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VIA FACSIMILE AND FEDERAL EXPRESS

August 11, 2000

Mr. William F. Defibaugh
Compliance Officer
Orthopedic, Physical Medicine, and Anesthesiology Devices Branch
Office of Compliance
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, MD 20850

Re: Rejuvenique Facial Toning System

Dear Mr. Defibaugh:

On behalf of Salton, Inc., ("Salton"), this responds to your letter of July 12, 2000 in which you comment upon the status of Salton's Rejuvenique Facial Toning System ("Rejuvenique") and express the view that you consider it to be a medical device, even absent medical or therapeutic claims, because it affects the structure or function of the body. As discussed in detail below, we respectfully disagree with the FDA's conclusion that the Rejuvenique product or its components are properly subject to regulation as a "medical device".

The Rejuvenique Facial Toning System has the legal status of a cosmetic appliance and is labeled and promoted wholly within the concepts legally applicable to such products. Rejuvenique is not a medical device because it is intended only for beautifying, promoting the attractiveness, and temporarily altering the appearance of the face and skin. It is not intended for medical or therapeutic uses. Moreover, the effects associated with its use are transitory and innocuous. Under FDA's governing statute and implementing regulations, Rejuvenique should be treated no differently than razor blades, manicuring instruments, nail extenders, depilatories, hair curlers, hair dryers, hair straighteners, exercise equipment, electric razors, facial steamers, hot tubs -- that is, as ordinarily represented and unless medical claims are made for these products, they are either cosmetic appliances or consumer products and are not subject to regulation by FDA as medical devices.

The Warning Letter states FDA's conclusion that:

> Under a United States Federal Law, the Federal Food, Drug and Cosmetic Act, Rejuvenique is considered to be a medical device because it is intended to affect the structure or function of the body. . . . Also, because Rejuvenique is intended to affect the structure and function of the body by providing electrical current to various facial muscles to repeatedly contract them, it is a device, even if no claims are made for its specific use….

Under the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), a device is defined, in relevant part, as "an instrument, apparatus, implement, machine . . . which is -

> (1) . . .
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals . . . .

Section 201(h) of the FD&C Act, 21 U.S.C. § 321 (h).

The language "intended to affect the structure or any function of the body" must be read in the context of the Congressional regulation of foods, drugs, cosmetics, and medical devices, as established in the FD&C Act. Clearly if that language is read literally, almost every product that is intended to temporarily improve the appearance of skin would be a medical device (or drug) because the only way to improve the appearance of skin is to affect the skin's "structure." All cosmetics, including even color cosmetics, affect the structure of the skin at some level. Therefore, under a literal interpretation of the medical device definition, all cosmetic products should be regulated as medical devices (or as "drugs" under the analogous definition of “drug” which contains the same structure/function language).

The definitional difference between a cosmetic and a device under Sections 201(h) and (i) of the FD&C Act rests upon the "intended" use of the article. The legislative history makes clear that it is the representations that are made for an article that will determine its proper regulatory classification:

> The use to which the product is to be put will determine the category into which it will fall….The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put.

S.Rep.No. 361, 74th Cong., 1st Sess. 4 (1935). For example, in cases in which the distinction between a cosmetic and a drug was in contention, the courts have uniformly looked to the labeling and advertising of a product to determine the "intended" use. United States v. An Article …Sudden Change, 409 F.2d 734, 739-742 (2d Cir. 1969); United States v. An Article …"Line Away", 415 F.2d 369, 371-372 (3rd Cir. 1969). In National Nutritional Foods Association v. Mathews, 557 F.2d 325, 333-336 (2d Cir. 1977), the court held that FDA could not subject dietary supplements containing high levels of vitamin A and D to regulation as drugs merely because those high levels have a "drug" effect, unless it could also identify labeling claims or other evidence to show that these products were "intended" to function as drugs.

