listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AAL–7.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the System Management Branch, Air Traffic Division, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the System Management Branch, AAL–530, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace to accommodate aircraft executing the VOR instrument approach procedures at Huslia, AK. Controlled airspace extending upward from 700 to 1200 feet above the ground (AGL) is needed to contain aircraft executing the approach. This action will change the airport status from Visual Flight Rules (VFR) to Instrument Flight Rules (IFR). The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 of FAA Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1 (61 FR 48403; September 13, 1996). The intended effect of this proposal is to provide adequate controlled airspace for IFR operations, segregating aircraft using instrument conditions from other aircraft operating in visual weather conditions, at Huslia Airport, AK. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that these proposed regulations only involve an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Huslia, AK

Huslia Airport, AK
(Lat. 65° 41′ 50″ N, long. 156° 23′ 21″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Huslia Airport.

* * * * *

Issued in Anchorage, AK, on June 3, 1997.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 97–15308 Filed 6–10–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 97N–0199]

General and Plastic Surgery Devices: Reclassification of the Tweezer-Type Epilator

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the tweezer-type epilator from class III to class I when intended to remove hair. FDA also proposes to exempt this device from the premarket notification requirements. This reclassification is being proposed on the Secretary of Health and Human Services' own initiative based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA).

DATES: Written comments by September 9, 1997. FDA proposes that any final regulation based on this proposal become effective 30 days after date of publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Stephen P. Rhodes, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The act, as amended by the 1976 amendments (Pub. L. 94–295) and the SMDA (Pub. L. 101–629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the

regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as post amendment devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, *supra*, 422 F.2d at 951.) However, regardless of whether data before the agency are past or new data, the ''new information'' on which any reclassification is based is required to consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA (see section 520(c) of the act (21 U.S.C. 360j(c)).

Section 513(d)(2)(A) of the act authorizes FDA to exempt, by regulation, a generic type of class I device from, among other things, the requirement of premarket notification in section 510(k) of the act after stating the reasons for making such requirement inapplicable. Such exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA. If FDA has concerns about certain types of changes to a particular class I device, the agency may grant a limited exemption from premarket notification for that generic device.

In 1990, the SMDA added section 515(i) to the act. This section of the act requires FDA to issue an order to manufacturers of preamendment class III devices and substantially equivalent postamendments devices for which no final regulation requiring the submission of PMA's has been issued. This order requires such manufacturers to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information that has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, distributors, and device user facilities to submit adverse event reports of certain device-related events and reports of certain corrective actions taken. Section 515(i) of the act also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III and establish a schedule for the issuance of a rule requiring the submission of PMA's for those devices remaining in class III.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA announced the availability of a document setting forth its strategy for implementing the provisions of SMDA that require FDA to review the classification of preamendments class III. Under this plan, the agency divided preamendment class III devices into the following three groups: Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness, but are no longer used or are in very limited use; Group 2 devices are devices that FDA believes have a high potential for being reclassified; and Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA also announced its intention to call for submission of PMA's for the 15 highest priority devices in Group 3, and for all Group 1 devices. The agency also announced its intention to issue an order under section 515(i) of the act for the remaining Group 3 devices and for all Group 2 devices.

In the **Federal Register** of August 14, 1995 (60 FR 41984 and 41986), FDA published two orders for certain class III devices requiring the submission of safety and effectiveness information in accordance with the Preamendments Class III Strategy document for implementing section 515(i) of the act. The orders describe in detail the format for submitting the type of information required by section 515(i) of the act so that the information submitted would clearly support either reclassification of the device into class I or II or retention of the device in class III. The orders also scheduled the required submissions in groups of nine devices at 6-month intervals beginning with August 14, 1996. The devices proposed in this regulation were included in the August 14, 1995, Docket No. 94N–0417 Order on Group 2 devices.

II. Regulatory History of the Device

In the **Federal Register** of January 19, 1982 (47 FR 2810), FDA published a proposed rule to classify the tweezer-type epilator into class III. The preamble included the classification recommendation of the General and Plastic Surgery Devices Classification Panel (the panel). The panel's recommendation included a summary of the reasons why the device should be subject to premarket approval and identified certain risks to health

presented by the device, including: (1) Cataract formation: Nonionization radiation emitted from the device may cause heating of the lens of the eye leading to cataract formation (opacity of the lens of the eye); (2) pacemaker interference: Patients with pacemakers may experience arrhythmias from the use of the device; and (3) nonionizing radiation exposure: The 27 megahertz (MHz) electromagnetic radiation emitted from the tip of the tweezer may be potentially hazardous to organs other than the eye.

In the **Federal Register** of June 24, 1988 (53 FR 23856), FDA published a final rule classifying the tweezer-type epilator into class III (21 CFR 878.5360).

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA categorized the tweezer-type epilator as a Group 2 device, which FDA believes has a high potential for being reclassified. The agency also announced its intent to issue an order under section 515(i) of the act for Group 2 devices.

