Efalizumab for Plaque Psoriasis

Genentech, Inc., and Xoma, Ltd., have announced the approval of efalizumab (Raptiva™) by the U.S. Food and Drug Administration (FDA) for the treatment of chronic, moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy. This is the first biological agent that is designed to provide continuous control of the condition and that can be self-injected subcutaneously at home by patients once a week.

Psoriasis occurs when new skin cell growth rapidly accelerates, resulting in thick, red, scaly, inflamed patches on the skin surface. Plaque psoriasis, the most common form of the disease, is characterized by inflamed patches of skin (lesions) topped with silver-white scales. Although several medications do help to control the symptoms of psoriasis, no cure is available.

Raptiva™ is a humanized therapeutic antibody that selectively and reversibly blocks the activation, reactivation, and trafficking of T cells that lead to the development of psoriasis symptoms. Raptiva™ has demonstrated a rapid onset of action in reducing psoriasis-associated symptoms in some patients within four weeks of initiating treatment.

Adverse events included headache, infection (mostly upper respiratory), chills, nausea, pain, myalgia (muscle pain), flu syndrome, fever, back pain, and acne. Fewer than 1% of patients discontinued treatment because of acute adverse events.

Raptiva™ is an immunosuppressive agent and has the potential to increase the risk of infection and to reactivate latent, chronic infections. Many immunosuppressive agents have the potential to increase the risk of malignancy. The role of Raptiva™ in the development of malignancies is not known.

(Sources: Genentech, Inc., and Xoma Ltd.; National Psoriasis Foundation; www.allaboutpsoriasis.com.)

Memantine for Alzheimer’s Disease

The FDA has approved memantine (Namenda®, Forest Laboratories) for patients with moderate to severe Alzheimer’s disease (AD). The drug has long been sold in Germany. Previous treatments have been studied for less severe (mild to moderate) AD. Memantine appears to work by blocking the action of glutamate; the other approved drugs delay the breakdown of acetylcholine, which is vital for nerve cells to communicate.

Approximately 4.5 million Americans have AD, a degenerative condition that affects memory, judgment, and the ability to reason. The drug is an N-methyl-D-aspartate (NMDA) antagonist. Memantine helps to alleviate symptoms of AD in some patients, but there is no evidence that it modifies the underlying pathology of the disease.

The drug was studied in two double-blind trials involving about 650 patients. The first two studies, each about six months’ duration, were conducted in the U.S. The larger study was carried out in patients already taking donepezil (Aricept®, Eisai, Pfizer), a drug approved previously for the treatment of AD. During both studies, patients taking memantine experienced less deterioration in functioning and fewer symptoms than did patients taking placebo. In the third study, conducted in nursing homes in Latvia, memantine also showed a statistically significant advantage over placebo in 166 patients with severe AD.

Memantine has demonstrated a statistically significant advantage in reducing the burden of dementia and improving the patients’ overall condition. Measures used to evaluate the drug’s effectiveness included the Severe Impairment Battery to assess attention, orientation, language, memory, and social interactions, and the modified Alzheimer’s Disease Cooperative Study Activities of Daily Living scale, which assessed the ability of patients to eat, dress, bathe, travel, shop, and perform household chores. The Behavioral Rating Scale for Geriatric Patients assessed day-to-day functioning, and the Clinical Global Impression of Change assessed the patients’ overall condition.

The most frequently reported adverse events were dizziness (7%), headache (6%), and constipation (6%). The drug should be available for sale by January.


Estradiol for Menopause

The FDA has approved an estradiol topical emulsion (Estrasorb™, Novavax, Inc., and King Pharmaceuticals, Inc.) for short-term use to reduce moderate to severe vasomotor symptoms, including “hot flashes,” in menopausal women.

Estrasorb™ is a white lotion-like emulsion that women apply only to their legs, thighs, or calves on a daily basis. It is absorbed through the skin into the bloodstream to achieve its effect.

When applied to the skin, it delivers effective concentrations of 17β-estradiol, a naturally occurring estrogenic hormone, into the bloodstream. A “Micellar Nanoparticle” drug-delivery technology platform uses oil and water nanoemulsions, which are smaller than 1 micron in diameter.

