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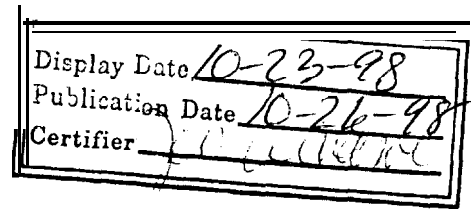

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to reclassify the tweezer-type epilator from class 111 (premarket approval) to class I (general controls) when intended to remove hair. FDA is also exempting this device from the premarket notification (510(k)) requirements, This action is taken 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), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This regulation is effective (insert *date .?0 days after date of publication in the* **Federal Register).**

FOR FURTHER INFORMATION CONTACT: Stephen P. Rhodes, Center for Devices and Radiological Health (HFZ–41 O), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, **301-594-3090.**

SUPPLEMENTARY INFORMATION:

I. Background

Inthe Federal Register of June 11, 1997 (62 FR 31771), FDA issued a proposed rule to reclassify the tweezer-type epilator from class III to class I based on new information respecting such device. FDA also proposed to exempt the device from premarket notification procedures.

Interested persons were given until September 9, 1997, to comment on the proposed rule. During the comment period, FDA received 10 comments.

One comment supported the proposed reclassification from class III to class I without providing any specific reason for endorsing the proposed reclassification. Nine comments were opposed to the proposed reclassification.

1. Two comments raised concerns about the device's safety. They stated that the device could cause burns and scars on the skin if it was improperly manufactured or used. One of these comments mistakenly believed that FDA was also proposing that the device be exempt from the current good manufacturing practices (CGMP'S) regulation.

FDA agrees that improper manufacturing and use of the device could result in bums and scars on the skin. FDA also is clarifying for the record that the device was not proposed to be exempt from the CGMP's regulation (21 CFR part 820). FDA, however, believes that these risks can be controlled by general controls such as the CGMP requirements and labeling requirements.

2. Eight comments (from professional associations, a professional magazine, practitioners, a former patient, and a manufacturer) opposed reclassification because they believe the device is not effective in permanently removing unwanted hair. Four of these eight comments stated that there are no published scientific data demonstrating that the device permanently destroys hair. Three of these comments stated that hair is a dielectric material, i.e., a nonconductor of electricity so that it is impossible for electricity to descend through the hair to the dermal papilla and destroy it. Two of these three comments stated that there is no evidence that the device destroys the dermal papilla of hair. Another comment indicated that the effectiveness claims for the device are anecdotal and that there is much information that the device is ineffective.

FDA acknowledges that the published literature contains no evidence of statistically significant data showing that the device is effective in achieving permanent removal of hair. In the proposed rule, FDA described the one published study using the device (Ref. 1) that reported that the difference in the hair counts before and after treatment was not significant. Also in the proposed rule, the agency described the results of two unpublished studies (Refs. 2 and 3) and evaluated these results as being only suggestive of effectiveness in permanently removing hair. Thus, FDA agrees with the comments that there is no body of significant information establishing the effectiveness of the device to permanently remove hair. FDA, however, still believes that the device can be reclassified into class I, because claims for the device can be addressed by the misbranding provision of section 502 of the act (21 U.S.C. 352).

3. Three comments stated that the first sentence of the revised identification statement that "the tweezer-type epilator is a device intended to remove hair by destroying the papilla of a hair" is misleading because the phrase "destroying the papilla of a hair" is equivalent to stating the device permanently removes hair. They pointed out that this phrase is part of the identification statement of another device intended to remove hair, the needle epilator, 21 CFR 878.5350.

Although there is no universally accepted medical definition of what constitutes permanent removal of hair, FDA acknowledges that the phrase "destroying the papilla of a hair" is widely accepted by many to be equivalent to stating the device permanently removes hair. FDA now believes that the use of this phrase in the device identification statement was inaccurate, and in this final rule, is removing this phrase from the device identification.

4. Six comments related to the promotional material for the device. They stated that this material frequently contains false and misleading claims, specifically that the device is effective for permanent or long-term removal of hair. Five of these six comments also stressed that it is FDA's duty to protect the public from false and misleading claims regarding a product's effectiveness and that reclassification into class I could increase the number of such claims.

FDA takes seriously its responsibility to protect the public from false and misleading claims about a product's effectiveness; however, false and misleading claims may be controlled by 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.

IL 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(1) to the act (21 U.S.C. 360(1)). Under section 501 of FDAMA, new section 5 10(I) became effective on February 19, 1998. New section 510(1) 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. 601–61 2). 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 maybe 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: 10-8-98

October 8, 1998

D.B. Burlington
Director
Center for Devices and Radiological Health

[FR Dec. **98-????** Filed '??-$??-98; 8:45 am]

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