In the Preamble to the Final Rule classifying physical medicine devices (including "powered muscle stimulators"), FDA stated:

> *FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them.* Examples of claims relevant to physical medicine devices that would cause a product to be considered a device include, but are not limited to, claims relating to the following: Re-education, correction, improvement, or maintenance of

> bodily functions impaired by abnormal bodily states or physiologic functions. Examples of abnormal bodily states or physiologic functions include, but are not limited to, the following: (1) Neuromuscular disorders (such as stroke, muscular dystrophy, multiple sclerosis, and cerebral palsy); (2) limb amputations; and (3) musculoskeletal disorders (such as arthritis, tendonitis, fractures, and low back pain). FDA has changed the regulations classifying many physical medicine devices to clarify that the regulations only apply to those products intended for medical purposes.[1]

Again, FDA makes clear that the intended use of an item is inferred from the representations and labeling associated with the product. Salton makes no medical device claims for Rejuvenique.

Clearly, Congress did not intend that the "structure/function" provision of the medical device (or drug) definition be read literally, and, obviously, FDA typically has not done so in the past. Applying the structure/function provision literally would mean that countless products on the market today would be classified as medical devices subject to FDA jurisdiction. Some products that are intended to affect the structure or function of the body, such as high heeled shoes (structure of the leg), alarm clocks (function of sleep), stereos (function of sound) and even guns (structure and function of the body), have no medical uses and, therefore, FDA simply does not regulate them.

FDA's regulation of cosmetics and drugs provides support for the position that the structure/function provisions of the FD&C Act cannot be applied literally and that a product's regulatory status should be based on claims made for the product. As the Agency knows, the definition of "drug" under the FD&C Act also has a structure/function provision. Section 201(g)(i) of the FD&C Act, 21 U.S.C. § 321(g)(1). The FD&C Act defines cosmetics as:

> articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance.

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[1] 48 Fed. Reg. 53032 (Nov. 23, 1983)(emphasis added).

As noted above, taken literally, all cosmetic products could be regulated as drugs or devices under the structure/function definition. Even moisturizers penetrate the skin and cause it to "plump," thus affecting the skin's structure. Exfoliating agents, such as alpha hydroxy acids, are commonly used in cosmetics to exfoliate skin cells. Other common cosmetic ingredients, such as zinc, urea, certain amino acids, and manganese, also exert various "physiological" effects below the stratum corneum which produce cosmetic benefits.[2] Therefore, applying the structure/function provision literally would lead to the impractical result that all of these products would be regulated as drugs.

Not only is a literal interpretation of the structure/function provision unworkable, but its application is contrary to Congressional intent. In expanding the FD&C Act's definition of drugs to include an "article intended to affect the structure or any function of the body," Congress was aware that the broad new provision could include some articles that also might fall within other definitions under the FD&C Act.[3] Yet, this does not mean that Congress meant the drug definition to encompass any article having some structural or functional effect on the body. The "structure or function" aspect of the definition was an amplification of the word "disease," not an effort to reach any product that touches the body.

It is clear from the cosmetic definition itself that Congress contemplated regulating as "cosmetics" articles "introduced into" the body, even though such an article could only achieve its intended cosmetic purpose by affecting the structure or function of the body in some way. Indeed, the definition was intentionally "drawn in broad terms to include all substances . . . intended for cleansing, or altering the appearance of, or promoting the attractiveness of the person" whether "used externally, orificially, or even internally, as in the case of the use of arsenic for clearing the complexion."[4] Further, specific legislative references to wrinkle remedies and other skin care products indicate that they have consistently been viewed by Congress as cosmetics, and not as drugs or devices.[5]

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[2] Fox, Skin Care Literature and Patent Review, 102 Cosmetics & Toiletries 45 (Apr. 1987).

[3] See, S. Rep. No. 361, 74th Cong., 1st Sess. 3 (1935) (emphasis added).

