Cervical Cancer Vaccine

The Food and Drug Administration (FDA) has approved Gardasil (Merck), the first vaccine developed to prevent cervical cancer, precancerous genital lesions, and genital warts caused by human papilloma virus (HPV) types 6, 11, 16, and 18 for females nine to 26 years of age.

This agent was evaluated and approved in six months under the FDA’s priority review process for products with the potential to provide significant health benefits. The Center for American Progress calls this approval “one of the greatest public health victories since the polio vaccination.”

A similar vaccine, produced by Glaxo-SmithKline, has been shown to be effective for women up to 55 years of age. The Merck and GlaxoSmithKline vaccines have proved 100% effective against the two strains of HPV that account for 70% of the cases of cervical cancer in the U.S. The Merck vaccine may also be effective against strains that cause vaginal and vulvar cancers and is 99% effective against the two strains of HPV responsible for 90% of genital warts.

Gardasil, a recombinant vaccine (containing no live virus), is given as three injections over a six-month period.

Females are not protected if they have been infected with an HPV type before vaccination. Because Gardasil does not protect against less common HPV types not included in the vaccine, routine Pap screening remains critically important to detect precancerous cervical changes.

Merck is conducting an ongoing study to evaluate Gardasil for males.

For more information on this vaccine, please see this month’s Pharmaceutical Approval Update, page 404.

Sources: FDA; Center for American Progress, June 8, 2006; www.fda.gov; www.fda.gov/womens/getthefacts/hpv.html.

Generic Approvals

Generic Omnicef for Infections

Lupin Pharmaceuticals has received FDA approval for its Abbreviated New Drug Application (ANDA) for Cefdinir Powder for Oral Suspension, 125 mg/5 ml. This is the AB-rated generic equivalent of Abbott’s Omnicef Suspension, 125 mg/5 ml.

Omnicef is a cephalosporin antibiotic that is used to treat mild-to-moderate infections, including acute flare-ups of chronic bronchitis, middle-ear infections (otitis media), throat and tonsil infections (pharyngitis/tonsillitis), pneumonia, sinus infections, and skin infections.

(Source: Lupin, June 6, 2006.)

Generic Proscar for Benign Prostatic Hypertrophy

The FDA has granted approval for Teva Pharmaceuticals to market the generic version of Merck’s Proscar (finasteride) 5-mg tablets. Finasteride is indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate gland and to reduce the need for prostate surgery.

(Source: Teva, June 19, 2006.)

Generic Zocor for Reducing Heart Disease Risk

Simvastatin tablets have been approved for reducing total cholesterol, low-density lipoprotein-cholesterol (LDL-C), apo B, and triglyceride levels in patients at high risk for coronary heart disease. This product is AB-rated and is bioequivalent to Merck’s Zocor tablets.

On June 23, the FDA approved generic formulations for 5-, 10-, 20-, and 40-mg tablets (manufactured by Ivax Pharmaceuticals for Teva Pharmaceuticals Industries) and for 80-mg tablets (made by Ranbaxy Pharmaceuticals).

(Source: Teva, June 23, 2006; Medscape Today, June 30, 2006.)

Extended-Cycle Oral Contraceptive

The FDA has approved the NDA for Seasonique (levonorgestrel/ethinyl estradiol 0.15 mg/0.03 mg and ethinyl estradiol 0.01 mg) tablets (Barr Pharmaceuticals/Duramed) to prevent pregnancy. Seasonale, Barr’s earlier extended-cycle oral contraceptive, was launched in 2003 as a 91-day regimen. Tablets containing the active hormones are taken for 12 weeks (84 days), followed by seven days of placebo (inactive) tablets, thus offering the convenience of just four menstrual periods per year.

Seasonique provides continuous hormonal support in the form of a low dose of estrogen in place of seven placebo tablets taken during the month. Patients take the active tablets for 84 consecutive days, followed by seven days of 0.01 mg of ethinyl estradiol. The regimen is also designed to reduce the number of withdrawal bleeding periods to four times per year.

Barr received an approvable letter for Seasonique in August 2005. In March 2006, the FDA determined that no additional clinical studies would be required to support the approval.

(Source: Barr, May 25, 2006.)

