NEW DRUGS

Generic Version of Extended-Release Biaxin

The U.S. Food and Drug Administration (FDA) has granted final approval for Teva Pharmaceuticals' Abbreviated New Drug Application for its clarithromycin extended-release tablets, 500 mg.

This medication is the AB-rated generic equivalent of Abbott's macrolide antibiotic Biaxin® XL Filmtabs.

(Source: Teva, May 18, 2005.)

NEW FORMULATIONS

Oral Fenofibrate Available for Lipid Disorders

The FDA has approved Triglide™ (First Horizon), a fenofibrate that will be available in 160-mg and 50-mg dosages. This agent is an oral treatment for lipid disorders such as elevated levels of cholesterol and triglycerides. The main drawback of fenofibrate is insolubility in water, resulting in variable uptake from the stomach and requiring patients to take the tablets with food. The new formula allows patients to take the drug at any time, whether or not they have eaten, thus contributing to improved compliance. It will be manufactured and supplied by SkyePharma.

(Source: First Horizon, May 9, 2005.)

Once-Daily Ciprofloxacin For Uncomplicated UTIs

Depomed, Inc., has received the FDA's approval of ciprofloxacin HCl (Proquin™ XR), a once-daily, extended-release formulation for the treatment of uncomplicated bacterial urinary tract infections (UTIs). UTIs are frequently caused by *Escherichia coli* and are typically treated with antibiotics.

This is the first version of ciprofloxacin for which nausea and diarrhea are listed as "uncommon" adverse events in its label rather than "common" adverse events. As a class of compounds, fluoroquinolones and ciprofloxacin are cited in the literature as a cause of nausea and diarrhea; these side effects are reportedly the most frequent reason that patients discontinue ciprofloxacin treatment.

The drug is gradually released over six hours. The extended-release formula avoids the "dumping" of large quantities of the drug into the intestinal system, where it can cause side effects or interactions with gastrointestinal drugs.

(Sources: Depomed, Inc., May 20, 2005; www.drugs.com.)

NEW INDICATIONS

IGIV Liquid for Primary Immunodeficiency Disorders

Baxter Healthcare has announced the approval of Gammagard® Liquid (IGIV), or Immune Globulin Intravenous

(Human) 10% Solution for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity.

The ready-to-use sterile preparation, compared with 5% concentrations, allows for a shorter infusion time.

A three-step virus-reduction process is used to help ensure safety. Gammagard® 10% is devoid of added sugar, sodium, and preservatives. The packaging is latex-free.

The liquid will be available in five vial sizes (1, 2.5, 5, 10, and 20 g) to allow for tailored dosing and to reduce waste. It can be stored for up to nine months at room temperature or for up to 36 months if refrigerated.

A black-box warning for Gammagard® states that IGIV products have been associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Many licensed IGIV products containing sucrose as a stabilizer accounted for a disproportionate share of the total number of these events. The 10% liquid product does not contain sucrose; it is made from human plasma. However, health practitioners are reminded that products made from human plasma may carry a risk of transmitting infectious agents, such as viruses.

(Source: Baxter Healthcare, May 2, 2005, www.baxter.com.)

Infliximab Approved For Psoriatic Arthritis

Infliximab (Remicade®, Centocor) is now approved to reduce the signs and symptoms of active arthritis in patients with psoriatic arthritis, an immune-mediated inflammatory disease. Psoriatic arthritis is often manifested by joint inflammation (arthritis) and skin lesions (psoriasis). Symptoms include stiff and tender joints and surrounding tissue, a reduced range of motion, nail changes, and redness and pain of the eye.

Infliximab is also indicated for Crohn's disease, rheumatoid arthritis, and ankylosing spondylitis.

In the U.S., infliximab with methotrexate is indicated for patients with moderately to severely active rheumatoid arthritis.

(Source: Centocor, May 17, 2005.)

DRUG NEWS

Shingles Vaccine in the Works

An experimental vaccine to prevent shingles, a painful skin rash, is showing promise. Also called herpes zoster, shingles is caused by the resurfacing of the chickenpox virus. The vaccine cut the risk of acquiring shingles by 50% in a study of older people, and the cases that did develop were milder. It also reduced the serious complication of nerve pain.

Merck & Co., the vaccine's manufacturer, applied in April for marketing approval from the FDA.

(Source: Associated Press, June 1, 2005; *N Engl J Med*, June 2, 2005.)

COX-2 Inhibitors May Raise Blood Pressure

Cyclooxygenase-2 (COX-2) inhibitors can cause both systolic and diastolic elevations in blood pressure (BP), compared with placebo and nonselective nonsteroidal anti-inflammatory drugs (NSAIDs), say investigators from Australia.

After analyzing data from 45,451 patients in 19 clinical trials, the rise in systolic BP, compared with diastolic BP, on average, was "disproportionate" with COX-2 use, adding that this potentially widened pulse pressure could influence cardiovascular risk.

