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June 24, 2004

VIA FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2003N-0539

**Comments on Over-the-Counter Drug Products; Safety and Efficacy
Review; Vaginal Lubricants and Vaginal Moisturizers**

Dear Sir/Madam:

On behalf of our client C.B. Fleet Company, Incorporated (C.B. Fleet), we hereby submit these comments in response to the Request for Data and Information ("RDI"), Docket Number 2003N-0539, published in the Federal Register on December 31, 2003 at 68 Fed. Reg. 75585.

C B. Fleet, located at 4615 Murray Place, Lynchburg, Virginia, is an international producer, manufacturer and distributor of, among other things, feminine care over-the-counter ("OTC") drug and cosmetic products.

I. BACKGROUND OF REQUEST FOR DATA AND INFORMATION

Beginning in 1972, the U.S. Food and Drug Administration ("FDA" or "the Agency") commenced the OTC drug review wherein the Agency evaluated the safety and efficacy of then currently marketed OTC drug products. As part of that review process, FDA published various

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calls for data that invited interested parties to submit data and information to FDA and created Advisory Review Panels concerning the safety and efficacy of identified categories of OTC drug products. The Advisory Review Panels reviewed many of the OTC drug categories identified in the requests for data and information but those panels did not review every OTC drug category due to resource limitations and constraints. Nor were those Panels empowered to review the safety and efficacy of cosmetic products.

One of the panels, the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products, reviewed OTC drug products for a number of vaginal uses, including anti-microbial and topical analgesic use.¹ That Panel, however, did not review those products for vaginal lubricating or moisturizing uses, nor did they discuss them or consider them to be drug claims, as they did with certain other claims.² Today, a number of vaginal lubricants and/or moisturizers are marketed as cosmetic products, and, in certain cases when indicated for use with devices as medical devices.

On December 31, 2003, FDA published the RDI in Docket Number 2003N-0539, wherein it noted that there are numerous OTC vaginal products marketed as lubricants and/or moisturizers for uses including: "acts as a moisturizer for vaginal dryness," "replenishes your natural moisture for days at a time," and "with regular use provides continuous vaginal moisture for most women."³ In the RDI, FDA stated that it considers "such claims to be drug claims

¹ 48 Fed. Reg. 46694 (Oct. 13, 1983).

² Id., at 46761-62.

³ 68 Fed. Reg. 75585, 75588-89 (Dec. 31, 2003).

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because they discuss affecting the structure or function of the body and, in some cases, may relate to the mitigation of a disease."⁴ FDA further stated that it does not consider vaginal moisturizing claims to be cosmetic claims "because they do not relate to cleansing, beautifying, promoting the attractiveness, or altering the appearance" of the vagina.⁵ FDA stated that it was seeking data and information concerning this position.⁶

II. COMMENTS

C. B. Fleet disagrees with FDA's position that vaginal moisturizing claims are drug claims. Specifically, C. B. Fleet believes that the Agency and the industry have always stated that "moisturizing" claims are permissible cosmetic claims; the part of the dermis where such a product is to be used is irrelevant.

A. **Moisturizing Claims are Cosmetic Claims and not Drug Claims**

Section 201 (i) of the Federal Food, Drug and Cosmetic Act ("FFDCA") defines cosmetics as articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.⁷ In FDA's online Cosmetic Labeling Manual, the Agency states that "included in this definition are products such as skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, shampoos,

⁴ *Id.* at 75589.

⁵ *Id.*

⁶ *Id.*

⁷ 21 U.S.C. § 321 (i).

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permanent waves, hair colors, toothpastes, deodorants, and any material intended for use as a component of a cosmetic product."⁸ Indeed, they specify that skin care products intended as moisturizers are cosmetics.⁹ The FFDCA defines drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man . . . or articles intended to affect the structure or any function of the body."¹⁰ Thus a product is deemed to be a cosmetic, and not a drug, if the claims made for the product demonstrate that the product is intended to be used for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions.

A product can be both a cosmetic and drug.¹¹ Examples of products which are drugs as well as cosmetics are anticaries toothpastes (e.g., "fluoride" toothpastes), hormone creams, and sunblocks. The courts, in deciding whether a product is a "cosmetic", a "drug", or both a "drug" and a "cosmetic", have relied principally on the consumer's perception of the meaning of a label statement and less so on the interpretation of the meaning of a label statement by the labeler or a regulatory agency.

In the RDI, FDA states for the first time that it believes that vaginal moisturizing claims such as "safe and immediate relief of vaginal dryness" are drug claims "because they discuss affecting the structure or function of the body." However, until this December 31, 2003

⁸ FDA Cosmetic Labeling Manual, <<http://www.cfsan.fda.gov/~dms/cos-lab1.html>> visited on June 3, 2004.