[4] See, S. Rep. 361, 74th Cong. 1st Sess. 3 (1935) (emphasis added).

[5] See, 83 Cong. Rec. H415-20 (Jan. 12, 1938) (debating proposed Wheeler-Lea Amendments to Federal Trade Commission Act) (remarks of Rep. Coffee, describing claims that products would smooth wrinkles, remove lines, or rebuild skin tissue as potentially subject to

In considering whether cosmetic products should be regulated as drugs on the basis of labeling and advertising claims, Courts have refused to adopt such a "broad reading of the definition of drug" that "any claim of physical change or effect makes [an] . . . article a drug."[6] The essential question, rather, is whether the claims "may fairly be said to constitute a representation that the product[s] will affect the structure of the body in some medical -- or drug-type fashion, i.e., in some way other than merely 'altering the appearance."[7]

This issue arose in a line of cases decided in the late 1960s and early 1970s that examined the "drug" versus "cosmetic" character of claims made for various wrinkle creams which employed albumin proteins to smooth the surface of the skin. The first district court to rule on the issue held that because the product was intended to "smooth, firm and tighten the skin" it "[o]bviously ... ha[d] as its objective affecting the structure of the skin [and h]ence . . . falls within the literal definition of a drug." United States v. An Article . . . "Line Away . . .", 284 F. Supp. 107, 109 (D. De. 1969). However, a second district court refused from the outset to construe the definition literally stating that "contrary to Congress' express intention, this reasoning would convert all cosmetics -- as well as other items -- into drugs." United States v. An Article . . . "Sudden Change . . .", 288 F. Supp. 29,. 34 (E.D.N.Y. 1968). On appeal, the Second Circuit likewise focused its analysis not on the literal language of the definition, but on how the particular claims

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regulation as false cosmetic advertisements); Drug Industry Act, 1962: Hearings on H.R. 11581 and 11582 Before the House Comm. On Interstate and Foreign Commerce, 87th Cong., 2d Sess. 106 (remarks of Rep. Sullivan, characterizing "potions . . . which are supposed to take out wrinkles" as cosmetics subject to proposal requiring declaration of ingredients).

6 United States v. An Article . . . "Helene Curtis Magic Secret . . .", 331 F. Supp. 912 915-16 (D. Md. 1971)(summarizing and adopting prior case law).

7 United States v. An Article . . . "Sudden Change . . .", 409 F.2d 734, 742 (2d Cir. 1969); see also United States v. An Article . . "Line Away . . ."; 48 Fed. Reg. 5852, 5861-62 (1983) (Tentative Final Monograph, External Analgesic Drug Products) (distinguishing between drug claims, which describe "therapeutically significant" characteristics, and claims describing nontherapeutic characteristics of product performance, which would fall outside OTC drug review).

would be understood by the buying public.[8] This approach was also adopted in the final case on the matter, Magic Secret.[9]

Several other courts have refused to construe the FD&C Act's definitions so broadly that other definitional categories would be subsumed or made meaningless. For example, in Action on Smoking and Health v. Harris,[10] the court concluded that Congress did not intend the "structure or . . . function" definition to be "as all-inclusive as it literally appears," since "anything which stimulates any of the senses may be said . . . to affect the function of the body."

Both the statute and the legislative history indicate that questions of classification under the device and drug definitions must be resolved by examining a product's intended use.[11] As stated by the Second Circuit in Sudden Change, intended use may be determined from "labeling, promotional materials, advertising and any other relevant source."[12] Similarly, the legislative history indicates Congress' expectation that products would be classified on the basis of intended use as "clearly shown by the labeling and advertising."[13] Indeed, it was noted that the manufacturer itself could control the product's classification by means of "fai[r] and unequivoca[l]" representations about the product's intended use.[14]

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8 United States v. An Article . . . "Sudden Change . . . ", 409 F.2d 734, 740 (2d Cir. 1969) rev'g 288 F. Supp. 29 (E.D.N.Y. 1968).

