THE TOOLS

PHOTOGRAPH/RICHARD TULL FOTOLIA

[Approved Drugs]

■ Genzyme Corp. and Bayer HealthCare Pharmaceuticals Inc. (Cambridge, Mass. and Wayne, N.J.) announced that the Food and Drug Administration (FDA) has approved a supplemental biologics license application (sBLA) for **Campath® (alemtuzumab)** and granted regular approval for single-agent Campath for the treatment of B-cell chronic lymphocytic leukemia (B-CLL).

■ ImClone Systems Incorporated and Bristol-Myers Squibb Company announced that the FDA has approved an update to the **Erbitux® (cetuximab)** product labeling to include overall survival data as a single agent in epidermal growth factor inhibitor (EGFR)-expressing metastatic colorectal cancer patients after failure of both irinotecan- and oxaliplatin-based regimens.

■ The FDA has approved Eli Lilly and Company's (Indianapolis, Ind.) osteoporosis drug **Evista® (raloxifene HCl)** for a new use to reduce the risk of invasive breast cancer in two populations: postmenopausal women with osteoporosis and postmenopausal women at high risk for invasive breast cancer. Evista is already approved for the prevention and treatment of osteoporosis in postmenopausal women.

■ GlaxoSmithKline (Philadelphia, Penn.) recently announced that its oral **Hycamtin® (topotecan) capsules** were approved by the FDA for the treatment of relapsed small cell lung cancer (SCLC). Hycamtin capsules are indicated for patients who had a complete or partial response to first-line chemotherapy and who are at least 45 days from the end of that treatment. This product will be available in 2008.

■ The FDA has granted approval of **Ixempra™ (ixabepilone)** as monotherapy for the treatment of patients with metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine. The FDA has also granted approval of Ixempra in combination with capecitabine for the treatment of patients with metastatic or locally advanced breast cancer resistant to treatment with an anthracycline, and a taxane, and or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated.

■ Sanofi-aventis (Bridgewater, N.J.) announced that the FDA has approved **Taxotere® (docetaxel) Injection Concentrate** in combination with cisplatin and 5-fluorouracil for induction therapy of locally advanced squamous cell carcinoma of the head and neck before patients undergo chemoradiotherapy and surgery.

[Drugs in the News]

■ The FDA has granted orphan drug designation to Advanced Life Sciences Holdings, Inc.'s (Woodridge, Ill.) oncology product, **ALS-357**, for the topical treatment of metastatic melanoma.

■ MGI Pharma, Inc. (Minneapolis, Minn.) and Helsinn Healthcare SA, announced FDA approval of a supplemental new drug application (sNDA) for **Aloxi® (palonosetron hydrochloride) Injection**, allowing for repeated dosing for cancer patients receiving multiple day chemotherapy regimens. This sNDA includes the removal of a dosing recommendation, which limited Aloxi use to once per seven day interval, from the product's label.

■ Sanofi-aventis (Bridgewater, N.J.) has launched a new 200 mg single-use vial of its chemotherapy treatment **Eloxatin® (oxaliplatin injection)** for patients who have adjuvant Stage III colon cancer and advanced colorectal cancer.

■ Infinity Pharmaceuticals, Inc. and MedImmune, Inc. (Cambridge, Mass. and Gaithersburg, Md.) announced that the FDA has granted orphan drug designation to **IPI-504** for the treatment of gastrointestinal stromal tumors (GIST).

■ The FDA has granted orphan drug designation to Metabasis Therapeutics Inc.'s (San Diego, Calif.) liver cancer treatment **MB07133**. MB07133 is designed to inhibit cell proliferation and induce cell death.

■ MethylGene Inc. and Pharmion Corporation (Montreal, Quebec, and Boulder, Colo.) announced that the FDA has granted orphan drug designation to **MGCD0103**, the companies' histone deacetylase inhibitor, for the treatment of Hodgkin's lymphoma.

■ Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals, Inc. (Wayne, N.J. and Emeryville, Calif.) announced that the sNDA for **Nexavar® (sorafenib) tablets** for the treatment of patients with hepatocellular carcinoma (HCC) has been accepted for review and granted priority review status by the FDA.

■ The FDA has granted Pharmion Corporation (Boulder, Colo.) fast track designation for the company's **oral Azacitidine** in the treatment of myelodysplastic syndromes (MDS).