



DEPARTMENT OF HEALTH & HUMAN SERVICES

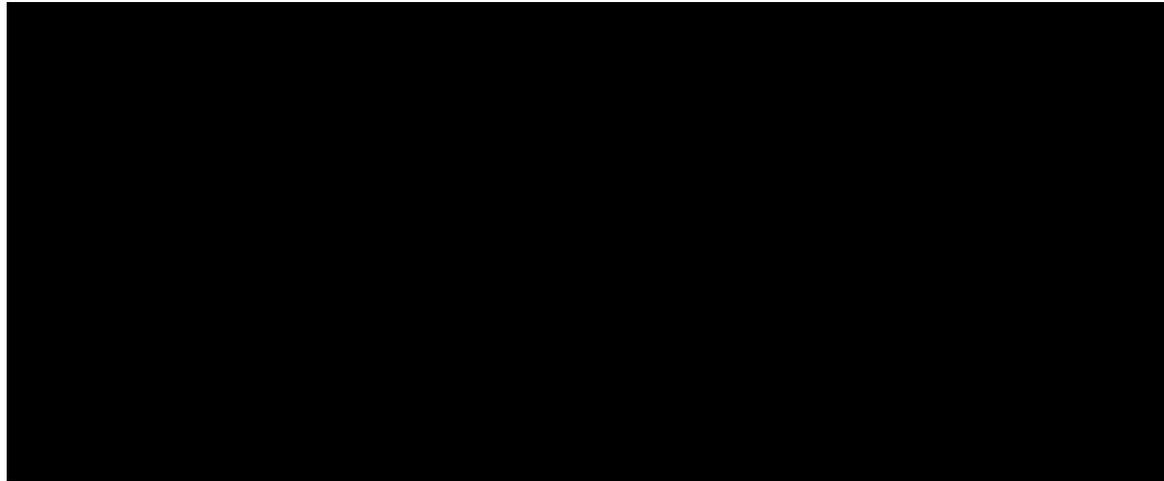
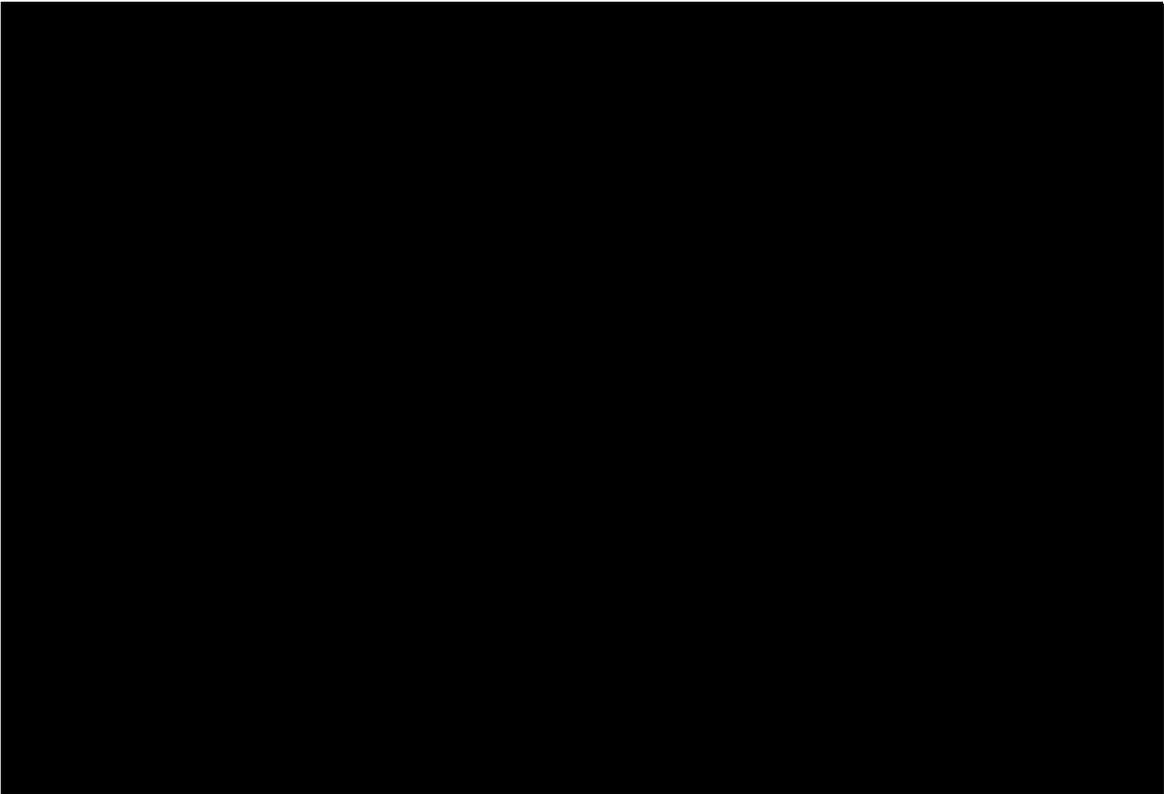
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