CPG Sec. 393.200 Laser(s) as Medical Devices for Facelift, Wrinkle Removal, Acupuncture, Auricular Stimulation, etc.

BACKGROUND:

Some practitioners, mainly chiropractors and facial care establishments, have been advertising laser treatments for facelifts, acupuncture, wrinkle removal and other nonsurgical procedures. In surgical facelifts or wrinkle removal treatment, the laser beam is directed to certain points on the face or is scanned across the parts of the face to be treated. At present the effectiveness of these treatment procedures remains unproven. To date only low power lasers (class II under 21 CFR 1040.10 and 1040.11) with outputs of approximately one-half milliwatt have been used for treatments. At this level of output there does not appear to be any direct health hazard from the use of these devices provided that they are not directed into a person's eye. Chronic exposure of the eye to light from low powered lasers can cause eye injury; however, this condition is unlikely if appropriate safety procedures are followed and the eye is protected against direct exposure from laser light.

Laser devices for these uses have been identified as investigational devices and are therefore classified into class III and are regulated by the Investigational Device Exemption (IDE) Regulation under the Medical Device Amendments. The commercial distribution or sale of such investigational devices is prohibited. The devices may not be used on human subjects unless an investigational protocol is approved by an Institutional Review Board (IRB) and satisfies the requirements of 21 CFR 812.2(b)(2) for non-significant risk devices. At this time the agency has no reason to believe that these devices pose significant risk. (All laser devices must also comply with the radiation safety performance standard, 21 CFR 1040.10, under the Radiation Control for Health and Safety Act.)

Through discussions with professional and medical groups the *Center for Devices and Radiological Health* has found that these groups are concerned about the improper use and questionable claims made by some users of these devices. They have expressed a willingness to inform members of their professions of the regulatory status of such devices.

The *Center* has also informed all state licensing boards about the Agency's position.

POLICY:

At the present time no information has been submitted to FDA, nor is FDA aware of any studies that could constitute valid scientific evidence of the safety and effectiveness of medical laser devices for facelift, wrinkle removal, acupuncture, auricular stimulation therapy, biostimulation, or other related uses. Therefore, all such laser devices are considered to be class III Investigational Devices limited to use in accordance with the IDE regulation.

The commercial promotion, distribution, sale, or use of these investigational devices without IRB approval for non-significant risk devices, or without FDA approval of an IDE application for a significant risk device is considered a violation of 501(f)(1) and/or 502(f) of the FD&C Act.

Extensive investigations into the use by health professionals is not warranted since these laser devices are not of significant risk.

Warning letter or seizure recommendations may be submitted if devices are found to be in use by non-health professionals with medical claims that are clearly without basis.

Issued: 12/1/82
Revised: 3/95

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