9 United States v. An Article . . . "Helene Curtis Magic Secret . . .", 331 F. Supp. 912 915-16 (D. Md. 1971)(summarizing and adopting prior case law).

10 655 F.2d 236, 240 (D.C. Cir. 1980) (upholding FDA refusal to regulate cigarettes as drugs, citing FTC v. Liggett & Myers Tobacco Co., 108 F. Supp. 573 (S.D.N.Y. 1952), aff'd 203 F.2d 955 (2d Cir. 1953).

11 See, S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935) ("The use to which the product is to be put will determine the category into which it will fall."). See also United States v. An Article of Drug . . . "Helene Curtis Magic Secret . . .", 331 F. Supp. 912, 915 (D. Md. 1971) (intended use controls determination).

12 409 F.2d at 739.

13 S. Rep. No. 361, 74th Cong. 1st Sess. 4 (1935)(emphasis added)

14 Id.

Further, there are other products that we refer to as "dual use" products, which incidentally affect the structure or function of the body and have both appropriate medical and non-medical uses. Dual use products include such things as exercise equipment, massagers, light bulbs, beds, steam rooms, hot tubs, support stockings, athletic supporters, razor blades, manicure instruments, and vibrators. Clearly, in the absence of medical claims, none of these products should be, or are, considered a "medical device." In fact, FDA has dealt with the jurisdictional issue for all of these products by taking the position that whether these products are regulated as medical devices depends solely on whether the products are intended for medical uses based on representations made in their labeling. For example:

- Exercise Equipment. Obviously, all exercise equipment is intended to affect the structure (muscles) or function (cardiovascular system) of the body, and FDA has classified four types of exercise equipment as medical devices: Exercise Component, 21 C.F.R. § 890.5350; Measuring Exercise Equipment, 21 C.F.R. § 890.5360; Nonmeasuring Exercise Equipment, 21 C.F.R. § 890.5370; and Powered Exercise Equipment, 21 C.F.R. § 890.5380. FDA's definition of all of these devices requires that they be "*intended for medical purposes*, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity." (emphasis added).

  To further clarify when exercise equipment will be regulated as a medical device, FDA has stated that "FDA regulates as devices only those products intended for medical purposes."[15] The Agency also provided the following examples of claims that would not cause a product to be a medical device: "*provides aerobic fitness*"; "*improves circulation*"; "*improves physical fitness*"; "*improves muscle size*", "*improves muscle or body tone*"; "*reduces inches*"; "*slims, trims, or firms the body or muscles*"; "*burns calories*"; "*promotes or aids weight loss*", "*body shaping*", or "*contouring*"; and "*develops or improves endurance, strength, or coordination*".[16]

- Massagers. Many massagers are promoted to relax the body (function) and are not regulated as medical devices. A "therapeutic massager," on the other hand, is a

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[15] See, FDA CPG Manual 7382.836, Agency-Wide Health Fraud Consumer Education Program FY 91/92.

[16] Id.

medical device that is defined as a device intended for *medical purposes*, such as to relieve minor muscle aches and pains." 21 C.F.R. § 890.5660 (emphasis added).

- Beds. Even though many beds claim to "improve sleep" (function), only beds that are for medical purposes are regulated as medical devices. *See, e.g.*, "Air-fluidized bed" 21 C.F.R. § 890.5160 (". . . intended for *medical purposes* to treat or prevent bedsores . . ."; "Powered flotation therapy bed" 21 C.F.R. § 890.5170 (". . . intended for *medical purposes* to treat or prevent a patient's bedsores . . ."); "Manual patient rotation bed" 21 C.F.R. § 890.5180 (". . . intended for *medical purposes* to treat or prevent bedsores . . ."); Manual adjustable hospital bed" 21 C.F.R. § 880.5120 (". . . intended for *medical purposes* . . .").