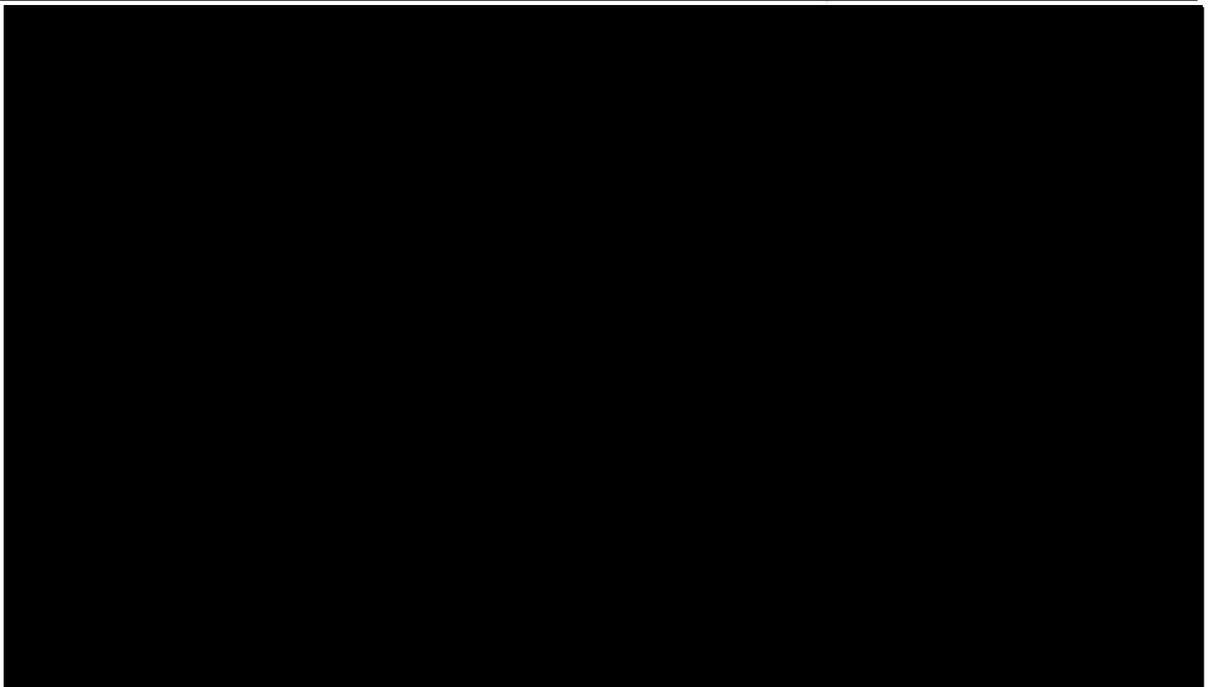
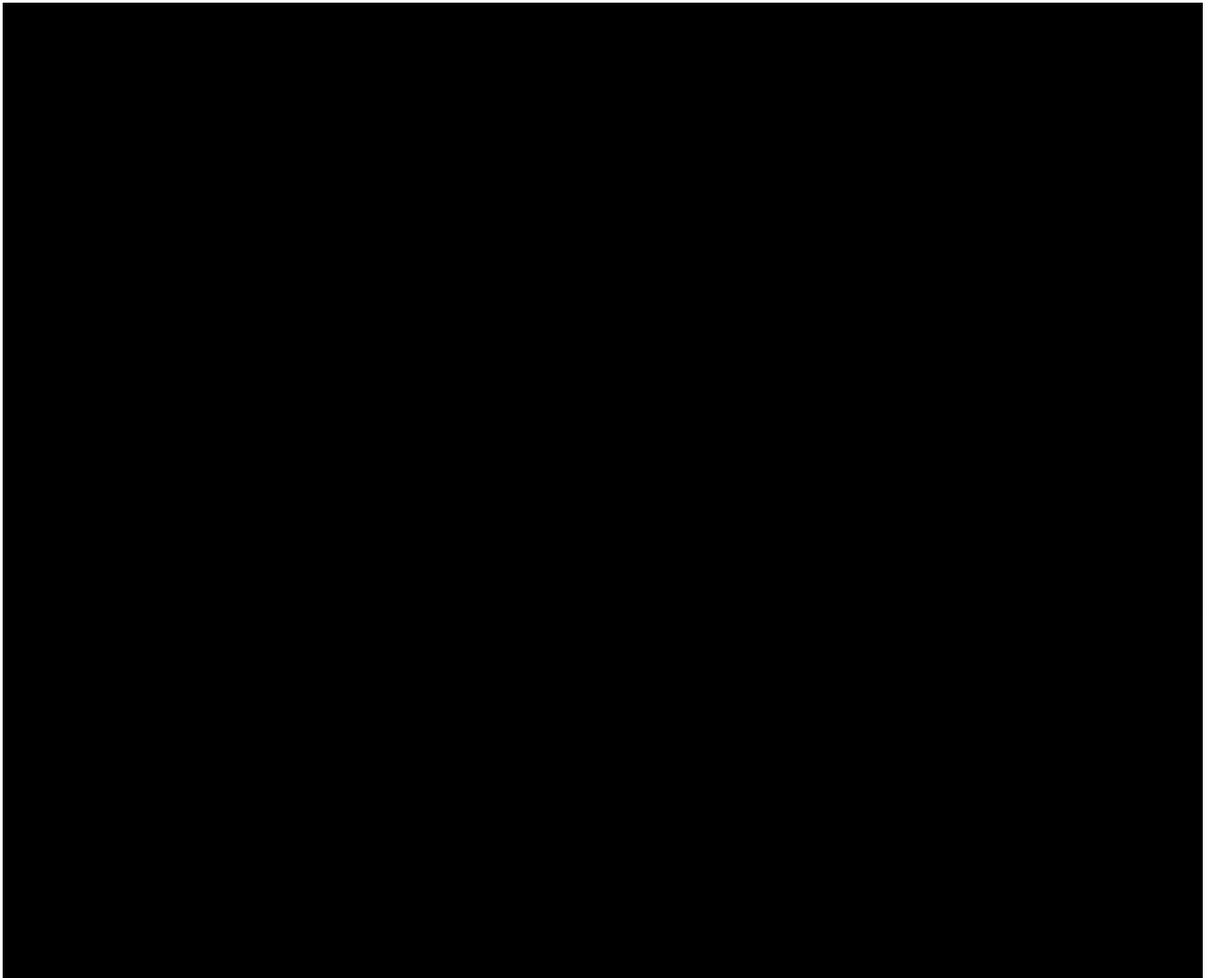
Food and Drug Administration  
Silver Spring, MD 20993-0002

MEMORANDUM

DATE: October 4, 2011  
TO: CDER Clearing Officials  
FROM: Office of Unapproved Drugs and Labeling Compliance (OUDLC)  
SUBJECT: Rationale for 503A Policy and Regulatory Strategy

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