First Oral Rosacea Therapy

Oracea (doxycycline, CollaGenex) has been approved for the treatment of inflammatory lesions in adults with rosacea, a dermatological condition. This is the first FDA-approved, orally administered, systemically delivered drug to treat rosacea.

This 40-mg capsule offers the convenience of once-a-day administration and contains a combination of immediate-release and delayed-release beads. Rosacea primarily affects the face; it is...
characterized by the appearance of papules and pustules, erythema, and telangiectasia (spider veins). If allowed to progress to a moderate-to-severe condition, rosacea can cause itching, pain, and thickening of the skin.

(Source: CollaGenex, May 30, 2006.)

**Hyaluronic Acid Dermal Fillers For Facial Wrinkles**

Allergan, Inc., has announced the approval of the Juvederm gel family of products to correct facial wrinkles and folds.

Three formulations were approved; one adds volume to facial wrinkles, one corrects deeper wrinkles, and another subtly corrects wrinkles. These formulations contain higher concentrations of non-animal and cross-linked hyaluronic acid than other dermal fillers.

The FDA’s approval was based on data from a double-blind, randomized, controlled clinical trial. In clinical studies, adverse events were usually mild to moderate.

(Sources: Allergan, June 6, 2006; www.JuvedermComingSoon.com.)

**Fast Approval: Dasatinib for Leukemia**

The FDA has granted accelerated approval for dasatinib (Sprycel, Bristol-Myers Squibb), a new oral treatment for patients with chronic myeloid leukemia (CML). CML is a rare cancer that is characterized by the uncontrolled growth of white blood cells. CML affects about 4,600 people annually in the U.S.

The FDA has also given regular approval to this drug for use in the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph + ALL), a more serious form of leukemia. Both approvals are for patients who have experienced resistance or intolerance to prior therapy.

Dasatinib is indicated for patients with CML who are no longer responding to, or who can no longer tolerate, therapy with imatinib mesylate (Gleevec, Novartis), which was approved in 2001. It works by reducing the activity of one or more proteins responsible for the uncontrolled growth of the leukemia cells.

Dasatinib is considered an orphan drug for these indications. Its approval was based on evidence from four single-arm studies in more than 400 patients.

(Source: FDA, June 29, 2006.)

**Ranibizumab for Age-Related Wet Macular Degeneration**

The FDA has approved ranibizumab injection (Lucentis, Genentech) for the treatment of neovascular (wet) age-related macular degeneration (AMD). AMD is a major cause of painless central vision loss and is a leading cause of blindness in people over 55 years of age.

The wet form of AMD is caused by the growth of abnormal blood vessels. (The dry form is associated with atrophic cell death of the central retina or macula.)

This agent is designed to inhibit the formation and leakage of new blood vessels in the back of the eye, the primary cause of central vision loss associated with this disease.

It is a recombinant humanized IgG1-kappa isotype therapeutic antibody fragment that binds to and inhibits the biologic activity of human vascular endothelial growth factor A (VEGF-A), a protein that is believed to play a critical role in the formation of new blood vessels. VEGF-A has been shown to lead to wet AMD disease progression and central vision loss.

Ranibizumab was developed by Genentech and the Novartis Ophthalmics Business Unit. The approval was based on data from two large phase 3 clinical trials (MARINA and ANCHOR). Nearly all patients (95%) who received ranibizumab maintained their vision in these trials. Vision improved by at least three lines (15 letters) on the eye chart in up to 40% of the patients at one year.

This 0.5-mg intravitreal injection is recommended to be used once a month. If monthly injections are not feasible, treatments can be reduced to one injection every three months after the first four monthly injections.

**NEW INDICATIONS**

**First Drug for Seasonal Depression**

Bupropion HCL extended-release tablets (Wellbutrin XL, GlaxoSmithKline) have been approved for the prevention of major depressive episodes in patients with a history of Seasonal Affective Disorder (SAD). The drug had been previously approved for patients with Major Depressive Disorder.

SAD is characterized by recurrent major depressive episodes that usually coincide with the seasonal decrease of daylight during autumn and winter. Even though patients may have depressive episodes during other times of the year, the diagnosis of SAD requires that the number of seasonal episodes substantially outnumber the non-seasonal episodes during the individual’s lifetime.

