Memorandum

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

To: Solomon Iyasu, M.D., M.P.H.
Division of Pediatric Drug Development
Office of Counter-Terrorism and Pediatric Drug Development

From: LCDR David Moeny, USPHS, R.Ph
Drug Use Information Specialist
Division of Drug Surveillance, Research, and Communication Support

Through: Toni Piazza-Hepp, Pharm.D., Acting Director
Division of Drug Surveillance, Research, and Communication Support

Date: 02-08-06

Re: One Year Post-Pediatric Exclusivity Post-marketing Adverse Event Review: Drug Use Data for Clofarabine (Clolar®) injection (NDA 21-673)

Section 17 of the Best Pharmaceuticals for Children Act (BPCA), requires the FDA to analyze the reports of adverse events associated with the use of a drug in children during the one-year period following the date on which the drug received pediatric marketing exclusivity. In support of this mandate, the Division of Surveillance, Research and Communication Support (DSRCS) provides an analysis of the drug use trends for each drug granted exclusivity.

The Pediatric Exclusivity Board of the FDA granted pediatric exclusivity for Clolar® (NDA 20-333) on March 30, 2004 and the product was approved for marketing on December 28, 2004, for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. Using the available drug utilization databases at the Agency's disposal, the following data were returned regarding the patterns of use for Clolar.

The IMS Health IMS National Sales Perspectives™ data provide national estimates of the amount of drug products sold by manufacturers into various channels of distribution in the retail and non-retail markets. Outlets within the retail market include the following pharmacy settings: chain drug stores, independent drug stores, mass merchandisers, food stores, and mail service; outlets within the non-retail market include clinics, non-federal hospitals, federal facilities, HMOs, long-term care facilities, home health care, and other miscellaneous settings. For this analysis, the IMS database reported no sales from the time of marketing through November 2005. IMS staff reported that due to contractual agreements, IMS is unable to capture sales data for this product.

In an attempt to characterize the use of Clolar® in the hospital setting, we queried the Premier Informatics database. Premier's database is a large hospital drug utilization and financial database. Information is available from over 450 acute care facilities and includes approximately 18 million inpatient records. On an annual basis, this constitutes roughly one out of every seven inpatient discharges in the United States. The data have a lag time of up to six months. As of November 28th, 2005 there were no discharges associated with Clolar® use in the Premier database. Another setting that may capture Clolar® use would be chemotherapy clinics, however, DSRCS does not have an access to a database which allows us to evaluate drug use within hospital-based or stand-alone outpatient clinics; therefore, we are unable to characterize the use of Clolar in this setting.

In summary, we are unable to document any use of Clolar® in the outpatient, inpatient or sales databases currently available to FDA.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Moeny
2/8/2006 12:26:35 PM
DRUG SAFETY OFFICE REVIEWER

Toni Piazza Hepp
2/8/2006 05:25:02 PM
DRUG SAFETY OFFICE REVIEWER