

FDA Report to PharmPAC
September 6, 2007
Compiled by CDR Matthew Tarosky, Pharm.D., U.S.P.H.S.

New Approvals

- FDA approved a new drug application (NDA) for Pfizer's maraviroc (Selzentry) under the accelerated approval provisions. Selzentry is a first-in-class new HIV treatment that works by blocking viral entry into white blood cells. It is to be used in combination with other antiretroviral therapies for treatment of adults infected only with detectable CCR5-tropic HIV-1, who have evidence of viral replication and who have HIV-1 strains resistant to multiple antiretroviral agents. The product will be available in the U.S. by mid-September.
- FDA approved Acambis' ACAM2000, a second generation smallpox vaccine, intended for the inoculation of people at high risk of exposure to smallpox and could be used to protect people during a bioterrorist attack. ACAM2000 contains live vaccinia virus (similar to Dryvax) so care must be taken to prevent the virus from spreading from the inoculation site to other parts of the body and to other individuals. CDC has stockpiled 192.5 million doses.

Advisory Committee Meeting

- FDA's Cardiovascular and Renal Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee will hold a joint meeting September 11, 2007 to consider risks and benefits for use of erythropoiesis-stimulating agents (e.g., Amgen's Aranesp and Epogen and Johnson & Johnson's Procrit - for anemia in chronic renal failure). The advisory committee scrutiny follows a March public health advisory that included adding a "black box" label warning on risk of serious side effects with aggressive dosing of ESAs.

Career Development

- FDA's Center for Drug Evaluation and Research (CDER) has partnered with Georgetown University to develop the Georgetown University Public Health Certificate Program. This CDER-funded pilot program includes the following five courses offered at FDA's White Oak Campus: Health Services Administration, Biostatistics, Epidemiology, Behavioral Sciences/Health Education, and Environmental Health Sciences. Contact: CDR Louis Flowers

Budget

- While Congress works to pass the legislation that reauthorizes the prescription drug and medical device user fees, FDA Commissioner Dr. Andrew von Eschenbach will use limited carryover resources to postpone any reduction in force notices.

News

- FDA and the Department of Defense are collaborating to share data and expertise related to the review and use of FDA-regulated drugs, biologics, and medical devices. FDA will use data from the U.S. Military Health System -- such as prescriptions, lab results, and patient weight -- to spot trends, which may identify potential concerns as well as product benefits.
 - <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01675.html>
- A FDA "White Oak Commissioned Corps Group" meets the second Monday of each month from 12-1 pm at FDA's White Oak Campus to discuss various topics relevant to Commissioned Corps Officers stationed at White Oak. This group has been responsible for posting flags at the entrance circle and setting up a track for the APFT. CDR Joe Toning (joseph.toning@fda.hhs.gov) is the contact person for meeting information. When the FDA

move to White Oak is completed, close to 600 PHS officers, comprising almost 10% of the Commissioned Corps will be stationed at White Oak, making White Oak the single largest duty station for Commissioned Corps officers.

Labeling Changes

- Warfarin (Coumadin) labeling has been updated to indicate that some patient's genetic makeup may influence how they respond to the drug. Specifically, people with variations in two genes may need lower warfarin doses than people without these genetic variations. The two genes are called CYP2C9 and VKORC1. The CYP2C9 gene is involved in the breakdown (metabolism) of warfarin and the VKORC1 gene helps regulate the ability of warfarin to prevent blood from clotting.

Office of Regulatory Affairs Transformation

- On August 17, 2007, FDA Associate Commissioner for Regulatory Affairs Maggie O'Glavin announced that she is canceling plans to close 7 of 13 FDA laboratories and consolidate 20 FDA District Offices into 16 District Offices.

Regulations

- On August 23, 2007, FDA proposed a new regulation that sets standards for OTC sunscreen drug products with UVA and UVB protection. The UVB rating scale will be revised for the Sunburn Protection Factor (SPF) from a maximum of SPF 30+ to SPF 50+. The new UVB rating scale will be SPF 2 to SPF 50. A new UVA rating would include a scale of one to four stars with one star representing low UVA protection, two stars representing medium protection, three stars representing high protection and four stars representing the highest protection. Products that do not provide at least a low level of protection would need to be labeled "no UVA protection" on the front label near the SPF value. In addition, all sunscreen product manufacturers will be required to have a warning on their labeling indicating "UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen." The warning is intended to increase awareness that sunscreens are only one part of a sun protection program.