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ABC MISSION:

*To champion the elimination
of cardiovascular disparities
through education, research
and advocacy.*

April 26, 2010

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research, FDA
White Oak Bldg. 51 Room 6133, Mail Code: HFD-001
10923 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock,

The Association of Black Cardiologists (ABC) applauds the Food and Drug Administration's (FDA) recent actions to remove unapproved drugs from the market, specifically unapproved nitroglycerin products. Our members share an interest in heart related health issues, so we are especially encouraged to see that the Agency is working to remove unapproved heart medications from pharmacy shelves as part of the Unapproved Drugs Initiative.

Unapproved nitroglycerin products have not been subjected to FDA's approval process. Due to this, there is no way of knowing vital, often time life-saving information regarding these drugs, including whether the drug is safe or effective, the drug's chemical composition, whether or not the information on the drug's labeling (if there is any) is accurate and correct dosage information. Patients often buy unapproved drugs without knowing they are unapproved.

Approved nitroglycerin products are safe, effective and available to patients. Knowing as little as we do about unapproved nitroglycerin products and the risks posed to patients who use them, there is no reason why dangerous, unapproved versions of nitroglycerin should be prescribed or even on the market.

If we can be of any assistance to the FDA in removing dangerous unapproved drugs from the marketplace, please contact me personally at: 202-375-6524 or awilliams@abccardio.org. Thank you.

Sincerely,

Andre' H. Williams,
Chief Executive Officer