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ERSP Refers Advertising for Plymouth Direct's 'BeActive' Brace to FTC, FDA

New York, NY – Dec. 11, 2014 – The Electronic Retailing Self-Regulation Program (ERSP) has announced it will refer direct-response advertising for the "BeActive Brace," marketed by Plymouth Direct Inc., to the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) after the marketer failed to agree to comply with ERSP's recommendations to modify or discontinue certain claims.

ERSP is an investigative unit of the advertising industry's system of self-regulation and is administered by the Council of Better Business Bureaus. The marketer's advertising came to ERSP's attention pursuant to an anonymous competitive challenge.

Claims at issue in the initial inquiry included:

- "The point specific pressure brace for fast effective sciatic back pain relief."
- "Relieves tension up the sciatic nerve with firm trigger point acupressure."

- "Reduces both short term and chronic sciatic back pain."
- "Helping you live pain free & enjoy being active again."
- "You need BeActive, the revolutionary new acupressure system that instantly helps ease discomfort in your lower back, buttocks, and legs."
- "You'll instantly begin experiencing relief."
- "Back pain often radiates from the lower back to the lower extremities, but apply BeActive to the trigger point on the calf muscle to instantly relieve pain."
- "The secret is the acupoint pressure pad that gently compresses, alleviating pain at the sciatic nerve and lower back for instant relief."

ERSP, in its decision, noted that "collectively, the marketer's evidence was persuasive in demonstrating that when pain does radiate from the trigger point compressed by the BeActive brace (i.e., the trigger point located just below the knee) the product may provide perceptible relief for users, it was also concluded that any general, broadly-stated claims indicating that the BeActive brace is effective to relieve pain in the 'lower back' are inaccurate."

ERSP determined that the evidence in the case record did not support claims indicating that the product would be effective in providing relief from all sciatica conditions, particularly those that originate in the upper extremities, and sciatica pain that is referred from the two trigger points in the soleus muscle that are not stimulated by the BeActive brace.

ERSP also recommended that the claim that use of the product will result in consumers being "pain" free" was not adequately substantiated and that the marketer should discontinue the claim "Expensive pain-relievers wear off, but BeActive is always there to deliver the pain relief you need" and the accompanying visual in future advertising for BeActive.

The company, in its marketer's statement, did not indicate that it would agree to modify or discontinue the advertising as recommended by ERSP. Therefore, pursuant to section 3.1(D) of the ERSP Policy and Procedures, this matter has been referred to the FDA and FTC.

Plymouth Direct Inc., in its marketer's statement, said the company "appreciates the opportunity to participate in the Electronic Retailing Self-Regulation Program's self-regulatory process.

"Plymouth Direct Inc. will continue to use lower back pain and sciatica claims that are based on consultations with and clinical data performed by experts in the relevant field and that are consistent with FDA's express classification and clearance for our product.

"We will take into consideration ERSP's recommendations for future marketing projects. Thank you for your attention."

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