The FDA states that estrogen treatments pose important risks; they should be used in the lowest dose and for the shortest duration required to provide relief of menopausal symptoms and should not be used to prevent heart disease, heart attacks, or strokes. Estrogen should not be used by women with known or suspected pregnancy, breast cancer, or estrogen-dependent neoplasia;
undiagnosed abnormal genital bleeding; blood clots; stroke; or myocardial infarction. Women are advised not to apply sunscreen and Estrasorb™ at the same time because this may affect the amount of estradiol absorbed.

Novavax and King will co-promote the emulsion in the U.S. and Puerto Rico. (Sources: News release, October 10, 2003; www.fda.gov.)

**NEW DRUG APPLICATIONS**

**Prussian Blue for Radiation Contamination**

The FDA has approved a New Drug Application for insoluble Prussian blue capsules (Radiogardase™) to treat people exposed to radiation contamination caused by harmful levels of cesium 137 or thallium. The capsules contain ferric hexacyanoferrate.

The approval of the Radiogardase™ application is part of the FDA's continuing efforts to provide the American public with medical countermeasures in the event of a terrorist attack.

Radiogardase™ works by increasing the rate of elimination of these substances from the body. For several decades, Prussian blue has been used to enhance the excretion of cesium 137 and thallium from the body into the stool. Contamination with cesium 137 or thallium can occur through various routes, including ingestion, inhalation, or wounds, and can cause serious illness or death when high radiation doses are absorbed and delivered to critical organs. At lower doses, such contamination has been associated with the development of cancer.

Cesium 137 is widely used in industry and to treat certain cancers. Non-radioactive thallium is used in industry and as a rat poison. The radioactive form of thallium (201l) is an approved drug for use in medical imaging procedures and is very safe at low doses.

Contamination by cesium 137 is of particular concern because of its potential use as a component of conventional explosive devices containing radioactive material (“dirty bombs”). Although this radiological dispersal device is not a nuclear bomb, it can spread radioactive material and contaminate people and property.

Possible side effects include constipation and upset stomach. Treatment should begin as soon as possible after exposure to radioactive cesium or thallium. When the sources of radiation contamination are multiple or unknown, other drugs (such as potassium iodide) can be used together with Radiogardase™.

(Source: FDA, October 3, 2003; www.fda.gov/oc/opacom/hottopics/bioterrorism.html.)

**Escitalopram Oxalate for Generalized Anxiety Disorder**

Forest Laboratories, Inc., has announced that it has received an approvable letter from the FDA to expand the use of escitalopram oxalate (Lexapro™) to include the treatment of generalized anxiety disorder (GAD).

Lexapro™, a selective serotonin re-uptake inhibitor (SSRI), is currently indicated for the initial and maintenance treatment of major depressive disorder. A supplemental New Drug Application (sNDA), which was based on three placebo-controlled studies in patients with GAD, was submitted to the FDA in November 2002. Forest expects to launch Lexapro™ to treat GAD in early 2004 after final approval.

GAD is characterized by excessive anxiety about everyday events or activities for a period of six months or more. This constant worry affects daily functioning and can cause physical symptoms. GAD often co-occurs with mood disorders, including depression. In addition, up to 80% of depressed people also experience anxiety.

As with all SSRIs, the drug should not be taken with monoamine oxidase inhibitors.

(Source: News release September 29, 2003; www.lexapro.com.)

**NEW INDICATION**

Eplerenone for Congestive Heart Failure After a Heart Attack

Eplerenone tablets (Inspra™, Pfizer) have been approved for the treatment of congestive heart failure in patients who have had a myocardial infarction (MI).

An aldosterone blocker, the drug inhibits the effects of aldosterone, a hormone that may contribute to the development and progression of hypertension and congestive heart failure (CHF), with resulting damage to the blood vessels, kidney, and heart.

Nearly five million Americans have CHF, and up to 700,000 new cases are diagnosed each year. CHF is five times more likely to occur in patients who have had an MI than in those who have not. Among patients over age 65, CHF is the primary reason for hospital admissions and the leading cause of death.

The FDA's approval of eplerenone for this indication is based on results of the Epleronone Post-acute Myocardial Infarction Heart Failure Efficacy and Survival Study (EPHESUS) trial. In more than 6,600 patients who were hospitalized for MIs, there was a 15% reduction in the risk of death among patients who received eplerenone, compared with those receiving placebo, in addition to standard treatment. The eplerenone-treated patients also experienced a reduced risk of cardiovascular death and hospitalization.