⁹ See 21 C.F.R. § 720.4(c)(12)(vi).

¹⁰ 21 U.S.C. § 321 (g).

¹¹ 21 U.S.C. §§ 201 (g), (i) and 359.

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announcement, FDA had never stated that any moisturizing claim is a drug claim. In fact, in FDA's Cosmetic Labeling Guide, the Agency states the opposite. In the Guide, FDA states "that if cosmetic claims, e.g., moisturizing, deodorizing, skin softening etc., are made on a label, the product is a cosmetic."¹² There is no qualification in this statement as to whether such claims qualify as cosmetic claims depending on the part of the skin moisturized.

There are numerous other examples of where FDA has stated that moisturizing claims are cosmetic claims and not drug claims. For example, in Title 21 of the Code of Federal Regulations, Section 720.4 (c)(12)(4), Information Requested About Cosmetic Products, the regulations state that as part of a voluntary cosmetic product ingredient submission, that manufacturers should include the product's cosmetic category. "Moisturizing" is included as an appropriate cosmetic category to select. Additionally, in discussing the required warning statements that must appear on cosmetic suntanning preparations the regulations state that "the term 'suntanning preparations' include gels, creams, liquids, and other topical products that are *intended to provide cosmetic effects* on the skin while tanning through exposure to UV radiation (e.g., *moisturizing* or conditioning products)."¹³ In the preamble to the Final Rule for Sunscreen Drug Products for Over-the-Counter Human Use, the Agency also stated that "if a product is

¹² FDA Cosmetic Labeling Guide, <<http://www.cfsan.fda.gov/~dms/cos-lab3.html>>, visited on June 3, 2004.

¹³ 21 C.F.R. § 740.19. (Emphasis added.)

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intended solely to provide cosmetic effects on the skin (e.g., moisturizing the skin while sunbathing) . . . then the product may be marketed as a cosmetic."¹⁴

The feminine hygiene industry presently markets numerous cosmetic products marketed with "moisturizing" claims, including various vaginal moisturizing products such as:

- McNeil-PPC, Inc., markets K-Y® Brand SILK-E™ Vaginal Moisturizer with the claims "safe, immediate relief of vaginal dryness." "K-Y® Brand SILK-E™ Vaginal Moisturizer with pure vitamin E is exclusively designed to feel like your own natural moisture."
- LDS Consumer Products markets the Replens® Vaginal Moisturizer. Claims for this product include "Replenishes Vaginal Moisture," and "Freedom from vaginal dryness."
- Vagisil® Intimate Moisturizer, marketed by Combe Incorporated, contains the claims "Vagisil® Intimate Moisturizer is like bringing back your own natural moisture" and "Relieves vaginal dryness instantly, making intimate moments more pleasurable."

¹⁴ 64 Fed. Reg. 27666, 27669 (May 21, 1999).

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- At Last, Inc., markets Wild Yam Vaginal Moisturizing Gel with the claims "Provides soothing relief and lasting comfort for vaginal dryness" and "Helps restore a woman's natural lubrication."

These cosmetic products have been marketed and used safely for years to consumers who believe these products to be cosmetics. FDA has not proffered any reason or evidence as to why these products "affect the structure or function of the body" while other cosmetic products that bear moisturizing claims do not. Indeed, FDA has always conceded that since moisturizing is only a **temporary effect**, it does not meet the definition of a drug. In fact, the statements in the regulations discussed above demonstrate that FDA has always considered "moisturizing" claims to be cosmetic claims for the reason that any moisturizer produces only a temporary effect and, hence, **a moisturizer does not alter the structure or function of the body**. Nor does any such claim imply anything more than a temporary effect resulting from the addition of moisture to the skin. If the Agency were to adopt the position stated in the RDI, it would have to retract those regulations and numerous other Agency statements that have always stated that "moisturizing" claims are permissible cosmetic claims and disallow such claims on numerous products that are currently marketed as cosmetics.

