Southwest
Oncology Group
A National Clinical Research Group

December 15, 2005

TO: ALL SOUTHWEST ONCOLOGY GROUP MEMBER, CCOP AND AFFILIATE MEDICAL ONCOLOGISTS

FROM: The Southwest Oncology Group Operations Office

RE: FDA MedWatch - Methotrexate for Injection (preservative free): One lot recalled due to low levels of ethylene glycol

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MEMORANDUM

MedWatch - The FDA Safety Information and Adverse Event Reporting Program - has forwarded the following information.

FDA and Bedford Laboratories, a division of Ben Venue Laboratories, Inc., Bedford, Ohio, announced that it is voluntarily recalling one lot of Methotrexate for Injection (preservative free), USP 1 gram per vial (NDC 55390-143-01), Lot # 859142, exp 09/07, because the active drug substance ("ADS") used to manufacture Lot # 859142, contained low levels of ethylene glycol. Preservative-free methotrexate is the only formulation that is acceptable for intrathecal administration. Healthcare professionals and suppliers should not distribute these vials and should contact Bedford Laboratories for return instructions. Consumers that have received this product and have questions should contact their physicians.

Read the complete MedWatch 2005 Safety summary, including a link to the firm press release, at:

http://www.fda.gov/medwatch/safety/2005/safety05.htm#Methotrexate

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