

UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

CR15-40001

Plaintiff,

FACTUAL BASIS STATEMENT

vs.

STANLEY DEAN BROWER,
d/b/a BROWER ENTERPRISES,
INC., and HEALTH ENTERPRISES,

Defendant.

The undersigned parties stipulate that the following facts are true and establish a factual basis for the plea in the action pursuant to Federal Rules of Criminal Procedure 11(b)(3):

On or about October 10, 2012, the Defendant, Stanley Brower received approximately 1000 bottles of product labeled "Reumofan Plus" from a wholesaler in Cupertino, California. The product known as Reumofan Plus, received by Mr. Brower, contained the active ingredients dexamethasone (a corticosteroid), diclofenac sodium (a non-steroidal anti-inflammatory drug), and methocarbamol (a muscle relaxant). All three of these active ingredients are found in prescription drugs approved by the Food and Drug Administration. Reumofan Plus was manufactured in Mexico and the label for Reumofan Plus

[2]

was written in Spanish and did not bear the common or usual name of each of these active ingredients.

After he received the 1,000 bottles of Reumofan Plus, the Defendant relabeled the bottles and renamed the product "WOW," a dietary supplement. The "WOW" label listed the same ingredients as the Reumofan Plus label, but in English as opposed to Spanish. Like the original label, the new label for "WOW" did not list the common or usual name for the active ingredients of dexamethasone, diclofenac sodium, and methocarbamol.

At the time of Mr. Brower's receipt of the Reumofan Plus and prior to relabeling it, Mr. Brower knew that the Reumofan Plus contained these active pharmaceutical ingredients, and he intended to relabel the product without indicating their presence. Other than relabeling, Mr. Brower did not alter the Remofan Plus product he received.

After relabeling, he offered the product as "WOW" for delivery to individuals who paid for the drug via various forms of marketing including multi-level marketing, a website, and word of mouth. "WOW" was falsely marketed as a 'dietary supplement' intended for the mitigation of various diseases or ailments, including rheumatoid arthritis. Mr. Brower knew that the product he was holding out for delivery contained a materially false label, and intended that its false label would mislead individuals and cause them to purchase the product.


[3]

Brower's "WOW" product was a drug within the meaning of 21 U.S.C. 321(g)(1)(B) because it was intended for the treatment, mitigation or cure of various medical conditions, such as rheumatoid arthritis. The drugs were misbranded, both at the time Brower received the drugs in interstate commerce, and after relabeling when he offered their delivery to consumers for pay, within the meaning of 21 U.S.C. §§ 352(a) (in that their labeling was false and misleading) and 352(e)(1)(A)(ii) (in that their labeling failed to list each active ingredient). Brower intended to defraud and mislead consumers when he proffered the delivery of these misbranded drugs. All of these acts committed by Mr. Brower were in violation of 21 U.S.C. §§ 331(c) and 333(a)(2).

RANDOLPH J. SEILER
UNITED STATES ATTORNEY

December 2, 2016

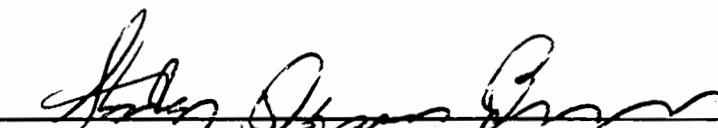
Date



Jeffrey C. Clapper
Assistant United States Attorney
P.O. Box 2638
Sioux Falls, SD 57101-2638
Telephone: (605)357-2351
Facsimile: (605)330-4410
E-Mail: Jeff.Clapper@usdoj.gov

11/19/16

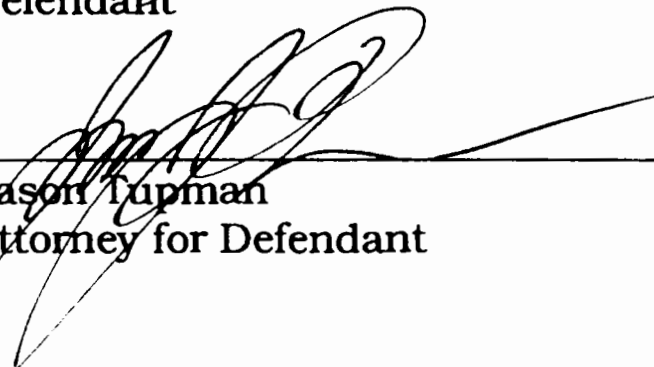
Date



Stanley Dean Brower
Defendant

11/30/16

Date



Jason Lupman
Attorney for Defendant