

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from SmartScience Laboratories, Inc. and its president, Gene Weitz, (together, "SSL") settling charges that they engaged in a large-scale deceptive advertising campaign for JointFlex, a skin cream.

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves alleged misleading representations for JointFlex. Respondents sold this cream through advertisements in national newspapers and magazines (including USA Today, the Washington Post, and Newsweek), more than 200 other major and minor local newspapers, and two websites that are not currently operative. According to the FTC complaint, SSL advertisements represented that JointFlex eliminates significant pain due to disabling joint conditions, crushed vertebrae, arthritis, herniated disk, and other conditions; that JointFlex provides more pain relief than other over-the-counter pain creams; and that testimonials from consumers appearing in the advertisements for JointFlex represent the typical or ordinary experiences of members of the public who use the product. According to the complaint, SSL lacked a reasonable basis to substantiate these claims. The complaint also alleges that respondents ads represented that the glucosamine sulfate and chondroitin sulfate in JointFlex contribute to pain relief when applied topically, but that respondents do not possess competent and reliable evidence that the glucosamine sulfate and chondroitin sulfate in JointFlex, a topically applied cream, penetrates the skin sufficiently to induce a pharmacological effect.

The complaint further alleges that SSL made several false advertising claims. It alleges that the ads represented that a competent and reliable survey of JointFlex users shows that ninety-five percent experienced reduction or elimination of pain due to use of JointFlex. This claim is alleged to be false because the survey respondents relied on was not competent and reliable, because there is no assurance that any pain reduction the responding consumers reported was due to use of the product, and because the ninety-five percent figure reflects responses to the question, "do you feel that the product helped your symptoms," not a question about pain relief, and the surveys also inquired into relief from stiffness, swelling, redness, and protuberances. The complaint alleges that SSL falsely characterized the results of certain testimonials, by overstating the nature of their injuries at the time they used the JointFlex product.

The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future. Part I of the order would require, with regard to JointFlex or any drug or supplement, competent and reliable scientific substantiation for future claims about the absolute or comparative efficacy of the product in reducing, relieving, or eliminating pain from any source; the health benefits, performance, safety or efficacy of any such

product; or the ability of glucosamine sulfate, chondroitin sulfate, or any other ingredient to relieve pain or provide any other health benefit when applied topically.

Part II prohibits respondents, in connection with any product, from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, survey, or research.

Part III provides that, in connection with any product, respondents shall not misrepresent the experience of any testimonialist or endorser. It further provides that respondents shall not represent that the experience represented by any user testimonial or endorsement of the product represents the typical or ordinary experience of members of the public who use the product, unless the typicality claim is substantiated by competent and reliable scientific evidence; or respondents disclose, clearly and conspicuously, and in close proximity to the endorsement or testimonial, either what the generally expected results would be for users of the product, or the limited applicability of the endorser's experience to what consumers may generally expect to achieve, that is, that consumers should not expect to experience similar results.

Part IV of the order is a safe harbor, providing that the order does not prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration. Part V is a safe harbor, providing that the order does not prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

Parts VI-XI are standard record keeping, order distribution, reporting, compliance, and sunset provisions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.