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Client: Equibal Labs

Subject: Nufree Hair Removal System

Health and Product Risk Assessment/Management Advisory

Note: This report contains information pertaining to confidential communications between Equibal Labs and Bio-Control Consultants, Inc.

Introduction:

A number of state Boards of Cosmetology follow a general policy that states when using a standard wax hair removal system, one should attempt to “ensure that the wax product remains free of contamination” and that one should “never double dip” when using a disposable applicator stick for this purpose. Apparently, there is a concern that STDs or other pathogenic microbial contamination may be transferred from infected individuals to wax hair removal products where they could possibly survive and grow. The same standard pertaining to “double dipping” is apparently also being applied to other non-wax hair removal systems that have significantly different product properties and application characteristics. The Nufree Hair Removal System is one of these. It is a unique anhydrous soy based, non-wax antimicrobial formulation that has been successfully and safely used in salons for over 32 years. Although the application function is similar to that of old style waxing techniques, Nufree does not adhere to skin as does wax thus reducing the possibility of significant skin abrasion or damage. The discussion presented here is intended to establish and verify the product’s excellent antimicrobial and microbial resistance profiles while demonstrating that these properties coupled with a reduction in skin trauma can significantly reduce the probability of Nufree liquid becoming microbiologically contaminated during normal use by trained personnel.

STDs/Risk Assessment:

In general, an STD is a disease (infection) that has a negligible probability of transmission by means other than sexual contact, intimate skin-to-skin contact (mucous membranes) or via blood transfusions and/or hypodermic needles. Examples of typical STDs are chlamidia, genital herpes, gonorrhea, syphilis, hepatitis, HIV/AIDS and HPV. The presence of other non-STD microorganisms such as *Staphylococcus aureus* and *Candida albicans* may also be of clinical significance and/or be related to STD infections. Transmission of STDs via fomites, i.e. inanimate objects, liquids, gels and creams, is

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generally not considered to be a significant factor. Considering the mode of transmission for STDs, the risk of transferring STD organisms from the skin of one person to the Nufree hair removal product and having the organisms survive long enough to be transferred to yet another person is extremely low or non-existent.

General Considerations:

According to federal regulation, personal care and salon products containing excessive levels of microbial contamination, as defined by the Food, Drug and Cosmetic Act, are considered to be adulterated and a potential hazard to the consuming population. Anhydrous antimicrobial products such as Nufree present a rather unique situation in regard to contamination control. Unlike aqueous or semi-aqueous based materials that may provide the ideal conditions for microbial survival and growth, anhydrous systems, by nature of their low moisture content, have an extremely low probability of developing a flourishing, growing microbial population when under proper conditions of storage and handling. It is generally recognized by a number of authorities that the Water Activity (Aw) of anhydrous formulations is normally far below the threshold required for microbial growth and proliferation, i.e. less than 0.50.

According to the literature, the following Water Activity (Aw) requirements for the growth of the various classes of microorganisms have been established:

Mold	0.70 to 0.98
Yeast	0.88 to 0.91
Gram + Bacteria	0.86 to 0.98
Gram - Bacteria	0.91 to 0.98

The Nufree product system, by nature of its inherent low moisture content, falls into this low risk category and has either no or an extremely low probability of developing a flourishing, growing microbial population when used as per handling and application instructions.

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Antimicrobial Studies:

In order to verify the low probability of developing a flourishing, growing microbial population in this system, an FDA certified testing laboratory was commissioned to conduct preservative effectiveness studies on the Nufree Nudesse Hair Removal product. The test protocol used was that specified in USP <51> “Antimicrobial Effectiveness” and included evaluations using the pathogens *Staphylococcus aureus* and *Candida albicans* as well as two other pathogenic bacteria and a mold at challenge levels in excess of one million organisms/gram of product. In all cases, the product easily passed the USP criteria for preservative effectiveness with the contaminating organisms being totally eliminated in less than 24 hours. At no point during the four week study was there any indication that any of the purposefully introduced contaminating microorganisms were able to survive. It was concluded that this product was highly capable of resisting incidental microbial contamination encountered during normal product use.

Antibacterial Studies:

Additional studies were conducted by the same laboratory in order to verify the antibacterial capability of Nufree Nudesse and support an antibacterial claim as per FDA 21 CFR333.470; In-Vitro Antibacterial Testing. A Time Kill study, which measures how fast organisms are destroyed, was initiated whereby three pathogenic organisms were exposed to Nufree Nudesse for time periods ranging from 15 seconds to 2 minutes. For all three organisms, after 15 seconds exposure to Nufree Nudesse, a reduction of greater than 99.9% was observed. These results are well within the requirements and established criteria for claiming this product to be antimicrobial. In a practical sense, this can be interpreted as suggesting that any organisms that may inadvertently cling to the Nufree coated applicator stick would be destroyed or eliminated within 15 seconds of contact. Based upon these findings, it is more than likely that this product could be classified as being self-sanitizing.

Conclusions:

Based upon the information presented, it is reasonable to conclude that the Nufree Hair Removal product appears to be highly capable of resisting microbial contamination inadvertently introduced during the application process.

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Considering the self-sanitizing properties of Nufree, the risk of transferring STD organisms from the skin of an infected client, having it survive in the Nufree hair removal product and transferring it to another person is extremely improbable.

By nature of its inherent low moisture content, the Nufree liquid product has either no or an extremely low probability of developing a flourishing, growing microbial population when used as per handling and application instructions.

In view of the product properties and antimicrobial profile presented, there does not appear to be any reasonable need to retain the restriction on double dipping on the Nufree hair removal product system. This product is uniquely different from typical wax based hair removal systems and shares none of the potential risks associated with those types of products.

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