FDA NEWS RELEASE
(Logo: http://photos.prnewswire.com/prnh/20090824/FDALOGO)
For Immediate Release: Sept. 12, 2011
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FDA announces changes in drug center's oncology office
Review divisions to be aligned by expertise, disease-specific areas

Today, the U.S. Food and Drug Administration announced organizational changes within the office responsible for reviewing all drug and biologic applications for cancer therapies. The Center for Drug Evaluation and Research's (CDER) Office of Oncology Drug Products has been reorganized and renamed the Office of Hematology and Oncology Products (OHOP).

"Under the new office structure, the agency anticipates greater clarity and more transparent interactions with companies about the requirements to bring cancer treatments to market," said CDER director Janet Woodcock, M.D. "We don't expect these changes to slow down pending applications, in fact, we expect to see greater efficiencies that will better support our work to get cancer treatments to patients."

Richard Pazdur, M.D., who joined the FDA in 1999 and became director of the office in 2005, will continue to serve as the office director. Dr. Pazdur will also continue to head the agency-wide oncology program that coordinates oncology activities within the FDA as well as with external stakeholders. This program will remain in OHOP.

"As the practice of oncology and the treatments being developed for these diseases have become more complex, we've recognized the need and importance of taking a more disease-specific review approach to these therapies," said Dr. Pazdur. "Reorganizing the office in this manner also aligns FDA with the organizational structure of leading cancer treatment centers, academic programs and the National Cancer Institute."

The previous structure contained three divisions: Division of Hematology Products (DHP), Division of Drug Oncology Products (DDOP), and Division of Biologic Oncology Products (DBOP).

The new structure contains four divisions: Division of Hematology Products (DHP), Division of Oncology Products 1 (DOP1), Division of Oncology Products 2 (DOP2), and Division of Hematology Oncology Toxicology (DHOT).

Two unique features of the reorganization include the creation of DOP1 and DOP2, the agency's primary review divisions for cancer solid tumor therapies, and the creation of DHOT, which will review nonclinical information.

DOP1 and DOP2 will have disease-specific therapeutic areas of responsibility regardless of whether the product is a drug or biologic. DHOT is a newly created division that will be dedicated to reviewing nonclinical pharmacology and toxicology aspects of cancer therapies. DHP will continue

reviewing hematology therapies, including those for benign disorders and malignancies. The division directors for each division are listed below.

New OHOP Structure and Division Therapeutic Areas			
DOP1	**DOP2**	**DHP**	**DHOT**
Division Director Robert Justice, M.D., M.S.	Division Director Patricia Keegan, M.D.	Division Director Ann Farrell, M.D.	Division Director John Leighton, Ph.D.
Breast, Gynecologic, Genitourinary, Supportive care (non-hematologic)	Gastrointestinal, Lung/Head & Neck, Neuro-oncology/Rare cancers/Pediatric Solid Tumor, Melanoma/Sarcoma	Benign hematology, Hematologic malignancies, Hematology support, Pediatric Hematology	Nonclinical Review Division for Hematology/Oncology products

OHOP at-a-glance
130: total employees in OHOP
55: number of medical oncologists in OHOP
39: number of pharmacists, nurses and non-clinical Ph.D.s in OHOP
19: Number of medical oncologists, nurses and pharmacists still treating patients
24: OHOP staff published in 2010
10: number of new drug indications approved in 2010
7: number of new molecular entities approved to date in 2011

For more information:
FDA: Office of Hematology and Oncology Products
http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm091745.htm
FDA: Information for companies
http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm271326.htm
FDA: Spotlight on Drug Innovation – Update of FDA's novel drug approvals in 2011
http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm254242.htm

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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