Although the incremental change in BP was small in this study, the widespread use of COX-2 inhibitors makes it an important consideration.

In trials that compared rofecoxib (Vioxx®) and celecoxib (Celebrex®), the relative risk of developing a clinically important elevation was 1.50 for systolic BP and 1.55 for diastolic BP. The differential effects on BP by seemingly similar agents may relate to differences in pharmacokinetic and pharmacodynamic properties, such as celecoxib's shorter half-life. Most of the patients in these trials had arthritis.

(Source: *Arch Intern Med* 2005;165: 490–496.)

Ornidazole Helps Break Cycle in Crohn's Disease

Many patients with ileal or ileocolonic Crohn's disease need resection of the diseased bowel because of complications or intractable disease. New lesions, however, are common after resection, and these lead to recurring symptoms and eventually to additional complications and a need for further surgery. Ornidazole (Ornidal®, Abatra, China), a nitroimidazole antibiotic, may enable the intestines to recover.

In a study from Leuven, Belgium, 80 patients were randomly assigned to take ornidazole 1 g/day or placebo, started within one week of resection and continued for one year. At 54 weeks, only three (7.9%) of the 38 patients taking ornidazole had clinical recurrence of lesions, compared with 15 of 40 (37.5%) patients taking placebo.

Unfortunately, the effect was observed for only as long as the drug was given.

(Source: *Gastroenterology* 2005;128: 856–861.)

NSAIDs, Aspirin, and Breast Cancer Risk

A new study from the University of Southern California in Los Angeles indicates that women using the NSAID ibuprofen every day for five years or longer are 50% more likely than nonusers to develop breast cancer, whereas women using aspirin every day for five

years or longer are 81 percent more likely than non-users to develop the estrogen-receptor, or progesterone receptor–negative, subtype of cancer.

The researchers had expected NSAIDs to reduce the risk of cancer.

No link was observed between acetaminophen use and breast cancer risk.

Further study is needed, in view of the well-known benefits of low-dose aspirin for preventing cardiovascular disease.

(Source: *J Natl Cancer Inst,* June 1, 2005, RxPG JNCI Newsletter.)

No Need to Stop Ibuprofen So Soon Before Surgery

It is a common practice to advise healthy patients to stop taking aspirin seven to 10 days before surgery. But researchers from the Mountain States Regional Hemophilia and Thrombosis Center at the University of Colorado say that it's probably all right to eliminate ibuprofen just 24 hours preoperatively.

Eleven healthy volunteers were tested at baseline and at 40 minutes, eight hours, and 24 hours after they completed seven days of taking ibuprofen every eight hours. Forty minutes after the last dose of ibuprofen, platelet function was abnormal in seven patients; by 24 hours, it was normal in all patients.

Few studies have evaluated the duration of platelet dysfunction after discontinuation of therapy with ibuprofen or other NSAIDs, and only two published studies have evaluated participants taking long-term NSAIDs. There is little agreement on when it is safe to withdraw conventional NSAIDs before surgery.

It is not well understood how long NSAID therapy must be suspended before reliable diagnostic testing for bleeding disorders should be done. This is a significant concern, given that one in 100 Americans has von Willebrand's disease.

The researchers were intrigued to find that contraceptive use had a mitigating effect on ibuprofen-induced platelet dysfunction. Platelet function remained normal at all time points in four of the 11 participants, including all three who were taking contraceptives, perhaps as a result of estrogen's prothrombotic effects.

(Source: *Ann Intern Med* 2005;142: 506–509.)

Three NRTIs in One HIV Drug

GlaxoSmithKline has received traditional approval status for Trizivir® for the treatment of human immunodeficiency virus (HIV) infection. This combination tablet contains three nucleoside reverse transcriptase inhibitors: Epivir® (lamivudine, 3TC), Retrovir® (zidovudine, ZDV), and Ziagen® (abacavir sulfate, ABC).

The FDA grants traditional approval for a drug based on data from trials of 48 weeks or more; the agency granted accelerated approval for Trizivir® in 2000, based on an analysis of 24-week data.

This agent is taken as a single tablet, twice a day, with no food or water restrictions. It can be used in combination with other antiretroviral agents or alone.

The company also markets two other fixed-dose-combination tablets: Combivir® (Epivir®/Retrovir®) and Epzicom™ (Epivir®/Ziagen®).

(Source: GlaxoSmithKline, May 16, 2005.)

Linosopril/Candesartan Reduces Blood Pressure

The Candesartan and Lisinopril Microalbuminuria (CALM) study was one of the first to show that combining two drugs—an angiotensin-coverting enzyme (ACE)–inhibitor and an angiotensin II receptor blocker—might be more effective than one drug in keeping blood pressure (BP) down in patients with diabetes. The CALM II study aimed to compare the long-term safety and efficacy of dual blockade with a single drug.