- Steam. While steam rooms can relax (function) the body, and facial steamers can open the pores of the face (structure) to facilitate the removal of oily and dead skin cells, only steamers that are promoted for medical purposes are regulated as medical devices by FDA. A "Moist Steam Cabinet" is defined as ". . . a device intended for *medical purposes* that delivers a flow of heated, moisturized air to a patient in an enclosed unit." 21 C.F.R. § 890.5250 (emphasis added).

- Hot Tubs. Similarly, hot tubs are promoted to relax (function) the body. However, FDA only regulates as medical devices "hot tubs" that are intended for medical purposes. An "immersion hydrobath" is defined as ". . . a device *for medical purposes* that consists of water agitators . . ." 21 C.F.R. § 890.5100 (emphasis added).

- Support Stockings. Many stockings are promoted to affect the shape (structure) of a woman's body to improve one's contours. However, a "medical support stocking" is a medical device when it is intended to " . . . apply controlled pressure to the leg and that is intended for *medical purposes."* 21 C.F.R. § 880.5780(b) (emphasis added).

- Athletic Supporters. Athletic supporters, which are generally not regulated as medical devices, are, of course, intended to support (structure) a part of the body. However, once medical claims are made for the product, they are regulated as medical devices. FDA has defined "Therapeutic Scrotal Support" products to be products "intended for *medical purposes* that consists of a pouch attached to an elastic waistband and that is used to support the scrotum." 21 C.F.R. § 880.5820 (emphasis added).

- Razor Blades. Razor blades are intended to affect the hair of the body (structure). FDA takes the position that razor blades "as ordinarily represented" are not medical devices.[17] Of course, this implies that if a razor blade makes representations that are not ordinary (i.e., medical claims), it could regulated as a medical device.

- Manicure Instruments. Like razor blades, manicure instruments are intended to affect the nails (structure) of the body. FDA has issued a policy stating that manicure instruments "as ordinarily represented" are not medical devices.[18] Of course, this implies that if manicure instruments make representations that are not "ordinary" (i.e., medical claims) they will be regulated as medical devices.

- Vibrators. Further, many vibrators that are intended to affect the structure or function of the body in a non-medical way are not regulated as medical devices. However, FDA has defined a class of medical devices called "Therapeutic vibrators," which are defined as ". . . electrically powered devices intended for *medical purposes* . . . " 21 C.F.R. § 890.5975 (emphasis added).

- Magnets. FDA has also applied the medical/non-medical dichotomy in regulating magnets. Any magnet placed near the body can affect the structure of the body. However, with respect to magnets, FDA has clearly limited its attention to those making therapeutic claims. Magnets *marketed with medical claims* are considered to be medical devices because they are promoted to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices, including magnets *intended for medical use*, obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.[19]

According to the reasoning set out in FDA's Warning Letter to Salton, even in the absence of any claims, all of the above products, which are intended to affect the structure or function of the body in one manner or another, should therefore be regulated as medical

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17 CPG 7124.04. September 24, 1987.

18 Id.

19 See, CDRH Internet Home Page (www.fda.gov/cdrh/consumer/c-products.shtml).

devices. FDA's new literal interpretation of the structure/function provision is absurd. If followed, FDA would have to regulate as medical devices (or drugs) most things that touch the human body, including air, water, cosmetics, food, detergents, pesticides, household appliances, alcohol, tobacco, firearms, etc…. For this reason, the intended use of the product is primarily determined by claims made by the manufacturer in labeling and advertising.

There is no basis under the FD&C Act for treating Rejuvenique differently than razor blades, manicuring instruments, nail extenders, depilatories, hair curlers, hair dryers, hair straighteners, exercise equipment, electric razors, facial steamers, hot tubs. If an exercise machine can "improve muscle or body tone" and "firm the body" and not be a medical device, then certainly Rejuvenique, which makes claims such as "improves skin tone" and "improves the appearance of fine lines and wrinkles" is also not a medical device. Further, there is also no basis under the FD&C Act for treating face products differently than body products, or for treating electric products differently than non-electric products (which is why other types of electric products, such as hair dryers and curling irons, are not regulated as medical devices).

