

a general control, namely the misbranding provision of section 502 of the act. Additionally, FDA acknowledges that there is no statistically significant scientific data available at this time to support promotional claims of permanent or long-term removal of hair through use of the device.

II. FDA's Conclusion

FDA has concluded based on review of the available information that use of the tweezer-type epilator removes hair and that use of the device does not present a potential unreasonable risk to the public health. FDA has also concluded that general controls would provide reasonable assurance of the safety and effectiveness of the device, and therefore, the device should be regulated as a class I device.

On November 21, 1997, the President signed FDAMA into law. Section 206 of FDAMA, in part, added a new section 510(l) to the act (21 U.S.C. 360(l)). Under section 501 of FDAMA, new section 510(l) became effective on February 19, 1998. New section 510(l) provides that a class I device is exempt from the premarket notification requirement under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness injury (hereafter "reserved criteria"). FDA has determined that the device does not meet the reserved criteria, and, therefore, it is exempt from the premarket notification requirements.

FDA also notes that 21 CFR 878.9(a), Limitations of exemptions from section 510(k) of the act, requires manufacturers to submit a premarket notification for any tweezer-type epilator whose intended use is different from the intended use of legally marketed tweezer-type epilators.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this final rule 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612). 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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. Because this final rule would reduce a regulatory burden for all manufacturers of tweezer-type epilators covered by this rule, the agency certifies that the final 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.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Verdich, J., "A Critical Evaluation of a Method for Treatment of Facial Hypertrichosis in Women," *Dermatologica*, 168:87-89, 1984.

2. 515(i) Submission submitted by the Helen Edgar Corp., received September 10, 1996.

3. 515(i) Submission submitted by Removatron International Corp., received September 24, 1996.

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, 21 CFR part 878 is 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: 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 an electrical device intended to remove 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 subject to § 878.9.

Dated: October 8, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98-28579 Filed 10-23-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences under the District of Columbia Code

AGENCY: United States Parole Commission, Justice.

ACTION: Interim rule; amendments.

SUMMARY: The U.S. Parole Commission is amending the Point Assignment Table it uses to determine the suitability for parole of prisoners serving sentences under the District of Columbia Code. The amended Point Assignment Table is intended to clarify the scoring instructions pertaining to prisoners whose crimes involve violence, and to make it clear that a prisoner who has negative institutional behavior can improve his record and gain credit for subsequent program achievement. These amendments are intended to ensure that the Point Assignment Table serves as a reliable measure of risk in the case of violent offenders, as well as an accurate measure of a prisoner's institutional record.

DATES: *Effective Date:* October 26, 1998. Comments must be received by December 1, 1998.

ADDRESSES: Send comments to Office of General Counsel, U.S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815.

FOR FURTHER INFORMATION CONTACT: Pamela A. Posch, Office of General Counsel, U.S. Parole Commission, 5550

Friendship Blvd., Chevy Chase, Maryland 20815, telephone, (301) 492-5959.

SUPPLEMENTARY INFORMATION: Under Section 11231 of the National Capital Revitalization and Self-Government Improvement Act of 1997 (Pub. L. 105-33) the U.S. Parole Commission assumed, on August 5, 1998, the jurisdiction and authority of the Board of Parole of the District of Columbia to grant and deny parole, and to impose conditions upon an order of parole, in the case of any imprisoned felon who is eligible for parole or reparole under the District of Columbia Code. At 63 FR 39176, Part IV (July 21, 1998), the Commission published interim regulations, with a request for public comments, to govern this new function. These regulations contain a Point Assignment Table that measures the risk of recidivism, the seriousness of the risk, and the institutional record presented by each parole applicant. See 28 CFR 2.80(f).

Use of the Point Assignment Table since August 5, 1998 has shown the need for clarification in some of the application instructions. The amended Point Assignment Table will: (1) Clarify that points scored under Category III for "high level violence" are always added to points scored under Category II for "violence in current offense;" (2) clarify Category III by explaining that "other high level violence" means any offense involving "high level violence" except a homicide or attempted murders; (3) amend Category IV by distinguishing between "aggravated" and "ordinary" negative institutional behavior; and (4) amend Category V by deleting the requirement for "acceptable institutional behavior" so that Category V does not conflict with the provision

in § 2.80(d) that permits the deduction of points for positive program achievement despite prior "negative institutional behavior" during the same time period. (This provision is intended to encourage prisoners to improve their conduct.)

It is to be emphasized that these are not substantive changes to the Point Assignment Table, which has been implemented by the Commission since August 5, 1998, in a manner consistent with the amended instructions.

As implemented since August 5, 1998, the Point Assignment Table at § 2.80 appears to be fulfilling the purpose of providing an improved measure of the risk to the public safety presented by candidates for parole. Preliminary figures show that decisions to override the Point Assignment Table and deny parole notwithstanding a favorable Total Point Score have occurred in approximately ten percent of the cases decided since August 5, 1998. On the other hand, approximately 40 percent of the cases decided under the revised Point Assignment Table were granted parole. (These are prisoners without significant prior records or aggravated current offense factors.) This is consistent with historical rates of parole, on both state and federal levels, in the United States.

The interim regulations, including the Point Assignment Table at § 2.80, remain open for public comment, and will be subject to revision by the Commission as further experience is gained.

