Southwest
Oncology Group
A National Clinical Research Group

December 1, 2006

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

FROM: SOUTHWEST ONCOLOGY GROUP OPERATIONS OFFICE

RE: **S9629** and **S9635**

MEMORANDUM

The Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), NCI has withdrawn the DCTD-sponsored IND for 776C85, NSC-687296, **effective November 17, 2006**.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signed informed consent documents and all drug accountability records for at least two years after the IND has been withdrawn.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 **November 17, 2008**.

The Pharmaceutical Management Branch, CTEP has previously sent letters to all CTEP investigators and their designees to whom 776C85 was supplied, advising them that CTEP was withdrawing the IND for this agent and requested the return of all CTEP-supplied 776C85 NSC-687296. If you have not already done so, please return all CTEP-supplied 776C85 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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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

DATE: November 21, 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 **776C85**. The following information is provided regarding this IND:

Proper Name:	**776C85**
Date Withdrawn:	November 17, 2006
IND Number:	52087
NSC Number:	687296, 710026
FDA Division:	CDER – Office of Oncology Drug Products Division of Drug Oncology Products
Collaborating Drug Company:	GlaxoSmithKline
PIO Treatment Code:	Eniluracil (GW776); Eniluracil / 5-FU Combination Tablet (GW776 / 5-FU)

Jennifer Wong
for Jan Casadei, Ph.D.

Distribution:

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