

Proposed Alternatives for Isolagen Email, September 1, 2009 - Laviv

From: Jessica Allmond [jallmond@cbrintl.com]
Sent: Tuesday, September 01, 2009 12:40 PM
To: Tull, Lori
Cc: Jeanne Novak
Subject: Proposed Alternatives for Isolagen Indication Statement (BLA STN 125348)

Importance: High

Dear Lori,

This email is being sent on behalf of Dr. Jeanne Novak (Isolagen's Authorized Regulatory Representative), and is a follow-up to an informal teleconference on Aug. 26th to discuss possible revisions to the Isolagen indication statement (BLA STN 125348). For ease of reference, the indication statement provided in the original BLA is as follows: Isolagen Therapy™ is an autologous cell therapy indicated for the treatment of moderate to severe nasolabial fold wrinkles in adults 18 years of age.

As discussed during our call, please find below suggested changes to the current indication statement for Agency consideration. Changes in original text are highlighted in bold below.

1. PREFERRED OPTION: Isolagen Therapy™ is an autologous cell therapy indicated for the treatment of moderate to severe nasolabial fold wrinkles for at least six months in adults 18 years of age.
2. ALTERNATIVE OPTIONS:
 - a. Isolagen Therapy™ is an autologous cell therapy indicated for the treatment of moderate to severe nasolabial fold wrinkles in adults 18 years of age for at least six months duration.
 - b. Isolagen Therapy™ is an autologous cell therapy indicated for the treatment of moderate to severe nasolabial fold wrinkles in adults 18 years of age for up to six months duration.
 - c. Isolagen Therapy™ is an autologous cell therapy indicated for the treatment of moderate to severe nasolabial fold wrinkles in adults 18 years of age, with improvement for at least six months.
 - d. Isolagen Therapy™ is an autologous cell therapy indicated for the improvement of moderate to severe nasolabial fold wrinkles in adults 18 years of age for at least six months duration.
 - e. Isolagen Therapy™ is an autologous cell therapy indicated for at least six months of improvement to moderate to severe nasolabial fold wrinkles in adults 18 years of age.
 - f. Isolagen Therapy™ is an autologous cell therapy indicated for the improvement of moderate to severe nasolabial fold wrinkles for at least six months in adults 18 years of age.

- g. Isolagen Therapy™ is an autologous cell therapy indicated for the improvement of moderate to severe nasolabial fold wrinkles for up to six months in adults ≥ 18 years of age.
- h. Isolagen Therapy™ is an autologous cell therapy indicated for the improvement of moderate to severe nasolabial fold wrinkles in adults ≥ 18 years of age for up to six months duration.
- i. Isolagen Therapy™ is an autologous cell therapy indicated for at up to six months of improvement to moderate to severe nasolabial fold wrinkles in adults ≥ 18 years of age.

If you have any questions or comments about this email, then please do not hesitate to contact Dr. Novak (jnovak@cbrintl.com) or myself as an alternative. Please note that Dr. Novak is currently out of the office this week in support of Isolagen's Pre-License Inspection at their Exton, P.A. facility.

Kind regards,

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