The product’s labeling includes a “black box” warning about an increased risk of suicidal thoughts and behavior in children treated with antidepressants.

The extended-release form is indicated only for patients who meet strict diagnostic criteria of seasonal major depressive episodes.

For more information on SAD and bupropion XL, see the Pharmaceutical Approval Update column, page 404.

(Source: FDA, June 13, 2006.)

**Topotecan/Cisplatin For Late-Stage Cervical Cancer**

The FDA has approved a combination
of the antineoplastic drug topotecan HCl (Hycamtin, GlaxoSmithKline) and the alkylating agent cisplatin (Platinol, Bristol-Myers Squibb) as the first pharmaceutical treatment for women with late-stage cancer of the cervix for which surgery or radiation therapy is unlikely to be effective.

Hycamtin was approved in 1996 for treating ovarian cancer and in 1998 for treating small-cell lung cancer. The combination is specifically indicated for women with stage IVB (incurable), recurrent, or persistent cervical cancer.

(Source: FDA, June 17, 2006.)

Rivastigmine for Dementia in Parkinson’s Disease

Rivastigmine tartrate (Exelon, Novartis) has been approved for patients with mild-to-moderate dementia associated with Parkinson’s disease (PD). Rivastigmine was previously approved for the treatment of mild-to-moderate dementia of the Alzheimer’s type.

Steven Galson, MD, MPH, Director of the FDA’s Center for Drug Evaluation and Research, explains that dementia associated with PD differs from dementia associated with Alzheimer’s disease (AD). Until now, however, no treatment had proved effective specifically for dementia associated with PD.

Approximately 0.2% to 0.5% of people over 65 years of age are affected by PD dementia.

This approval of rivastigmine was based on the results of a randomized, placebo-controlled clinical study. (Source: FDA, June 27, 2006.)

European Union Approves Adalimumab for Severe Ankylosing Spondylitis

Abbott Laboratories has received approval from the European Commission to market adalimumab (Humira) for treating severe active ankylosing spondylitis (AS), a spinal arthritic disease.

This chronic autoimmune disease of the axial skeleton and large peripheral joints causes inflammatory back pain and stiffness. It is also associated with other inflammatory diseases of the skin, eyes, and intestines. Over time, severe AS can result in complete spinal fusion, causing extreme physical limitation, and may lead to inflammation that predisposes patients to spinal vertebral fractures.

The drug has also been approved in the European Union for the treatment of severe, active, and progressive rheumatoid arthritis and psoriatic arthritis.

Unlike many other rheumatic conditions, AS primarily affects young men and commonly begins before age 35. It is the most overlooked cause of persistent back pain in young adults.

The approval of this agent for the treatment of AS was based on data from the ATLAS (Adalimumab Trial Evaluating Long-Term Efficacy and Safety in AS) study.

Adalimumab will be available immediately to patients with AS in Germany, Spain, Finland, and Denmark. Abbott’s application for adalimumab for AS in the U.S. is currently under review. (Source: Abbott Labs, June 7, 2006.)

Ezetimibe for Reducing LDL and Total Cholesterol

Merck and Schering-Plough have announced the FDA’s approval of ezetimibe (Zetia), along with diet and in combination with fenofibrate, for lowering elevated total cholesterol and low-density lipoprotein-cholesterol (LDL-C) in patients with mixed hyperlipidemia when diet alone is not enough. Mixed hyperlipidemia is characterized by elevations of LDL-C and triglycerides and reduced high-density lipoprotein-cholesterol (HDL-C) levels.

Fenofibrate is commonly used along with diet to treat hyperlipidemia and has proven efficacy in lowering triglyceride levels and increasing HDL-C. The use of ezetimibe with fibrates other than fenofibrate is not yet recommended.

(Source: Merck, June 9, 2006.)

Canada Approves Abraxane For Metastatic Breast Cancer

Injectable-suspension paclitaxel powder (Abraxane for Injectable Suspension, Abraxis BioScience) has been approved by the Therapeutic Products Directorate of Health Canada for the treatment of metastatic breast cancer in Canada.

Through its Canadian affiliate, Abraxis Oncology, the company plans to launch Abraxane in the third quarter of 2006.