In the **Federal Register** of August 14, 1995 (60 FR 41986), FDA published an order requiring manufacturers of tweezer-type epilators to submit safety and effectiveness information in accordance with the Preamendments Class III Strategy document for implementing section 515(i) of the act. Between August 8, 1996, and September 24, 1996, four summaries of safety and effectiveness information were submitted to the agency (Refs. 1 through 4). These summaries recommended that the tweezer-type epilator be reclassified into class I or class II and provided information to assist FDA in reclassifying the device.

III. Device Description

FDA is proposing the following device description based on the agency's review: 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. This new device description reflects the entire array of energy sources of tweezer-type epilators on the market.

IV. Proposed Reclassification

FDA is proposing that the tweezer-type epilator intended to remove hair should be reclassified from class III to class I. FDA believes that class I would provide a reasonable assurance of safety and effectiveness of the device for its intended use. FDA is also proposing that the device be exempt from premarket notification requirements.

V. Risks to Health

When the tweezer-type epilator was proposed for classification into class III in 1982, the panel identified certain risks to health that they believed use of the device presented. The risks to health identified were: (1) Cataract formation: Nonionization radiation emitted from the device may cause heating of the lens of the eye leading to cataract formation (opacity of the lens of the eye); (2) pacemaker interference: Patients with pacemakers may experience arrhythmias from the use of the device; and (3) nonionizing radiation exposure: The 27 MHz electromagnetic radiation emitted from the tip of the tweezer may be potentially hazardous (47 FR 2810). No other risks to health were identified by FDA when the device was classified into class III in 1988 (53 FR 23856).

One of the 515(i) submissions identified an additional potential risk to health, burning of the skin, associated with the use of electronic tweezer-type epilators (Ref. 2). If the tweezers touch the skin accidentally during the procedure, the skin is instantly burned and the burned tissue is pulled away on the tip of the tweezer. Another 515(i) submission stated that heat buildup during the use of galvanic tweezer-type epilators could potentially result in smoking, sizzling, and even a mild shock (Ref. 3).

VI. Summary of the Reasons for the Reclassification

In accordance with section 513(e) of the act and 21 CFR 860.130, based on new information with respect to the device, FDA, on its own initiative, is proposing to reclassify the tweezer-type epilator from class III to class I when intended to remove hair because general controls would provide reasonable assurance of safety and effectiveness. FDA is also proposing to exempt the device from premarket notification procedures because: (1) There is no history of significant risks to health; (2) the characteristics of the device necessary for safety and effectiveness are established; (3) any anticipated changes that could affect safety and effectiveness of the device could be readily detected and will not likely result in a change of classification of the device; and (4) there is no significant history of false and misleading claims associated with the use of the device.

Another reason for proposing reclassification of the tweezer-type epilator into class I is that the needle epilator also intended to remove hair by destroying the dermal papilla of hair was reclassified from class II into class I and exempted from premarket notification procedures in 1996 (61 FR 44013, August 27, 1996). FDA believes proposing reclassification of the tweezer-type epilator into class I provides consistency in the classification of the device.

VII. Summary of Data Upon Which the Reclassification is Based

A. Previously Identified Risks to Health

No reports of cataract formation, pacemaker interference, or any other adverse nonionizing radiation exposure effects associated with the use of the tweezer-type epilator were found in the literature, in FDA's voluntary Device Experience Network (DEN) and Mandatory Device Reporting (MDR) data bases, or in the 515(i) submissions (Refs. 1 through 4).

One of the 515(i) submissions (Ref. 4) did address the possible risks to health of cataract formation and pacemaker interference. This submitter had its device tested for radio frequency and microwave radiation emission. There was no detectable emission from the device in the 10–300 MHz range. Radio frequency tweezer-type epilators utilize 13.56, 27.12 or 40.68 MHz to remove hair. Thus, the probability of the use of radio frequency tweezer-type epilators leading to cataract formation and causing pacemaker interference is low during the proper use of the device.

B. Burning of the Skin and Electrical Shock

Although one 515(i) submission identified burning of the skin as a potential risk to health (Ref. 2) and another 515(i) submission identified electrical shock as another potential risk to health (Ref. 3), no reports of burning of the skin or electrical shock associated with use of the device were found in the literature or in the agency's DEN or MDR data bases.

C. Adverse Experience Reports

The DEN data base included some reports of lack of clinical effectiveness and misleading claims of permanent hair removal associated with use of the device. There also was one report of pain, infection, and inadequate directions; one report of scarring; and two reports of ingrown/infected hairs. There were no reports of these or any other adverse effects associated with the use of the device found in the MDR data base. There also were no reports of adverse effects in the records of the Consumer Product Safety Commission.

Based on the new information submitted to it, and the agency's own review of the literature and its DEN and MDR data bases, FDA has concluded

that the risks to health identified when the device was classified into class III and the new potential identified risks to health do not appear to be risks to health when the device is used properly. FDA now believes that general controls are sufficient to reasonably ensure that the device is safe and effective for its intended use. FDA also believes that the device should be exempted from the premarket notification procedures because agency review of premarket notification submissions will not increase the safety and effectiveness of the device.