Moreover, FDA's letter states that "Rejuvenique is similar in technology to a "powered muscle stimulator" device identified under 21 Code of Federal Regulations (CFR) 890.5850." Even assuming, *arguendo*, that Rejuvenique does use technology similar to "powered muscle stimulators," the fact that a product is similar in technology to a medical device does not, *ipso facto*, make it a medical device. With all of the "dual use" products noted above, the FDA has clearly concluded that whether a product is a medical device depends on the representations and claims made for the product. Certainly non-medical exercise equipment can use exactly the same technology as medical exercise equipment. In fact, the same piece of exercise equipment can be a medical device if it is advertised for medical use (muscle re-education), but not be a medical device if it is marketed for other uses (muscle toning). Indeed, a product that may use a technology similar to a powered muscle stimulator can serve a valid and appropriate cosmetic function regardless of whether it also incidentally has some effect on the structure or function of the body. Thus, even assuming, *arguendo*, that Rejuvenique is similar in technology to a powered muscle stimulator, that does not mean it should be classified as a medical device.

In a guidance document, FDA provided the following indications for muscle stimulators:[20]

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[20] See, FDA Guidance for Industry, FDA Reviewers/Staff and Compliance for Powered Muscle Stimulator 510(k)s, Office of Device Evaluation, June 9, 1999.

- Relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

The Rejuvenique Facial Toning System does not bear any of the above claims in its labeling or advertising nor is intended for any of these uses. Thus, Rejuvenique does not fit within FDA's definition of "powered muscle stimulator."

FDA's current position belies its own regulation that, even absent medical claims, a product that is electrically powered and contracts muscles by passing electrical currents through electrodes is a medical device. Indeed, FDA's regulation clearly states that powered muscle stimulators are *not medical devices if they are not intended for medical purposes*.

> A powered muscle stimulator is an electrically powered device *intended for medical purposes* that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.

21 C.F.R. § 890.5850 (emphasis added).

Clearly, had FDA intended to regulate all electrically-powered appliances as medical devices, the Agency would not have included the phrase "...intended for *medical purposes*…" in its regulation. In asserting that Rejuvenique, even absent claims, is a medical device because it may use technology similar to that of a powered muscle stimulator, FDA is acting contrary to its own current regulation.

As FDA is well aware, if the Agency wished to change its current regulation to make all electrically powered appliances that contract muscles medical devices -- regardless of whether or not they are intended for medical purposes -- FDA should have done so through notice and comment rulemaking.[21] Should FDA now seek to change its regulation of such products -- regardless of whether such product is intended for a medical purpose -- the Agency must do so by notice and comment rulemaking through the issuance of a Proposed Rule in the Federal Register as required by the Administrative Procedures Act, 5 U.S.C. § 551 et seq[22]. FDA must solicit comments from all interested parties on deleting the phrase "*intended for medical purposes*" from the definition of a powered muscle stimulator.[23] Without doing so, FDA cannot take administrative action on this basis.[24]

Based on the claims that "*Rejuvenique creates a gradual reduction in the appearance of fine lines and wrinkles resulting in a face that looks more youthful*", "*that the first change people notice is the appearance of reduced puffiness of your face*", "*that it tightens skin and provides increased skin elasticity*", "*that lines that come when one grins will be fewer*", and "*that wrinkles and bags around ones eyes will seem less noticeable*", it is evident that the Rejuvenique is not intended for medical purposes. The product is intended only for beautifying, promoting attractiveness, and temporarily altering the appearance of the face and skin. The effects associated with Rejuvenique's use are transitory and innocuous. Claims for the product do not state or imply a permanent change to the skin. For example, the Owners Manual for the product provides: "If you stop using the system, you will notice a gradual change in skin tone and texture back to how they were before you started… If you stop using the system altogether, your face and skin will gradually return to its original condition."