In a head-to-head comparison with paclitaxel injection (Taxol, Bristol-Myers Squibb Oncology), Abraxane nearly doubled the overall target lesion response rate, resulted in a 37% improvement in progression-free survival, and achieved a prolonged time to tumor progression.

Abraxane is the first protein-bound particle chemotherapy; unlike other taxane-based chemotherapies, it does not include solvents to deliver the medication to tumors.

Abraxane was approved in the U.S. in January 2005 for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy.


Expanded Label for IV Antibiotic Daptomycin

Cubist Pharmaceuticals has announced the FDA’s approval of its supplemental New Drug Application for daptomycin for injection (Cubicin) as once-a-day therapy at 6 mg/kg for the treatment of Staphylococcus aureus (S. aureus) bloodstream infections, continued on page 370
NEW DRUGS

continued from page 364

including right-sided endocarditis caused by methicillin-susceptible S. aureus (MSSA) and methicillin-resistant S. aureus (MRSA).

Cubist estimates that these infections account for 30,000 deaths in the U.S. alone each year. This is the only IV antibiotic approved for this indication, which was based on the results of a prospective, randomized, controlled registration trial.

The drug was originally approved in 2003, at 4 mg/kg intravenously once daily for the treatment of complicated skin and skin structure infections caused by gram-positive organisms, including both susceptible and resistant strains of S. aureus (MSSA and MRSA, respectively).

Daptomycin is not indicated for patients with pneumonia. For patients with persisting or relapsing S. aureus infection or with a poor clinical response, a second blood culture specimen should be obtained.


NEW FORMULATION
Oral Disintegrating Prednisolone Tablets
Prednisolone sodium phosphate (Orapred ODT, BioMarin/Alliant) is now available as an orally disintegrating tablet to control acute exacerbations of asthma in children; to treat severe, persistent asthma; and to reduce inflammation in conditions such as arthritis and cancer.

The tablets do not need to be refrigerated, and the taste is masked. This is the first orally disintegrating tablet form of prednisolone available in the U.S.

Alliant expects to begin marketing the tablets in the fall.

(Source: BioMarin/Alliant, June 1, 2006.)

DRUG NEWS
FDA Advisory on ACE-Inhibitors in Pregnancy
A new study suggests that angiotensin-converting enzyme–inhibitors (ACE-inhibitors) may be associated with an increased risk of birth defects when they are used in the first three months of pregnancy.

ACE-inhibitors, which are used to treat high blood pressure, are already known to pose risks to the developing infant during the last six months of pregnancy. The prescribing information for all ACE-inhibitor drugs has long emphasized that women who become pregnant should discontinue ACE-inhibitors as soon as possible to avoid exposure to the fetus in the second and third trimesters.

The labels for all of these agents contain a boxed warning about pregnancy. All women of reproductive age should be counseled about the risks of these drugs, and pregnant women should take them only if the expected benefits clearly exceed the potential risks. Women who use ACE-inhibitors to treat hypertension should inform their health care professionals if they are planning a pregnancy or think they might be pregnant.


FDA to Require Electronic Tracking of Prescribed Drugs
The FDA has decided to track pharmaceuticals from the factory to the wholesaler to the pharmacy. An 18-year-old law requires wholesalers to track drugs from the factory to the pharmacy; the FDA will now enforce these long-delayed rules in December.

It is hoped that this move, aimed at stamping out the traffic of counterfeit drugs, will make it more difficult for criminals to slip fake products into the supply chain.

The regulations, stemming from a 1988 law intended to combat counterfeiting by verifying a drug’s pedigree, were originally drafted in 1999. But the FDA had repeatedly put a hold on the rules because the drug industry said it had no practical method of tracing all of its products. Now, delay of these “pedigree” rules is no longer excusable because of the development of electronic tracking technology, particularly digital identification tags that can be scanned with radio waves. The main reason for the delay in enforcement for the last 18 years was that wholesalers said they would go out of business if the law were enforced.

The radiofrequency tags are now small enough to be embedded in the labels of drug bottles and packages, and they can store more information than bar codes; they can also be scanned from farther away.

Only a few pharmaceutical companies are currently using radiofrequency identification (RFID). Pfizer has been applying the tags to all Viagra shipped from France; Purdue Pharma has been using it for OxyContin; and GlaxoSmithKline has begun tagging Trizivir.

