

Pharmaceutical Advertising Advisory Board
Conseil consultatif de publicité pharmaceutique

300-1305 Pickering Parkway, Pickering, Ontario L1V 3P2
Telephone: (905) 509-2275 Fax: (905) 509-2486 Internet: www.paab.ca

STAGE TWO DECISIONS

1. ADVERTISER: **Ethical Remedies**

COMPLAINANT: Biosyent

SUBJECT: c16-03 EBMFer (NPN80042242) APS

PRECLEARANCE: No

ALLEGATIONS: • *The claim to superiority in the promotion piece is a hanging comparison, which is an implicit comparison to all other iron products used for iron-deficient anemia (IDA), including FeraMax® 150. The absence of an express reference to the brand is irrelevant and is not a legitimate defense.*

• *Second, ER admits, in its response, that absorption data is not relevant to the question of clinical efficacy. It notes, specifically, that: "It's important to note that there has been no effort in the literature to link absorption with clinical efficacy in IDA ...". ER effectively admits that its absorption claims serve no legitimate purpose. They are used in the promotional piece to impliedly suggest that EMBFer™ has superior efficacy due to its allegedly superior absorption.*

• *Third, as was previously noted, ER does not have any studies or literature that supports the claimed 40% absorption figure in connection with the EMBFer™ formulation itself. ER response does not provide any authoritative data in support of such a cross-reference claim.*

DECISION: While we do not agree with all the Biosyent allegations, a PAAB review of this APS reveals the following:

- The heading is superlative, absolute, and hanging.
- In the context of a branded piece, claim "Ferrous Ascorbate has superior absorption ie >40%" along with the histogram depicting the absorption levels from the three studies suggests that this information is somehow relevant to the sponsor's brand. Although this is supposedly intended to convey information about dietary sources, this is not clear in the copy. More importantly, even if it were clear in the copy, the presentation would be incomplete unless the absorption of the ER products were included (along with a disclaimer that the clinical significance is unknown).
- It is still unclear whether the reference 4 study evaluates specifically to the sponsor's brand. This would be required as ingredients other than the iron salt may influence absorption.
- The piece has no indication of fair balance.

Thus this APS would be in violation of the PAAB Code of Advertising Acceptance and possibly the Food & Drugs Act containing potentially misleading information.

Summary and Penalty

Because the APS is in violation of the PAAB Code it should not be used for promotional purposes. Ethical Remedies states that it has not been used for one year. The PAAB would like to see some proof that the material has been retrieved from sales reps (a letter to sales reps requesting that would be sufficient) and attestation that it will not be used in future.

OUTCOME: Ethical Remedies complied with the PAAB.

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2. ADVERTISER: Searchlight Pharma

COMPLAINANT: novo nordisk

SUBJECT: c16-04 Estragyn leave behind

PRECLEARANCE: No

ALLEGATIONS: *The Price Chart constitutes off-label promotion and is misleading because the price of Estragyn® Vaginal Cream is promoted at a dose outside of the approved indication and promotion in this manner makes it appear that the Product is the cheapest local estrogen treatment available. The Estragyn® Vaginal Cream product monograph (Appendix II) states that "the recommended dose is 2.0 to 4.0 grams per day taken intravaginally". However, the Price Chart advertises the price at a dose of 0.5 grams taken 2-3 times per week.*

- *The Price Chart uses outdated and misquoted statements from the North American Menopause Society ("NAMS") regarding Estragyn® Vaginal Cream. In its most current version, the 2013 NAMS Position Statement on the management of symptomatic vulvovaginal atrophy (Appendix IV), the recommended dosage for Estragyn® Vaginal Cream is consistent with Searchlight Pharma's terms of market authorization: 2-4 g per day, intended for short-term use; progestogen recommended.*
- *The Price Chart fails to disclose that an appropriate dose of progestin is required when Estragyn® Vaginal Cream is prescribed to women with intact uteri to prevent endometrial hyperplasia/carcinoma.*

DECISION: Allegation 1 – I agree with novo nordisk. The Price Chart indeed contains off-label claims related to a dose outside of the approved indication and promotion in this manner makes it appear that Estragyn Vaginal Cream is the lowest cost local estrogen treatment available. This is a violation of PAAB Code s2.1 and 3.1.

Allegation 2 – I agree with novo nordisk. The NAMS statement is out of context and outdated with this APS and is not consistent with Estragyn Vaginal Cream TMA. This is a violation of PAAB Code s3.2.

Allegation 3 – I agree with novo nordisk that an appropriate dose of progestin is required when Estragyn Vaginal Cream is prescribed to women with intact uteri to prevent endometrial hyperplasia/carcinoma in accordance with the TMA.

It appears to me that this APS was possibly created by contracted employees of Searchlight Pharma and Searchlight Pharma officials should do everything possible to recall the material, stop further distribution and train its employees on truthful, ethical promotion.

PENALTY: This APS has several violations of the PAAB Code of Advertising Acceptance. Searchlight Pharma has an obligation to control the activities of its contracted sales reps. Therefore I would like to see proof the actions taken by Searchlight Pharma with respect to controlling the activities of their sales reps and copies of any messages sent to those employees (confidential to PAAB). I also remind Searchlight Pharma of the availability of the PAAB preclearance review service.

OUTCOME: Searchlight Pharma complied with the ruling



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