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21 5 U.S.C. §553 (b).

22 5 U.S.C. §553(c).

23 5 U.S.C. §553 (b).

24 D&W Food Centers, Inc. v. Block, 786 F.2d 751 (6th Cir. 1986) ("a rule required to be published which is not published is void, and may not be enforced against a non-complying party"); Northern California Power Agency v. Morton, 396 F.Supp. 1187 (D.D.C. 1975), aff'd sub nom; Northern California Power Agency v. Kleppe, 539 F.2d 243 (D.C. Cir. 1976) ("No administrative action taken pursuant to unpublished procedures can be allowed to stand against a person adversely affected thereby").

Indeed, all claims for the product are consistent with traditional cosmetic claims (*e.g.*, reduction in the appearance of lines and wrinkles, improves skin tone, etc.), and FDA's guidance on permissible claims for exercise equipment (*e.g.*, improves body tone; firms the body or muscles; promotes or aids body shaping or contouring). As a walk down the skin care aisle of any drug store demonstrates, the claims cited in FDA's letter (*e.g.*, "tones the skin to reduce the appearance of wrinkling and improves skin tone; the result is a face that is more toned," etc.), appear on countless cosmetic products on the market today. All of which would now have to be regulated as either drugs or devices applying FDA's analysis in this matter. Therefore, consistent with the legislative history of the FD&C Act, as well as FDA's treatment of products such as exercise equipment, massagers, beds, steam rooms, hot tubs, support stockings, athletic supporters, razor blades, manicure instruments, and vibrators, to name a few, and the way FDA previously has handled facial toning products, Rejuvenique should not be regulated as a medical device. The other assertions in your letter may or may not apply to particular products that are subject to classification as medical devices, but they do not apply to the Rejuvenique Facial Toning System.

Finally, and perhaps most significantly, FDA has been aware of the existence of electrically powered facial toning cosmetic appliances for, literally, decades. Such products have a long history of over-the-counter commercial availability and safe use in the U.S. Facial toning products bearing claims to improve the appearance of the skin have been extensively and safely used in the U.S. since the early 1900's, both in beauty salons and by consumers at home. In fact, these products are so ubiquitous that in a scene in the 1950 film "Sunset Boulevard," the star of the film, Gloria Swanson, is seen using such an appliance to improve her appearance. The Agency has never objected to the marketing and sale of such products directly to consumers (except when such products bore non-cosmetic claims). In fact, we are aware of at least one facial toning product that was permitted to remain on the market after an FDA investigation of claims was made for the product. The company marketing the product was contacted by FDA because of serious disease claims made for that product. Once the company changed its claims for the product, FDA had no further objection to the product and specifically permitted it to continue to be marketed. FDA's actual knowledge of the existence of electrically powered facial toning appliances, combined with their inaction to attempt to regulate such appliances as medical devices provided that they do not bear medical claims, is evidence of FDA's tacit consent for their commercial use as over-the-counter cosmetic appliances.

In order to better understand the Agency's position on these types of products, we have submitted several requests under the Freedom of Information Act (FOIA) for

information relating to the classification of Powered Muscle Stimulators and other similar products that FDA has had occasion to review. We have followed up these requests with telephone calls but, thus far, we have not received the requested information.

Salton would like to work with the FDA to resolve this matter as quickly as possible. Toward that end, we would like to meet with representatives of the Agency to discuss this matter directly and work towards addressing the Agency's concerns. We will be calling your office shortly in an effort to set up such a meeting.

Sincerely,

Georgia C. Ravitz
Wayne H. Matelski
Ivan J. Wasserman

Enclosures
cc: Raymond Mlecko (HFR-MW100)
District Director
Chicago District Office

Salton\warn1-resp801.doc