At this point, the question is not whether the technology can meet the drug industry’s needs but which of two competing frequency standards are to be used and how fast the technology can be rolled out. Most of the testing has been with conducted on older, “high-frequency” systems, some major customers have been supporting still higher-powered systems (ultra-high-frequency, or UHF) bandwidths. Some RFID companies (e.g., ADT/Tyco) want drug makers to switch to UHF. No one is yet sure whether radio signals will affect biological drugs, which consist of purified proteins, and testing has been limited.

Although counterfeiting is relatively rare in the U.S., the sophistication of counterfeiters has been growing.
Antidepressant Use by Children Decreases after Warnings

The number of children who are being prescribed antidepressants decreased by 9.8% after the FDA issued black-box warnings in October 2004.

A study presented by i3 Research at a June meeting of the New Clinical Drug Evaluation Unit of the National Institute of Mental Health (NIMH) showed that the number of patients receiving a selective serotonin reuptake inhibitor (SSRI) or a serotonin–norepinephrine reuptake inhibitor (SNRI) had decreased by 11.9%.

The FDA issued the boxed warning after a safety review indicated an increased risk of suicide among children using antidepressants. To determine the impact of this warning on antidepressant prescribing trends in the children, i3 Research examined de-identified health care claims data from a large U.S. health plan from one year before and for one year after the warnings were issued.

Of the 3.8 million eligible patients in the database, more than 62,000 patients who were 17 years of age and younger were prescribed an antidepressant prior to the warning, mainly for Major Depressive Disorder, whereas more than 56,000 were prescribed one after the warning.

About 50% of the patients were 15 to 17 years of age. The greatest decrease in use (by 14.5%) occurred in patients younger than nine years of age.

(Source: i3 Research, NIMH annual meeting, June 14, 2006.)

FDA and ISMP Campaign To Clarify Abbreviations

The FDA and the Institute for Safe Medication Practices (ISMP) have launched a nationwide campaign aimed at reducing the number of common sources of medication errors caused by the use of unclear medical abbreviations, symbols, and dose designations, which have often resulted in harm to patients. According to the Institute of Medicine (IOM) of the National Academies, more than 7,000 deaths each year are caused by medication errors.

The campaign focuses on eliminating potentially confusing abbreviations used by health care professionals, medical students, medical writers, the pharmaceutical industry, and FDA staff members in written drug orders; computer-generated labels; medication administration records; pharmacy or prescriber computer order entry screens; and drug labeling, packaging, and advertising. Here are a few examples:

• The campaign will attempt to eliminate common notations such as the letter U, which can be mistaken for cc, a zero, or the number 4; it should be written as “unit.”
• IU, which is sometimes misinterpreted as IV or the number 10, should be written as “international unit.”
• As for zeroes, a decimal point can easily be missed (five milligrams should be written as 5 mg, not 5.0 mg; however, a zero should be inserted before decimal points (e.g., 0.5 mg, not .5 mg)
• Because MSO₄ and MgSO₄ can be confused for one another, the intended term should be written as either morphine sulfate or magnesium sulfate.

Campaign materials include a brochure; print advertisements for trade publications; posters; an online tool kit of slides; and a video on patient safety.

(Sources: FDA, June 14, 2006; www.fda.gov/cder/drug/MedErrors; www.ismp.org/PDF/ErrorProne.pdf; www.ismp.org/tools/abbreviations.)

Safety Profile of Anti-Tumor Necrosis Factor Agents

The “striking effectiveness” of tumor necrosis factor (TNF) inhibition has re-defined therapy for rheumatoid arthritis (RA), say the Mayo Clinic researchers.

The investigators conducted a meta-analysis of nine trials, including 5,005 patients. However, their findings add to those that challenge the presumed safety profile of anti-TNF; they caution that it may raise the risk of serious infections and malignancies in patients with RA.

According to the study reports and additional verification of published and FDA data, 29 malignancies occurred among 3,493 patients who received at least one dose of an anti-TNF antibody, and three malignancies were found in the placebo group of 1,512 patients. Patients with RA were three times more likely to develop malignancies, such as lymphoma, rectal carcinoma, and basal cell carcinoma. In the treatment groups, 126 patients developed serious infections, compared with 26 patients in the control groups.

