



*United States Attorney  
Southern District of New York*

FOR IMMEDIATE RELEASE  
JUNE 30, 2011

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**MANHATTAN U.S. ATTORNEY OBTAINS COURT ORDER  
ENJOINING WEBSITE OPERATOR FROM VIOLATING  
FEDERAL DRUG-LABELING LAWS**

PREET BHARARA, the United States Attorney for the Southern District of New York, announced today that the United States has filed, and simultaneously settled, a civil lawsuit against HOWARD SOUSA, who does business as the "ARTERY HEALTH INSTITUTE, LLC," and "DESOUSA, LLC," and operates the website [www.arteryhealthinstitute.com](http://www.arteryhealthinstitute.com), seeking an order to stop him from making unapproved health claims about the products he sells. The settlement agreement, in the form of a consent decree, was approved yesterday by U.S. District Judge RICHARD M. BERMAN. It requires SOUSA and his website to cease making claims about the supposed ability of his products, including the claim that "Formula EDTA Oral Chelation" can cure, mitigate, treat, prevent, and/or reduce any disease unless and until the U.S. Food and Drug Administration ("FDA") reviews and approves such claims.

Manhattan U.S. Attorney PREET BHARARA said: "Howard Sousa misled customers with dubious and unapproved health claims about his products. Today's settlement will ensure that this unsubstantiated information is removed from his website."

According to documents filed in Manhattan federal court:

SOUSA's website contains numerous unapproved health claims about "Formula EDTA Oral Chelation," including that: it "may take calcium and other clogging materials off [sic] your arteries and washes the debris out through the kidneys;" it can help remove kidney stones; it "helps to reduce and prevent atherosclerotic plaques, thus improving blood flow to the heart and other organs;" and, it may prevent the need for coronary artery bypass graft surgery. None of these claims have ever been reviewed or approved by the FDA.

Last year, FDA investigators contacted SOUSA regarding his website, and notified him that it included several unapproved

health claims regarding the products he was selling. SOUSA removed some of the improper claims, but left many others, When contacted again by the FDA about the improper health claims remaining on his site, SOUSA refused to make any further changes.

The consent decree approved by the court requires SOUSA to cease all illegal operations immediately and to hire an independent consultant who must periodically review his website for improper medical claims and report them to the FDA.

Mr. BHARARA thanked the FDA for their investigative efforts in this case.

This case is being handled by the Office's Civil Frauds Unit. Assistant U.S. Attorney JEAN-DAVID BARNEA is in charge of the case.

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