

approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The Commissioner of Food and Drugs therefore certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

#### XI. Comments

Interested persons may, on or before September 9, 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. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments 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 878

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 878 be amended as follows:

#### PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues 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 878.5360 is revised to read as follows:

#### § 878.5360 Tweezer-type epilator.

(a) *Identification.* The tweezer-type epilator is a device intended to remove hair by destroying the dermal papilla of a hair. The energy provided at the tip of the tweezer used to remove hair may be radio frequency, galvanic (direct current), or a combination of radio frequency and galvanic energy.

(b) *Classification.* Class I (General Controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter.

Dated: May 30, 1997.

**Joseph A. Levitt,**

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

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[SIPTRAX No. PA4057b; FRL-5835-5]

#### Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Approval of VOC and NO<sub>x</sub> RACT Determinations for Individual Sources

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania for the purpose of establishing volatile organic compound (VOC) and nitrogen oxides (NO<sub>x</sub>) reasonably available control technology (RACT) for five major sources located in Pennsylvania. In the Final Rules section of this **Federal Register**, EPA is approving the Commonwealth's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule and the accompanying technical support document. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If adverse comments are received that do not pertain to all documents subject to this rulemaking action, those documents not affected by the adverse comments will be finalized in the manner described here. Only those documents that receive adverse comments will be withdrawn in the manner described here.

**DATES:** Comments must be received in writing by July 11, 1997.

**ADDRESSES:** Written comments on this action should be addressed to David

Campbell, Air, Radiation, and Toxics Division, Mailcode 3AT22, U.S.

Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; and the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

**FOR FURTHER INFORMATION CONTACT:** Ruth E. Knapp, (215) 566-2191, at the EPA Region III office or via e-mail at knapp.ruth@epamail.epa.gov. While information may be requested via e-mail, comments must be submitted in writing to the above Region III address.

**SUPPLEMENTARY INFORMATION:** See the information pertaining to this action, VOC and NO<sub>x</sub> RACT determinations for individual sources located in Pennsylvania, provided in the Direct Final action of the same title which is located in the Rules and Regulations Section of this **Federal Register**.

**Authority:** 42 U.S.C. 7401-7671q.

Dated: May 21, 1997.

**W.T. Wisniewski,**

*Acting Regional Administrator, Region III.*

[FR Doc. 97-15096 Filed 6-10-97; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[AZ 68-0011; FRL-5835-7]

#### Approval and Promulgation of State Implementation Plans; Arizona—Maricopa County Ozone Nonattainment Area

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Arizona on April 29, 1997, establishing a summertime gasoline Reid Vapor Pressure (RVP) limit of 7.0 pounds per square inch (psi) for gasoline distributed in the Maricopa (Phoenix) ozone nonattainment area. Arizona has lowered the summertime RVP limit for this area to reduce emissions of volatile organic compounds (VOC) in accordance with the requirements of the