Inspra™ will be available through a special Early Access program in November and to the public in December 2003.
The researchers concluded that letrozole therapy significantly improved disease-free survival after the completion of standard tamoxifen treatment.

Physicians will have to decide whether to prescribe letrozole for women who already completed tamoxifen therapy years ago.

The long-term safety of aromatase inhibitors is unclear; they may promote osteoporosis, although their safety profile seems better than that of tamoxifen, which increases the risk of endometrial cancer and blood clots.


Pioglitazone for Diabetes and Cardiovascular Therapy

Pioglitazone HCl (Actos®, Takeda, Eli Lilly), a thiazolidinedione (TZD) that is used to improve glucose control in type-2 diabetes, may have cardiovascular benefits for the patient even beyond its effects on blood glucose levels.

In a study of 136 patients with type-2 diabetes, researchers from Japan found that pioglitazone significantly reduced hyperglycemia, hyperinsulinemia, and hemoglobin HbA1c levels. The drug also significantly reduced high-sensitivity C-reactive protein (CRP), a marker of inflammation, and pulse-wave velocity, a direct parameter of arterial distensibility.

Although this trial was observational and nonrandomized, no previous studies had addressed whether TZDs can exert the antiatherogenic effect independently of the antidiabetic effect in humans, the researchers say. In their study, they looked at both responders (whose blood glucose and insulin levels improved with TZDs) and nonresponders. Interestingly, CRP levels were...
reduced more in the responders than in the nonresponders. This finding, the researchers believe, suggests that some of the antiatherogenic effects of pioglitazone are associated with improved glucose metabolism.

(Source: Diabetes Care 2003;26:2493–2499.)

**Clarithromycin and H. pylori**

Patients who have previously taken macrolide antibiotics may be at greater risk for clarithromycin-resistant *Helicobacter pylori* infection, say researchers from the Arctic Investigations Program, Centers for Disease Control and Prevention, Anchorage, Alaska. To their knowledge, this is the only trial to link previous antibiotic use to *H. pylori* resistance with subsequent treatment outcomes.

In their study of 125 adults, 83 (66%) had *H. pylori* isolates resistant to metronidazole (e.g., Flagyl®, Pharmacia) and 37 (30%) had isolates that were resistant to clarithromycin (Biaxin®, Abbott).

Resistance to clarithromycin was associated with previous use of all macrolide antibiotics. Of the 37 patients with clarithromycin-resistant *H. pylori*, 34 (92%) had taken a macrolide antimicrobial drug in the previous 10 years, compared with 50 of 88 (57%) with clarithromycin-susceptible *H. pylori*. The percentage of infections with clarithromycin-resistant strains increased with a greater number of previous courses of macrolide treatment.

Resistance to metronidazole was associated with previous use of this drug. More than half of patients with resistant isolates had taken the drug, compared with only 10% of those with metronidazole-susceptible isolates. The trend toward resistance held true even if metronidazole had been prescribed more than five years earlier. Nine of 42 patients who had taken metronidazole in the previous six to eight years had resistant isolates; one of 39 did not.

Infection with clarithromycin-resistant *H. pylori* was associated with a six-fold increased risk of treatment failure in patients who were taking clarithromycin. Among the 53 patients who were taking clarithromycin, therapy was unsuccessful in 77% of those with clarithromycin-resistant *H. pylori*, versus 13% of those with clarithromycin-susceptible strains.

In another trial, researchers from University Hospital in Uppsala, Sweden, and The Swedish Institute of Infectious Disease Control found that short-term treatment of *H. pylori* infection with clarithromycin had long-term consequences.

In a small study of five patients who took clarithromycin for duodenal ulcers associated with *H. pylori*, high-level clarithromycin resistance was present immediately after treatment, one year later, and even three years later.

The researchers considered the persistence of resistant bacteria in the absence of continued antibiotic selective pressure to be “unexpected.” Clarithromycin resistance did not develop in any of the control patients.

(Source: Ann Intern Med 2003;139:463–469; 483–487.)