D. Benefits of the Device

The psychological stress of embarrassingly excessive hair growth is well documented, and the elimination of unwanted hair through destruction of the papilla of the hair follicle is fairly well characterized (Refs. 5 through 9). FDA has concluded from the literature and its knowledge of the device that the tweezer-type epilator can remove hair and that the performance parameters of the device in regards to safety are also well documented and understood. The device has had a reasonable record of safety for over 20 years of use.

There is little published information in regards to the claims of hair removal by tweezer-type epilators and only one published clinical study (Ref. 8) specifically investigating the use of tweezer-type epilators. In this study, eight subjects were treated with a tweezer-type epilator. The same area of skin area on each subject was retreated with the device 5 to 7 months later and the epilated hairs were counted. In three of the subjects, fewer hairs were counted, and more hairs were counted in five subjects. The differences in hair counts were not significant in any of the subjects.

Two of the 515(i) submissions (Refs. 3 and 4) provided unpublished clinical information supporting the effectiveness of tweezer-type epilators for hair removal. Although the numbers of subjects in both studies are low, these study results are suggestive of clinical effectiveness. In one study (Ref. 4), 12 subjects with 14 epilation sites were treated monthly for 6 months with both a radio frequency tweezer-type epilator and the same tweezer-type epilator with the radio frequency energy source disabled. Use of the radio frequency disabled device was considered equivalent to manual plucking. The epilated hairs were counted at 6 months and at 9 months after 3 months of no treatment. After 6-month treatment, there were fewer hairs in both groups (52.3 percent fewer in the radio frequency tweezer-type epilator group and 19.1 percent fewer in the radio frequency disabled tweezer-type epilator group). After 3 months of followup with no treatment, the radio frequency treated group had 46.3 percent fewer hairs indicating that hair loss persisted 3 months after the last treatment. The radio frequency disabled tweezer-type epilator group had the same number of hairs as before treatment indicating there was no overall hair loss after the last treatment.

In the second unpublished study (Ref. 3), use of a radio frequency tweezer-type epilator weekly for 4 months was compared to use ''at an earlier time'' of a galvanic epilator in seven subjects for 9 weeks. The radio frequency tweezer-type epilator subjects were examined (hair counts) at 15 and 30 days after the last treatment given at 4 months. Hair loss was reported to be 79 percent in the radio frequency epilator group and about 60 percent in the galvanic epilator group. Because the treatment schedules of the two groups are not identical, it is not possible to draw a definitive conclusion from this report other than it is suggestive of sustained hair removal.

Use of the noninvasive tweezer-type epilator eliminates some risks to health associated with the use of the needle-type epilator. The needle-type epilator, an invasive device, removes unwanted hair by inserting a wire needle into the hair follicle to destroy the dermal papilla of a hair. Serious adverse device events associated with the use of needle-type epilators are also rare, but they include reports of temporary pain, edema, erythema, scarring, infection, and posttreatment hyper- and hypopigmentation; a case of diphtheroid endocarditis; and spreading of flat warts (Refs. 6 and 9).

FDA now believes, based on publicly available information, that the tweezer-type epilator can be regulated as a class I device (general controls) to reasonably assure the device's safety and effectiveness. FDA further believes that agency review of premarket notification submissions for the device will not enhance public health.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday:

1. 515(i) Submission submitted by Burke Associates International, Inc., received August 8, 1996.

2. 515(i) Submission submitted by Lucy Peters, International, Ltd., received September 5, 1996.

3. 515(i) Submission submitted by The Helene Edgar Corp., received September 10, 1996.

4. 515(i) Submission submitted by Removatron International Corp., received September 24, 1996.

5. Chernosky, M. E., ''Permanent Removal of Superfluous Hair,'' *Texas Medicine*, 67:72–78, 1971.

6. Hobbs, E. R., J. L. Ratz, and B. James, ''Electrosurgical Epilation,'' *Dermatologic Clinic*, 5:437–444, 1987.

7. McKinstry, C. T., M. Inaba, and J. N. Anthony, ''Epilation by Electrocoagulation: Facts that Result in Regrowth of Hair,'' *Journal of Dermatologic Surgery and Oncology*, 5:407–411, 1979.

8. Verdich, J., ''A Critical Evaluation of a Method for Treatment of Facial Hypertrichosis in Women,'' *Dermatologica*, 168:87–89, 1984.

9. Wagner, R. F., Jr., J. M. Tomich, and D. J. Grands, ''Electrolysis and Thermolysis for Permanent Hair Removal,'' *Journal of the American Academy of Dermatology*, 12:441–449, 1985.

IX. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the 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. Reclassification of this device from class III to class I will relieve all manufacturers of the device of the cost of complying with the premarket

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.

[FR Doc. 97–15312 Filed 6–10–97; 8:45 am]

BILLING CODE 4160–01–F

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_x 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_x) 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_X 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]

BILLING CODE 6560–50–P

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