Review and approval of oncology and hematology drugs at FDA from 2005 to 2007

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Over a two and half year period, beginning in 2005 when the U.S. Food and Drug Administration's oncology drug product's office began reviewing marketing applications, a total of 60 new oncology and hematology drugs were reviewed, of which 53 were approved, according to a new article published online January 29 in the *Journal of the National Cancer Institute*.

To provide an overview of recent regulatory actions by the FDA's Office of Oncology Drug Products in the Center for Drug Evaluation and Research, Rajeshwari Sridhara, Ph.D., of the FDA's Office of Biostatistics, in Silver Spring, Md., and colleagues identified all applications reviewed, as well as actions taken, from July 1, 2005, through December 31, 2007. Their review included "New Drug Application" and "Biologics Licensing Application" approvals.

Marketing applications for 60 new products were reviewed and regulatory action was taken on 58 of them based on a risk-benefit evaluation. Products that demonstrated efficacy and had an acceptable risk-benefit ratio (i.e., the magnitude of the treatment effect was statistically persuasive and clinically meaningful) were granted either regular or accelerated marketing approval. A total of 53 new indications were approved: 39 received regular approval, nine received accelerated approval, and five were converted from accelerated to regular approval. Two applications were withdrawn before action was taken, and five were not approved.

Approvals were based on various study designs and primary outcomes or endpoints. Some approvals were from single-arm, non-randomized controlled trials in cases when the FDA deemed it impractical to conduct randomized studies.

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