The review did not show an accumulation of malignancies with a longer study duration. This could be explained, the authors suggest, by an acceleration of pre-existing subclinical malignancies rather than by induction, which should result in clusters of events with prolonged exposure to the study drug. Accordingly, they say, patients who are being considered for anti-TNF antibody treatment should be thoroughly screened for subclinical malignancies, and they should be closely monitored.

Lowering the dose also might be a good idea, the authors add. They note that studies have already shown that the differences in terms of clinical efficacy between low doses and currently recommended higher doses were “marginal” and not statistically significant. Still, the researchers suggest evaluating...
the use of anti-TNF antibodies as induction therapy only.
(Source: JAMA 2006;295:2275–2285.)

Antiretroviral Agents and Hypertension

If patients with human immunodeficiency virus (HIV) infection are already at risk for cardiovascular disease, clinicians are advised to double-check the antiretroviral medication. Researchers from the University of Washington in Seattle discovered a two-fold increase in the risk of elevated blood pressure (BP) among patients receiving lopinavir/ritonavir (Kaletra, Abbott), compared with efavirenz (Sustiva, Bristol-Myers Squibb).

Of 444 patients, 83 experienced elevated systolic BP; 33 had elevated diastolic BP; and 11 had newly diagnosed hypertension after starting highly active antiretroviral therapy (HAART). Patients taking atazanavir sulfate (Reyataz, Bristol-Myers Squibb), efavirenz, nelfinavir mesylate (Viracept, Agouron) and indinavir sulfate (Crixivan, Merck) had significantly lower risk of high BP compared with patients taking lopinavir/ritonavir.

Their results suggest that different protease inhibitors influence BP through different mechanisms. For instance, the increased risk associated with lopinavir/ritonavir was related in part, the researchers say, to an increase in body mass index (BMI). Patients receiving atazanavir-based regimens were at a lower risk for elevated BP compared with those receiving efavirenz or lopinavir/ritonavir even after the researchers adjusted for changes in BMI.

Patients taking tenofovir (Viread, Gilead) and lamivudine (Epivir, GlaxoSmithKline) were more likely to experience high BP than patients using zidovudine (Retrovir, GlaxoSmithKline) and lamivudine. Tenofovir has been associated with a decline in renal function, the researchers note; their results suggest that the increase in risk, again, was mediated by BMI changes.

Although BP did not increase in all patients receiving indinavir, a subset of those patients who did develop hypertension had the highest rise among the cohort (more than a 40-mm Hg rise in systolic BP while using HAART). The researchers say this might represent secondary hypertension via a renal pathway. They advise further studies of, among other things, the role of intermediate variables such as lipoatrophy and lipohypertrophy in HIV-infected patients.

(Source: AIDS 2006;20:1019–1026.)

Bezafibrate May Fight Insulin Resistance

In patients with coronary artery disease (CAD), homeostatic indexes of insulin resistance (HOMA-IR) increase over time, say researchers from Israel. That was one of the major findings in their two-year study of 2,504 patients taking placebo or bezafibrate (Bezalip, Roche). The other major finding: bezafibrate can significantly attenuate the process.

Bezafibrate is a fibric acid derivative, and its long-term use in patients with CAD has reduced the incidence of diabetes. It is a pharmacological ligand for peroxisome proliferator-activated receptor alpha (PPAR-α). PPAR-α controls primarily the expression of genes involved in lipid metabolism and plays a role in glucose homeostasis and the development of insulin resistance.

HOMA-IRs were significantly correlated at baseline and during follow-up with glucose and triglycerides. During follow-up, the HOMA-IR rose only 6.6% among the patients taking bezafibrate, in contrast to 34% among the patients taking placebo. In a subgroup, patients with diabetes had a HOMA-IR that was 88% higher than those of counterparts without diabetes, and the HOMA-BCF (homeostatic index of percentage of beta-cell function) was 36% lower.

The researchers believe that this is the first large-scale report on the long-term effect of bezafibrate, but they caution that their study was a secondary analysis of a trial not designed to evaluate longitudinal changes in insulin resistance. Further studies are needed.

(Source: Arch Intern Med 2006;166:737–741.)

