DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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To: Office of Management and Budget (OMB)

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Subject: Drug Accountability Record (Form NIH 2564)
OMB#: 0925-0240, Expiry Date 2/28/2011

This is a request for OMB to approve the extension titled, "The Drug Accountability Record (Form NIH 2564) (NCI)," for 3 years.

The Food and Drug Administration (FDA) holds The National Cancer Institute (NCI), as a sponsor of investigational new drug (IND) trials, responsible for accountability of investigational agents by investigators in its clinical trials program. The information obtained from the Drug Accountability Record Form (DARF) is used to track the dispensing of investigational anticancer agents beginning with receipt from the NCI to dispensing or administration to patients. NCI and its auditors use this information for compliance and safety purposes.

The NCI, as an IND sponsor, has developed the "Drug Accountability Record" form (DARF) to help investigators using NCI sponsored drugs under NCI protocols to meet FDA requirements. These requirements include the responsibility to "maintain adequate records of the disposition of all receipts of the drug, including dates, quantity and use by subjects" (21 CFR 312.1). The DARF serves as the link between NCI's record of drug distribution to an Investigator and NCI's review of the clinical data on research patients; it ensures that investigational drugs are not diverted for inappropriate protocol or patient use.