

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Center for Biologics Evaluation and Research

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DATE April 20, 2010

FROM Solomon Yimam, Bioresearch Monitoring, HFM-664  
Division of Inspections and Surveillance  
Office of Compliance and Biologics Quality

THROUGH Patricia Holobaugh, Bioresearch Monitoring Branch Chief, HFM 664

TO Daryl L. Miller, HFM-475, Chair BLA Committee

BLA/STN 125296/0

PRODUCT Live Oral Type 4 Adenovirus Vaccine Tablet (ADV-4)  
Live Oral Type 7 Adenovirus Vaccine Tablet (ADV-7)

INDICATION A vaccine to combat a resurgence of Type-4 and Type-7 ADV-induced respiratory illnesses among military recruits undergoing basic training in the United States.

SUBJECT Summary of Bioresearch Monitoring Inspections

SPONSOR Duramed Research Inc.,  
One Belmont Avenue  
Bala Cynwyd, Pennsylvania 19004

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