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Stelkast Surpass Acetabular System
Manufacturer: Stelkast Company, McMurray, PA
Approval Date: May 12, 2006
Use Classification: This ceramic-on-ceramic artificial hip replacement system is surgically implanted to replace a hip joint.

Description: The system consists of a metal hip stem, the femoral head, a ceramic insert, and a socket-shaped part. The hip stem is placed into a hole drilled in the end of the thighbone. A ceramic, ball-shaped part (the femoral head) is attached to the top end of the hip stem. The femoral head fits into the ceramic insert. The metal, socket-shaped part (the acetabular shell) is implanted into the pelvis. The ceramic insert fits into the shell.

The ceramic femoral head slides around in the ceramic insert, which allows the artificial hip replacement system to move. The hip stem and shell are intended for cement-less use and are held in place by a press-fit into the surrounding bone. The system includes porous surface coatings on some metal components.

Purpose: To replace the hip joint by promoting increased hip function.
Benefit: The acetabular system is intended for patients who need a total hip replacement because of painful non-inflamatory arthritis (e.g., osteoarthritis), lack of blood flow to the bone (avascular necrosis), or joint damage caused by injury (traumatic arthritis). The system is intended to relieve pain. The system aids long-term fixation by allowing for tissue ingrowth.

Source: www.fda.gov/cdrh/mda/docs/p040051.html

Name: Birmingham Hip Resurfacing System
Manufacturer: Smith & Nephew, Inc., Memphis, TN
Approval Date: May 12, 2006

Use Classification: The Birmingham Hip Resurfacing System is a metal-on-metal artificial hip replacement system that is surgically implanted to replace a hip joint. It is called a resurfacing prosthesis because only the surface of the femoral head (ball) is removed to implant the femoral head resurfacing component.

Description: The system includes a socket in the shape of a shallow cup (the acetabular component) and a cap in the form of a ball head (the femoral resurfacing component). The cup replaces the damaged surface of the hip socket (the acetabulum). The cap covers the ball-shaped bone at the top of the thigh (the femoral head). It has a small stem that is inserted into the top of the thigh bone.

The cap moves within the cup. The surfaces that rub against each other (the bearing couple) are made from highly polished metal.

Purpose: To relieve hip pain and to improve hip function via the replacement of parts of the hip that have been severely damaged by degenerative joint diseases, such as osteoarthritis, rheumatoid arthritis, traumatic arthritis, dysplasia, and avascular necrosis.

Benefit: The system is intended for patients who, because of their relatively younger age or increased activity level, might not be suitable for traditional total hip replacement because they might need future hip joint revision. The system relieves pain and improves hip function.

Source: www.fda.gov/cdrh/mda/docs/p040033.html

Name: NovaSilk Synthetic Mesh
Manufacturer: Mentor Corporation, Santa Barbara, CA
Approval Date: May 24, 2006

Use Classification: The mesh is used to correct pelvic organ prolapse, which occurs when the pelvic floor muscles become weak or damaged and can no longer support the pelvic organs. The condition affects as many as 40% of women older than 50 years of age, or about 36 million women in the U.S. and Europe.

Description: The device is a macro-porous, knitted, soft and light monofilament polypropylene mesh.

Purpose: To treat prolapse of the pelvic organs. Physicians are increasingly treating prolapse with grafts and synthetic mesh because new clinical data are indicating higher failure rates for previous procedures (i.e., tissue plication).

Benefits: NovaSilk offers resistance to traction, allows tissue colonization, and facilitates positioning of the patient during surgery. The mesh can be used for pelvic-floor procedures for patients with cystocele, enterocele, rectocele, and vaginal vault prolapse.

Sources: www.pharmacyonesource.com; http://ir.mentorcorp.com

Device Recall
MRL, Inc., a Welch Allyn Company, announced that it is initiating a voluntary worldwide Class I recall of 580 AED20 Automatic External Defibrillators manufactured in Buffalo Grove, Illinois, between April 2003 and October 2003, with serial numbers 205199 through 205786. These defibrillators may experience failure or unacceptable delay in analyzing electrocardiograms and may not be able to deliver the appropriate therapy. This defect can result in a failure to resuscitate the patient. An error message on the device display reads “DEFIB COMM FAIL SELF TEST FAILED.” This problem occurs because of an intermittent electrical connection within the device.