**The Complexities of Simplifying HAART**

For clinicians who would like to simplify their patients’ HAART regimens (highly active retroviral therapies) by replacing the protease inhibitor (PI), nevirapine (Viramune®, Boehringer Ingelheim) or efavirenz (Sustiva®, Bristol-Myers Squibb Oncology) might be a better choice than abacavir (Ziagen®, GlaxoSmithKline), according to the Nevirapine/Efavirenz/Abacavir Study Team.

The researchers randomly assigned 460 adults who were virologically steady (maintaining plasma HIV-1 RNA levels below 200 copies/ml for at least six months) to switch from their current PI: 155 patients were switched to nevirapine, 156 were switched to efavirenz, and 149 were switched to abacavir.

At 12 months, despite virological failure (the inability to achieve or maintain viral suppression) in 19 patients, 117 patients were still taking nevirapine, 112 were still taking efavirenz, and 113 were still taking abacavir. Sixteen abacavir patients experienced virological failure while taking the study medication, compared with eight in the nevirapine group and five in the efavirenz group. At 12 months, two abacavir patients had progressed to acquired immunodeficiency syndrome (AIDS).

Patients who had previously had a “suboptimal” response to therapy with nucleoside reverse-transcriptase inhibitors (NRTIs) were more likely to do poorly with abacavir: 23 of the 29 patients with virological failure taking the study drug had received suboptimal prior therapy. However, patients who had done well had similar rates of viral suppression when they were switched to a study drug.

Although approximately 50% of the patients in each group experienced adverse drug effects (ADEs), patients taking abacavir were less likely to discontinue their study drug because of ADEs.


**Does Lithium Help Reduce Suicide Risk?**

Patients with bipolar disorder are less likely to attempt suicide if they are taking lithium carbonate (Eskalith®, GlaxoSmithKline; Lithobid®, Solvay) rather than divalproex sodium (Depakote®, Abbott), the most commonly prescribed mood-stabilizing drug in the U.S. Researchers who analyzed data from 20,638 patients in two managed care
organizations in California found that divalproex was associated with 1.5 to three times more suicide attempts or deaths than lithium was.

After the researchers adjusted for age, sex, comorbid conditions, and the use of other psychotropic drugs, the risk of suicide death was found to be 2.7 times higher with divalproex than with lithium. The difference in risk was consistent across all outcome measures: suicide attempts ending in death, suicide attempts resulting in hospitalization, and suicide attempts diagnosed in the emergency department.

The mechanism by which lithium might help prevent suicide attempts is unclear, although it has been shown to reduce aggressive and impulsive behavior. Suicide is associated with reduced functional capacity of central serotonin systems, and long-term lithium treatment enhances serotonin turnover.

To their knowledge, the researchers say that this is the first study comparing the two drugs and their associations with suicide. They suggest that lithium might be getting an undeserved bad reputation; it has fallen out of favor over the years, because younger clinicians prefer newer, better-publicized drugs. Despite these findings, though, clinicians should exercise caution before deciding to stop prescribing mood stabilizers.

(Source: JAMA 2003;290:1467–1473.)

Rofecoxib and Psoriasis

Although cases of psoriasis associated with rofecoxib (Vioxx®, Merck) and celecoxib (Celebrex®, Pharmacia) have surfaced worldwide, the first published report of psoriasis associated with a cyclooxygenase-2 (COX-2) inhibitor comes from a physician in New Zealand.

Severe psoriasis developed in a 46-year-old woman five days after she started taking rofecoxib 25 mg/day for neck strain. She had previously experienced a similar reaction to the non-steroidal anti-inflammatory drug (NSAID) diclofenac (e.g., Voltaren®, Novartis). In both instances, it took several months for remission to occur after the psoriasis treatment was halted.

Because this case represents evidence of a strong association between psoriasis and two types of NSAIDs, and because it describes a patient who had a similar experience with a nonselective NSAID, the trial author suggested that identifying triggers for relapse should be helpful in managing and preventing psoriasis.

(Source: Arch Dermatol 2003;139:1223 [letter]).

FDA Tackles Counterfeit Drugs

To combat the growing problem of counterfeit drugs, the government is searching for ways to tighten the security of medications and to make them more tamper-proof as they travel from factories to drugstores.

The FDA is considering asking manufacturers to ship tablets in smaller quantities (e.g., 30 pills in a blister pack instead of hundreds per shipment); smaller distributors would then rebottle them. Smaller sizes can make it more difficult for counterfeiters to sneak in fakes, although this step might put an end to companies that repackage or rebottle large shipments into the smaller bottles that patients receive.

