DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2000

Andrea J. James
1516 W, Waveland Avenue #3
Chicago, IL 6061313612

Re: Petition for Reconsideration of K8925 14 and K905125

Dear Ms. James:

This letter responds to your petition dated May 19, 1999, requesting reconsideration of our clearance of premarket notifications K8925 14 for the AHRS Epilator 629 and K905125 for the Guaranty Hair Removal (GHR) System. For each of these devices, you are requesting the following actions: 1) rescission of the device clearance as substantially equivalent to predicate needle-type epilators, 2) revision of device identification to match other tweezer-type epilators, 3) revision of language in device intended use, and 4) prohibition of implied device labeling claims of permanent hair removal. We are denying your requests for the reasons that follow:

First, you request that we rescind the device clearances as substantially equivalent to predicate needle-type epilators. The initial classification of the AHRS Epilator 629, as a needle-type epilator, was made in error. We corrected this mistake shortly after we determined the device to be substantially equivalent to a preamendment tweezer-type epilator. We accomplished the correction by issuing a revised order to the manufacturer that reflects the proper classification of the device. Concerning the GHR System, our records show that the device was not cleared for marketing as a needle-type epilator, but was also cleared as a tweezer-type epilator. Therefore, your request is based on an erroneous assumption that these devices have been found substantially equivalent to ueedlc-type epilators.

Second, you request that we revise the identification of the devices to match other tweezer-type epilators. Both of these devices are already classified as tweezer-type epilators under classification regulation 21 CFR § 8785360 (copy enclosed). Complete documentation to support this classification can be obtained through our Freedom of Information office by writing to the following address: Freedom of Information Staff (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Room 12A-16, Rockville, MD 20857.

With respect to your requested actions 3 and 4, FDA does not believe the identification language should be changed or that regulatory actions are currently warranted. FDA published the final rule reclassifying the tweezer-type epilator (21 CFR 8'785360) into class I in the Federal Register of October 26, 1998 (63 FR 57059). FDA also exempted these types of devices from premarket notification (section 510(k)) requirements subject to the routine limitations on exemptions (21 CFR 878.9).

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In this final rule FDA identified the tweezer-type epilator as "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." The intended use of the device in the device identification is to remove hair. The words "permanent" or '"long-term" are not part of the definition in the classification of tweezer-type epilators. The supplementary information section of the final rule, however, states that there is no statistically significant data available to support promotional claims of permanent or long-term removal of hair through use of the tweezer-type epilator. This statement was included in the preamble because there was insufficient information submitted in support of the reclassification to establish "permanent" or "long term" removal and because there is no universally accepted definition for these words when used in the context of hair removal.

While claims for permanent and long-term hair removal appeared in S 10(k)s K89251 4 and K905125, these words were used in accordance with a definition that was commonly used in the context of hair removal at the time that the clearances were &ranted. Although a debate over the proper 'use of these words in the context of hair removal has ensued, FDA does not believe that there is sufficient justification to change the regulatory status of these devices, or to take immediate regulatory action against manufacturers using the words "permanent" or "long-term" in their promotion and advertising materials.

In summary, at this time needle-type and tweezer-type epilators are class I, low risk devices that do not require 510(k) clearance before going to market as long as they do not exceed the routine limitations on the exemption. Like all class I devices exempt from the 5 I O(k) requirements of the Federal Food, Drug, and Cosmetic Act, they remain subject to the remaining general controls such as the registration and listing, good manufacturing practices and prohibitions against adulteration and misbranding. Manufacturers making claims related to device performance must maintain information *to* substantiate each claim.

Although we have not granted the relief requested in your petition, I hope that you find this letter responsive to your inquiry. If you have any questions regarding this letter or FDA's regulation of epilators, please contact Commander Stephen P. Rhodes, Chief, Plastic and Reconstructive Surgery Devices Branch, in our Office of Device Evaluation's Division of General and Restorative Devices. Commander Rhodes can be reached at (301) 594-3090.

Sincerely,

Linda Kahan

Linda Kahan
Deputy Director for
Regulations and Policy
Center for Devices and
Radiological Health

Enclosure