WASHINGTON – Eon Labs Inc. has agreed to pay the United States $3.5 million to resolve False Claims Act allegations relating to the company’s drug Nitroglycerin Sustained Release (SR) capsules, the Justice Department announced today. Eon Labs is a subsidiary of Sandoz Inc., which is in turn a subsidiary of Novartis AG.

In April 1999, the Food & Drug Administration (FDA) determined that Nitroglycerin SR lacked substantial evidence of effectiveness and published a notice proposing to withdraw approval of the product. The government contends that, after the FDA notice, Nitroglycerin SR no longer was legally eligible for reimbursement by government health care programs such as Medicaid.

The government further alleges that, from April 1999, and continuing through September 2008, Eon submitted false quarterly reports to the government that misrepresented Nitroglycerin SR’s regulatory status and failed to advise that Nitroglycerin SR no longer qualified for Medicaid coverage. As a result, the government contends, Eon knowingly caused false Medicaid claims to be submitted for Nitroglycerin SR.

“We expect manufacturers to be truthful about the regulatory status of their drugs, and we will pursue those companies that submit false information to obtain payment for unapproved drugs that are less than effective or on the market illegally,” said Tony West, Assistant Attorney General for the Civil Division.

The settlement resolves allegations against Eon in a multi-defendant whistleblower action entitled United States ex rel. Conrad v. Eon Labs, Inc., et al. The False Claims Act allows for private persons to file a qui tam or whistleblower suit on behalf of the government. If the government is successful in resolving or litigating its claims, the whistleblower may receive a share of the recovery. Under this settlement, the whistleblower will receive approximately $525,000.

“This is the first False Claims Act agreement with a drug company that sought to charge the government for less than effective drugs, and it shows that the Department of Justice will pursue those who market such drugs and expect the government to pay for them,” said Carmen Ortiz, U.S. Attorney for the District of Massachusetts.

This settlement is part of the government’s emphasis on combating health care fraud. One of the powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover approximately $2.2 billion since January 2009 in cases involving fraud against federal health care programs. The Justice Department’s total recoveries in False Claims Act cases since January 2009 have topped $3 billion.

This case was investigated by the Justice Department’s Civil Division, the U.S. Attorney’s Office of the District of Massachusetts and the Office of Inspector General of the Department of Health and Human Services.