When drugs are bought from a regularly licensed pharmacy, the chances of receiving a counterfeit drug are less than 1%, but buying drugs over the Internet can increase the risk. Counterfeit products are also showing up in drugstores more often. The FDA has investigated about 20 counterfeit cases per year since 2000, compared with five per year in the 1990s.

Earlier this year, more than 150,000 bottles of the cholesterol medication atorvastatin (Lipitor®, Pfizer) were recalled after consumers complained of a bitter taste. “Knockoffs” from overseas had been mixed into the authentic version.

The following options are also being considered:

- Using tamper-evident packaging on all drugs.
- Using packages that bear anti-counterfeiting technologies, such as hidden transmitters that pharmacists can scan, to be sure they have not bought a fake drug.
- Closely tracking the drugs that are most likely to be counterfeited by limiting the number of times they are sold in the supply chain.

In 1999, the FDA postponed enforcing rules that would have required a paper trail to validate every sale between drug makers and distributors. Critics recommend bringing back that paper system as a temporary solution.

Some drug companies are not waiting for FDA action. Bayer Biological Products, for example, will begin selling intravenous immune globulin (Gamunex®) with logo-embossed shrink-wrapping over each vial.

For more information on the FDA’s evolving role in improving safety, see the articles on pages 698 and 719 in this issue.

(Source: http://news.findlaw.com; Associated Press, October 3, 2003.)

Levetiracetam Increases Seizure-Free Days in Refractory Epilepsy

In a study of 846 patients, adding levetiracetam (Keppra®, UCB Pharma) to antiepileptic drug therapy offered patients with difficult-to-treat, partial-onset epilepsy more than five additional seizure-free days per quarter—the equivalent of nearly three weeks a year—compared with the number of days for
patients taking placebo.

In adults, partial-onset seizures are the most common manifestation of epilepsy, a condition that affects approximately 2.3 million Americans. Nearly a third of patients with partial-onset seizures have uncontrolled epilepsy that does not respond to drug therapy or other treatments. The quality of life in patients with epilepsy is directly related to the frequency of seizures, and seizure-free patients experience a health-related quality of life similar to that of the general population.

Central nervous system adverse drug events included somnolence and fatigue, coordination difficulties, and behavioral and hematological abnormalities. Dosage must be individualized according to the patient’s renal status.

The FDA approved Keppra® tablets in 1999 for the adjunctive treatment of partial-onset seizures in adults with epilepsy. Keppra® oral solution was approved in July 2003.

(Sources: *Epilepsia*, 2003;44(10):1351–1353; *Neurology*, 1999;53:162–166; www.keppra.com; www.neurology.org; Epilepsy Foundation of America.)

**Estrogen–Progestin HRT and Ovarian Cancer Risk**

Estrogen–progestin tablets do not appear to reduce the risk of ovarian cancer and may even increase it, according to the federally funded Women’s Health Initiative Randomized Trial. The study was stopped in 2002 because of evidence that the combination hormone replacement therapy (HRT) raised the risk of breast cancer, heart attacks, and strokes.

Researchers set out to determine the possible associations of estrogen plus progestin on gynecological cancers and related diagnostic procedures. The effects of continuous combined hormone therapy on gynecological cancers had not been investigated previously in a randomized trial setting.

A double-blind, placebo-controlled trial enrolled 16,608 postmenopausal women who had not had a hysterectomy at the baseline evaluation and who had been recruited from 40 clinical centers in the U.S. between 1993 and 1998.

The women received one tablet per day containing 0.625 mg of conjugated equine estrogens plus 2.5 mg of medroxyprogesterone acetate (n = 8,506) or placebo (n = 8,102).

The main outcome was invasive cancer of the ovary and endometrium. After 5.6 years of follow-up, there were 32 cases of invasive ovarian cancer, 58 cases of endometrial cancer, 1 case of non-endometrial uterine cancer, 13 cases of cervical cancer, and 7 cases of other gynecological cancers. The incidence of other gynecological cancers was low and did not differ according to the drug to which they had been assigned. More women taking estrogen plus progestin required endometrial biopsies.

The authors urged caution in prescribing the use of continuous combined hormones and mentioned that the increased burden of endometrial biopsies necessary to assess vaginal bleeding further limited the acceptability of the combination regimen.

