

U.S. Marshals Seize Unapproved Medical Devices

January 29, 2010

At the request of the U.S. Food and Drug Administration, U.S. Marshals today seized 79 ozone generators, models AOS-1M and AOS-1MD, from Applied Ozone Systems of Auburn, Calif. The seized goods, which are medical devices, are valued at \$75,900.

The FDA advises health care professionals and consumers to discontinue use of these devices, which Applied Ozone Systems claims can treat [cancer](#), AIDS, hepatitis, herpes, and a number of other diseases and conditions. The FDA has not determined that the seized products are safe and effective in treating the diseases or conditions, and officials at Applied Ozone Systems never responded to a Dec. 21, 2009 FDA request for a voluntary recall of these ozone generators.

In addition, the agency is concerned that patients who use these AOS ozone devices as directed by the manufacturer may believe that ozone therapy serves as an appropriate treatment and as a result delay or stop conventional or prescribed effective treatment. There is also a risk of infection from potential contamination of the applicator or catheter.

The FDA inspected Applied Ozone Systems in October 2009 after obtaining an inspection warrant when the owner of the company refused to allow agency staff to inspect the facility. The agency's inspection revealed significant deviations from the FDA's current good manufacturing practice (GMP) requirements for medical devices, and confirmed that the company has not obtained FDA marketing approval or clearance for these devices. The unapproved status of these devices and the conditions under which they were manufactured cause them to be adulterated and misbranded.

Ozone generators are devices that produce ozone from oxygen. Ozone is present in low levels throughout the earth's atmosphere and has many industrial and consumer applications. It also is an air pollutant that has harmful effects on the respiratory system.

Ozone administration methods suggested by the manufacturer of the AOS-1M Medical Ozone Generator and the AOS-1MD Ozone Generator include blowing ozonized air into the rectal and vaginal areas.

"The seized devices are potentially harmful to public health," said Michael Chappell, the FDA's acting associate commissioner for regulatory affairs. "The agency will take action to protect the public from FDA-regulated products that are in violation of the law."

Today's seizure action was jointly conducted by the FDA and the State of California Department of Public Health, Food and Drug Branch as part of ongoing efforts to ensure that unapproved medical devices that have not been found to be safe and effective do not enter the marketplace.