Good Cause Finding

The Commission is making these amendments effective on the date of this publication for good cause pursuant to 5 U.S.C. 553(d)(3). This is because the Point Assignment Table is currently

being implemented, and the amendments are intended to clarify the Commission's current decisionmaking practice.

Executive Order 12866 and Regulatory Flexibility Statement

The U.S. Parole Commission has determined that this amended interim rule is not a significant rule within the meaning of Executive Order 12866, and the amended interim rule has, accordingly, not been reviewed by the Office of Management and Budget. The amended interim rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Probation and parole, Prisoners.

The Amendment

Accordingly, the U.S. Parole Commission is adopting the following amendments to 28 CFR part 2.

PART 2—[AMENDED]

1. The authority citation for 28 CFR Part 2 continues to read as follows:

Authority: 18 U.S.C. 4203(a)(1) and 4204(a)(6).

Subpart C—District of Columbia Code Prisoners and Parolees

2. The Point Assignment Table at § 2.80(f) is revised to read as follows:

§ 2.80 Guidelines for D.C. Code Offenders.

* * * * *

(f) *Point assignment table.*

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POINT ASSIGNMENT TABLE

Category I: Risk of recidivism		(Salient factor score)
10-8 (Very Good Risk)		+0
7-6 (Good Risk):		+1
5-4 (Fair Risk):		+2
3-0 (Poor Risk):		+3
Category II: Current or Prior Violence		(Type of Risk)
Note: Use the highest applicable subcategory. If no subcategory is applicable, score = 0.		
A. Violence in current offense, and any felony violence in two or more prior offenses		+4
B. Violence in current offense, and any felony violence in one prior offense		+3
C. Violence in current offense		+2
D. No violence in current offense and any felony violence in two or more prior offenses		+2
E. Possession of firearm in current offense if current offense is not scored as a crime of violence		+2
F. No violence in current offense and any felony violence in one prior offense		+1

POINT ASSIGNMENT TABLE—Continued

Category I: Risk of recidivism		(Salient factor score)
Category III: Death of Victim or High Level Violence		
Note: Use highest applicable subcategory. If no subcategory is applicable, score = 0. A current offense that involved high level violence must be scored under both Category II (A, B, or C) and under Category III.		
A. Current offense was high level or other violence with death of victim resulting:		+3
B. Current offense involved attempted murder:		+2
C. Current offense involved high level violence (other than homicide or attempted murder):		+1
Base Point Score (Total of Categories I–III)		
Category IV: Negative Institutional Behavior		
Note: Use the highest applicable subcategory. If no subcategory is applicable, score = 0.		
A. Aggravated negative institutional behavior involving:		
(1) assault upon a correctional staff member, with bodily harm inflicted or threatened,		
(2) possession of a deadly weapon,		
(3) setting a fire so as to risk human life,		
(4) introduction of drugs for purposes of distribution, or (5) participating in a violent demonstration or riot:		+2
B. Ordinary negative institutional behavior		+1
Category V: Program Achievement		
Note: Use the highest applicable subcategory. If no subcategory is applicable, score = 0.		
A. No program achievement:		0
B. Ordinary program achievement:		– 1
C. Superior program achievement:		– 2
Total Point Score (Total of Categories I–V).		

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Dated: October 20, 1998.

Michael J. Gaines,*Chairman, U.S. Parole Commission.*

[FR Doc. 98–28629 Filed 10–23–98; 8:45 am]

BILLING CODE 4410–31–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 180, 185 and 186**

[OPP–300735; FRL–6035–8]

RIN 2070–AB78

Revocation of Tolerances and Exemptions from the Requirement of a Tolerance for Canceled Pesticide Active Ingredients**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This final rule announces the revocation of tolerances for residues of the pesticides listed in the regulatory text. EPA is revoking these tolerances because EPA has canceled the food uses associated with them. The regulatory actions in this document are part of the Agency's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the tolerance reassessment requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA). By law, EPA is required

to reassess 33% of the tolerances in existence on August 2, 1996, by August 1999, or about 3,200 tolerances.

DATES: This final rule becomes effective January 25, 1999.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Joseph Nevola, Special Review Branch, (7508C), Special Review and Reregistration Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location: Special Review Branch, CM #2, 6th floor, 1921 Jefferson Davis Hwy., Arlington, VA. Telephone: (703) 308-8037; e-mail: nevola.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Does this document apply to me?**

You may be affected by this document if you sell, distribute, manufacture, or use pesticides for agricultural applications, process food, distribute or sell food, or implement governmental pesticide regulations. Pesticide reregistration and other actions [see FIFRA section 4(g)(2)] include tolerance and exemption reassessment under FFDCA section 408. In this document, the tolerance actions are final in coordination with the cancellation of associated registrations. Potentially affected categories and entities may include, but are not limited to:

Category	Examples of Potentially Affected Entities
Agricultural Stakeholders.	Growers/Agricultural Workers Contractors [Certified/Commercial Applicators, Handlers, Advisors, etc.] Commercial Processors Pesticide Manufacturers User Groups Food Consumers
Food Distributors	Wholesale Contractors Retail Vendors Commercial Traders/Importers
Intergovernmental Stakeholders.	State, Local, and/or Tribal Government Agencies
Foreign Entities	Governments, Growers, Trade Groups

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this table could also be affected. If you have any questions regarding the applicability of this action to a particular entity, you can consult with the technical person listed in the "FOR FURTHER INFORMATION CONTACT" section.