The Women’s Health Initiative has also linked HRT with a possible risk of dementia. Women who take HRT for menopausal symptoms are advised to take the lowest possible dose for the shortest period of time.

An earlier study of menopausal women, who were observed from 1982 to 1996, reported that women who used supplemental estrogen for 10 years or more doubled their risk of dying from ovarian cancer, compared with nonusers. The risk persisted up to 29 years after the discontinuation of HRT. The actual risk of death from ovarian cancer was small (1%), although it increased to 2% in long-term estrogen users, according to the American Cancer Society. At that time, the possibly protective role of progesterone had not been examined.

It is known that taking estrogen alone increases the risk of endometrial cancer in women who still have a uterus. The combined regimen of estrogen and progesterone is thought to protect against endometrial cancer. More studies are needed to examine the possible link between ovarian cancer and HRT.


**UK Study Questions Effectiveness of Statins in Lowering Cholesterol**

According to the results of a recent clinical study, almost 50% of patients with heart disease were unable to reduce their cholesterol levels to recommended values after taking cholesterol-lowering statin drugs (statins).

Although the use of statins has increased dramatically throughout the Western world in recent years, only 48% of 14,000 patients evaluated in a study conducted in the United Kingdom reached national cholesterol goals. The findings were reported at a meeting of the Primary Care Cardiovascular Society in Dublin, Ireland.

The consultant cardiologist at Glasgow Royal Infirmary reported that fewer than two-thirds of patients had their cholesterol re-checked within three months of starting their medication and that a large proportion of patients never received an increased dose.

Most doctors, however, seemed to be unaware of the problem. A survey completed by 220 general practitioners as part of the study revealed that, in evaluating their own performance, general

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practitioners thought that 80% of their patients were achieving cholesterol targets.


Efficacy of Venlafaxine for Depression

According to recent studies comparing antidepressant treatments, more patients achieved remission, or virtual elimination, of their depression symptoms and resolution of both emotional and physical symptoms when they took venlafaxine (Effexor®, Wyeth) than other selective serotonin reuptake inhibitors (SSRIs) or placebo. The findings were revealed at the European College of Neuropsychopharmacology’s annual meeting in Prague, Czech Republic.

The data were pooled after completion of more than 30 comparable, randomized, double-blind, active, drug-controlled clinical studies conducted worldwide in more than 7,000 patients with major depressive disorder. Nine of these studies were also placebo-controlled. Investigators in all of the double-blinded studies randomly assigned patients to receive venlafaxine, extended-release venlafaxine (XR), or another SSRI.

Patients who took venlafaxine had significantly higher remission rates than those taking the other SSRIs, as measured by to the Hamilton Rating Scale for Depression (HAM-D17) or the Montgomery–Asberg Depression Rating Scale (MADRS).

Venlafaxine was also more effective than the SSRIs in reducing the anxiety and somatization symptoms associated with depression, according to the HAM-D21 scale. More patients taking venlafaxine achieved resolution of their general somatic symptoms of depression.

Backache, headache, muscle aches, loss of energy, fatigue, and heaviness in the limbs, back, and head can also occur in addition to the emotional symptoms inherent in depression. In these studies, 38% of the patients in the venlafaxine group achieved resolution of their general somatic symptoms, compared with 32% of the SSRI patients and 25% of placebo patients.

Venlafaxine is believed to increase levels of serotonin and norepinephrine, two of the brain chemicals thought to be implicated in depression, Generalized Anxiety Disorder (GAD), and Social Anxiety Disorder (SAD).

The most commonly reported adverse drug events were anorexia, asthenia, constipation, dizziness, dry mouth, ejaculation problems, impotence, insomnia, nausea, nervousness, somnolence, and sweating. Patients should be counseled about possible symptoms if they discontinue the medication abruptly or reduce the dose.

Venlafaxine is contraindicated in patients taking monoamine oxidase inhibitors, and in children and teenagers because of the potential risk of suicidal thoughts. Treatment is associated with sustained increases in blood pressure in some patients, and regular monitoring is recommended.


(Source: News release, Wyeth Pharmaceuticals, September 26, 2003.)

For daily synopses of FDA news, see the PharmScope daily briefing on PTcommunity.com.