



Joanne Robinett, Associate Vice President  
NA & Global Regulatory Affairs  
Sanofi-aventis US  
55 Corporate Drive  
Bridgewater, NJ 08807

**RE: NDA 206538**  
TOUJEO<sup>®</sup> (insulin glargine injection) U-300, for subcutaneous use  
MA 886

Dear Ms. Robinett:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed a Direct-to-Consumer broadcast television advertisement (TV ad) entitled "Mr. Groove" (US.GLT.16.08.002) for TOUJEO<sup>®</sup> (insulin glargine injection) U-300, for subcutaneous use (Toujeo) submitted by Sanofi-aventis US (Sanofi) under cover of Form FDA 2253. This TV ad makes false or misleading representations about the risks associated with Toujeo. Thus, the TV ad misbrands Toujeo within the meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act), and makes its distribution violative. 21 U.S.C. 352(n); 331(a). 21 CFR 202.1(e)(5). This violation is concerning from a public health perspective because it creates a misleading impression about the safety of Toujeo.

## **Background**

Below are the indication and summary of the most serious and most common risks associated with the use of Toujeo.<sup>1</sup> According to the FDA-approved product labeling (PI) (emphasis original):

TOUJEO is indicated to improve glycemic control in adults with diabetes mellitus.

### Limitations of Use

TOUJEO is not recommended for the treatment of diabetic ketoacidosis.

Toujeo is contraindicated during episodes of hypoglycemia and in patients with hypersensitivity to insulin glargine or one of its excipients. Toujeo is associated with serious risks. The PI contains warnings and precautions regarding sharing a Toujeo SoloStar pen between patients, hyperglycemia or hypoglycemia with changes in insulin regimen, hypoglycemia, medication errors, hypersensitivity and allergic reactions, hypokalemia, and fluid retention and heart failure with concomitant use of PPAR-gamma agonists. The most

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<sup>1</sup> This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional piece cited in this letter.

common adverse reactions associated with Toujeo are hypoglycemia, allergic reactions, injection site reaction, lipodystrophy, pruritus, rash, edema and weight gain.

### **False or Misleading Risk Presentation**

Promotional materials misbrand a drug if they are false or misleading with respect to risk.

The TV ad communicates the “major statement” of serious risks through the audio and on-screen SUPERS. At the same time, the TV ad presents fast-paced visuals that feature a man continuously dancing to music from the song “Let’s Groove” throughout multiple scene changes. Specifically, the man dances while cooking, working in an office, mowing his lawn, picking tomatoes with his children, and walking his dog. The presentation of these compelling and attention-grabbing visuals, all of which are unrelated to the risk message presented in the audio and on-screen SUPERS, in addition to the frequent scene changes and the other competing modalities such as the background music, compete for the consumers’ attention. As a result, it is difficult for consumers to adequately process and comprehend the risk information. The overall effect undermines the communication of the important risk information and thereby misleadingly minimizes the risks associated with the use of Toujeo. The presentation in the video is especially problematic from a public health perspective given the serious and potentially life-threatening risks associated with the drug.

### **Conclusion and Requested Action**

For the reasons discussed above, the TV ad misbrands Toujeo within the meaning of the FD&C Act and makes its distribution violative. 21 U.S.C. 352(n); 331(a). 21 CFR 202.1(e)(5).

OPDP requests that Sanofi immediately cease violating the FD&C Act, as discussed above. Please submit a written response to this letter on or before December 27, 2016, stating whether you intend to comply with this request, listing all promotional materials (with the 2253 submission date) for Toujeo that contain violations such as those described above, and explaining your plan for discontinuing use of such violative materials.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Amundson Avenue, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. To ensure timely delivery of your submissions, please use the full address above and include a prominent directional notation (e.g. a sticker) to indicate that the submission is intended for OPDP. Please refer to MA 886 in addition to the NDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. OPDP reminds you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Toujeo comply with each applicable requirement of the FD&C Act and FDA implementing regulations.

Sincerely,

{See appended electronic signature page}

Ankur Kalola, PharmD, RAC  
Regulatory Review Officer  
Division of Advertising & Promotion Review 2  
Office of Prescription Drug Promotion

{See appended electronic signature page}

Melinda McLawhorn, PharmD, BCPS, RAC  
Team Leader  
Division of Advertising & Promotion Review 2  
Office of Prescription Drug Promotion

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ANKUR S KALOLA  
12/12/2016

MELINDA W MCLAWHORN  
12/12/2016