



**Southwest
Oncology Group**

A National Clinical Research Group

September 1, 2006

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

FROM: SOUTHWEST ONCOLOGY GROUP OPERATIONS OFFICE

RE: SWOG-9150, SWOG-9151, SWOG-9237, SWOG-9241, SWOG-9305,
SWOG-9339, SWOG-9510 and SWOG-9518

MEMORANDUM

The Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), NCI has withdrawn the DCTD-sponsored IND for Topotecan Hydrochloride, NSC-609699, **effective August 11, 2006**. Their records indicate that all DCTD-sponsored studies using this agent are closed and that all patients are off treatment with this agent.

FDA regulations require investigators to retain all research records, including patient charts, case report forms, x-rays and scans that document response, IRB approvals, signed informed consent documents and all drug accountability records for at least two years after the IND has been withdrawn. Please retain records until at least **August 11, 2008**.

The Pharmaceutical Management Branch, CTEP has previously sent letters to all CTEP investigators and their designees to whom Topotecan Hydrochloride was supplied, advising them that CTEP was withdrawing the IND for this agent and requested the return of all CTEP-supplied Topotecan Hydrochloride, NSC 609699. If you have not already done so, please return all CTEP-supplied Topotecan Hydrochloride to the NCI Clinical Repository at 627 Lofstrand Lane, Rockville, MD 20850 ATTN: RETURNS. FDA regulations require all remaining supplies of this agent to be returned to the IND sponsor.

Please feel free to contact Dr. Dale Shoemaker for any regulatory questions and Mr. Charles Hall for any agent supply issues.

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National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

DATE: August 14, 2006
FROM : Acting Associate Chief, Regulatory Affairs Branch, CTEP, DCTD, NCI
SUBJECT: Notice of **Completed** IND Withdrawal
TO: See Below

The FDA has completed withdrawal of the IND for **Topotecan Hydrochloride**. The following information is provided regarding this IND:

Proper Name:	Topotecan Hydrochloride
Date Withdrawn:	August 11, 2006
IND Number:	34494
NSC Number:	609699
FDA Division:	CDER – Office of Oncology Drug Products Division of Drug Oncology Products
Collaborating Drug Company:	GlaxoSmithKline
PIO Treatment Codes:	Topotecan
Reason for Withdrawal:	All trials are either complete or closed to accrual and treatment, except for protocol A3973 which is closed to accrual. If patients (maximum of two) require treatment with topotecan, they will be provided with commercial product. The DCTD, NCI, does not plan to activate further trials under this IND since topotecan is commercially available.

for 
Jan Casadei, Ph.D.

Distribution:

Associate Director, CTEP
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