Court cases have also stated that moisturizing claims are inarguably cosmetic claims. In *Unites States v. Sudden Change*, 409 F.2d 734 (2d Cir. 1969) the Court, in determining whether certain claims were drug claims, stated if the "ignorant, unthinking or credulous" consumer understands a claim to be cosmetic claim, then it is so. While the Court ultimately ruled that the

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product did indeed make drug claims, the Court noted that claims that "a product will 'soften' or 'moisturize' a woman's skin are so thoroughly familiar" that even the ignorant, unthinking or credulous consumer would understand those claims to be cosmetic claims.¹⁵

In United States v. An Article of Drug... Shipping Cartons, More or Less... "Helene Curtis Magic Secret," 331 F.Supp. 912 (D.Md. 1971), the court held that the skin care product involved did not constitute a drug on the basis of its intended use claims. The court reviewed the claims, including the claim "tightening and moisturizing tired skin" to determine "whether the claim... constitutes a representation that the product will affect the structure of the body in some medical-or drug-type fashion."¹⁶ The court ruled that although the manufacturer made claims that Magic Secret tightened and moisturized tired skin and was a "pure protein" that caused an "astringent sensation," the product was not a drug on the basis of its claims.¹⁷ Thus, this case affirms that moisturizing claims alone made without other implications are not drug claims.

The Agency's position that such products are intended to alter the structure or function of the body of man and are, therefore, drugs is inconsistent with its prior statements as to the effect of moisturizers, as well as judicial precedent. The Agency cannot regulate vaginal moisturizers as drugs on this basis.

¹⁵ *Id.* at 742.

¹⁶ *Id.*

¹⁷ *Id.*

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B. FDA Has Not Proffered Any Evidence to Support Its Assertion That Vaginal Moisturizing Claims Imply Mitigation of a Disease, And, Even if It Had, There are Other Less Restrictive Means to Address Any Such Perception

In the RDI, FDA states that one of the reasons it believes that vaginal moisturizing claims are drug claims is because that those claims may imply the mitigation of a disease. However, FDA fails to state which claims and diseases these claims refer to. Furthermore, it cites no evidence that any such implications as to a disease are being made or that there is any consumer perception that such claims are drug claims. Last, FDA cites no evidence, nor is C.B. Fleet aware of any evidence, that the products constitute a safety concern. These products consist of well known safe ingredients, such as water, not associated with any side effects or health concerns. Thus, the Agency should clearly identify which claims and which diseases the Agency is referencing so that the industry can comment appropriately. Absent any such evidence, any rulemaking on this issue would not be based on substantial evidence, and would be arbitrary and capricious.¹⁸

Furthermore, even if those claims could potentially lead consumers to believe that these products can be used to mitigate a disease, there are less restrictive ways in which FDA can reduce that potential that any claim may imply such a product can be used to mitigate a disease, such as by ensuring that claims do not mention the disease by name or the chronic conditions

¹⁸ *Carson Products Co. v. Califano*, 594 F.2d 453 (5th Cir. 1979); *Grinspoon v. Drug Enforcement Admin.*, 828 F.2d 881 (1st Cir. 1987).

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that denote the disease or by use of a disclaimer.¹⁹ Requiring the products to be regulated as drugs is a more restrictive requirement, given the stricter requirements for drugs than for cosmetics.

It is important to note that FDA has no evidence that consumers actually interpret such claims as disease mitigation claims instead of cosmetic claims. The Agency's ad hoc determination of such is not sufficient evidence to outright categorize all vaginal moisturizing claims as drug claims. The burden of generating such data rests with the Agency before it can make such a determination. Additionally, as noted, appropriately worded disclaimers or warnings are a preferred less restrictive means to cure a consumer's ability to interpret a claim as a disease mitigation claim.²⁰ Absent consideration of any such alternative course of action, FDA's proposal is overly broad and an undue restriction on protected commercial speech.

¹⁹ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (April 29, 2002) (The Government's ban on advertising of pharmacy compounding services was too broad when there were other means to achieve the government's goal of prohibiting any misleading claims, such as by affirmative disclosures or disclaimers. As stated by the Court:

Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown.

535 U.S.376. *Pearson v. Shalala*, 164 F.3d 650, 661 (D.C. Cir. 1999) (The banning of only potentially misleading health claims was unlawful when a less restrictive means of curing the potentially misleading speech was available; use of disclaimers must be considered as a less restrictive alternative.)

²⁰ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (April 29, 2002); *Pearson v. Shalala*, 164 F.3d 650, 661 (D.C. Cir. 1999).

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III. CONCLUSION

For the reasons stated above, C.B. Fleet does not agree that vaginal moisturizing claims are drug claims. FDA's history of categorizing "moisturizing" claims as cosmetic claims, as well as judicial precedent, coupled with the fact numerous products on the market make such claims and are not associated with public health concerns, and that those products do not state or imply that they can affect the structure or function of the body or imply an effect on a disease state, demonstrate that vaginal moisturizing claims are in fact cosmetic claims. Absent any evidence to the contrary, or any evidence of a public health concern, any action by FDA to regulate such claims as drug claims would be invalid. Therefore, FDA should continue to regulate vaginal moisturizing claims as cosmetic claims.

Sincerely,

SONNENSCHN NATH & ROSENTHAL LLP

By:



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