPA may grant the program interim approval for a period of up to two years. Where a State requests source category-limited interim approval and demonstrates compelling reasons in support thereof, the EPA may also grant such an interim approval. If the EPA has not fully approved a program by two years after the date of November 15, 1993 or by the end of an interim program, it must establish and implement a Federal program.

B. Federal Oversight and Sanctions

If the EPA were to finalize this proposed source category-limited interim approval, it would grant that approval for a period of two years following the effective date of final interim approval, and the interim approval could not be renewed. During the interim approval period, the State of Texas would be protected from sanctions, and the EPA would not be obligated to promulgate, administer, and enforce a Federal permits program for the State of Texas. Permits issued under a program with interim approval have full standing with respect to part 70, and the State will permit sources based on the transition schedule provided in Regulation XII, Title 31 of the Texas Administrative Code (TAC).

Following final interim approval, if Texas has failed to submit a complete corrective program for full approval by the date six months before expiration of the interim approval, the EPA would start an 18-month clock for mandatory sanctions. If Texas then failed to submit a corrective program that the EPA found complete before the expiration of that 18-month period, the EPA would be required to apply one of the sanctions