Patients received either lisinopril (e.g., Zestril®, AstraZeneca) 40 mg daily or candesartan cilexitil (Atacand®, AstraZeneca) 16 mg daily and lisinopril 20 mg daily. Fifteen of the 75 patients also needed a thiazide diuretic because of insufficient BP reduction.

Both treatments reduced systolic BP and stabilized the urinary albumin-to-creatinine ratio. Dual blockade was more effective for daytime BP and 24-hour and night systolic BP, but the trend was not significant.

(Source: *Diabetes Care* 2005;28:273–277.)

Presurgery Antimicrobials: Room for Improvement

Most patients are receiving antimicrobial drugs before surgery, thanks in part to persistence by the National Surgical Infection Prevention Project. However, a study of 34,133 patients undergoing five types of major surgery has found that the gains are being undercut by bad timing and overuse.

Optimal prophylaxis depends on matching the drugs to the operations, using the safest and most effective drugs, maintaining effective serum and tissue levels throughout the operation, and stopping the drug when it is no longer benefiting the patient.

In this study, 93% of patients received a prophylactic antimicrobial regimen consistent with current guidelines, and more than half of the patients received the antimicrobials during the 60 minutes before incision, also in accordance with guidelines. However, only 79% were given regimens limited to recommended agents, which suggests that many antimicrobials are used unnecessarily.

The guidelines generally favor older, narrow-spectrum agents (first-generation and second-generation cephalosporins. There is no evidence that newer antimicrobials are more effective than

older options. Yet newer agents are often used when older ones would suffice.

These results raise concerns about antimicrobial resistance. Vancomycin continues to be used excessively. Even though its primary indication is beta-lactam allergy, in almost 50% of cases, no such allergy was documented. Moreover, 59% of patients received the prophylactic drugs more than 24 hours after surgery.

Although the optimal duration of prophylaxis is controversial, most experts support a short duration. As little as one dose was as effective as a longer-duration treatment in preventing infection.

(Source: *Arch Surg* 2005;140:174–182.)

Cerebral Edema After Overdose

In an unusual case reported from the University of California, a 19-year-old man died of cerebral edema after an intentional overdose of his prescribed medications, including valproic acid. Although the quantity of valproic acid was "unexceptional," it led to a dangerous roller coaster of ammonia levels.

When the patient was evaluated, approximately 90 minutes after the overdose, he was lethargic but awake. His electrocardiogram and chest radiograph results were normal. He was given 50 g of activated charcoal with sorbitol.

Electrolytes, liver enzymes, blood urea nitrogen, creatinine, and glucose levels were normal, but the ammonia level was 379 mcg/dl (roughly six times the normal range). The valproic acid level was 305.4 mcg/ml—three times normal, but a level the doctors termed "modest."

Eleven hours after the overdose, the ammonia level dropped to 76 mcg/dl, then rose to 193 mcg/dl six hours later, yet the patient was more awake and alert than before. Lactulose was given to reduce the ammonia level.

At 43 hours, his mental status began to worsen; by 48 hours, he was intubated. His ammonia level was 338 mcg/dl. Again it peaked and dropped, from 1,191 to 117 mcg/dl at 90 hours.

At 110 hours, the patient had fixed, dilated pupils and extensor posturing. Computed tomography showed cerebral edema. He was pronounced brain-dead; his ammonia level was 80 mcg/dl. The valproic acid level was 60.7 mcg/ml.

Severe complications with valproic acid are rare, the doctors say, especially with peak levels under 450 mcg/ml and with ingestions of less than 400 mg/kg. The co-ingestants—risperidone (Risperdal®, Janssen) and venlafaxine (Effexor®, Wyeth)—were of unknown significance, although hyperammonemic encephalopathy has occurred after combination therapy with valproic acid and other antiseizure drugs.

The doctors say that their case reinforces the importance of ongoing gastric decontamination in patients with persistently high or increasing serum valproic acid levels after an acute overdose. Carnitine supplementation, which was not used, seems "prudent," they concluded. Unfortunately, L-carnitine is not always available in sufficient quantities.

(Source: *Ann Emerg Med* 2005;45:337–338, letter.)

Drug–Disease Interactions in the Elderly

Forty percent of hospitalized elderly patients are at risk for at least one drug–disease interaction, according to researchers who studied 397 frail elderly patients in a trial conducted at 11 Veterans Affairs medical centers.

The most common potential interactions involved calcium-channel blockers and heart failure (12.3%) and beta blockers and diabetes (6.8%). In fact, beta blockers were implicated more than once, with peripheral vascular disease or Raynaud's disease and chronic obstructive pulmonary disease. Aspirin was linked to peptic ulcer disease. Patients aged 75 and older and those with multiple illnesses were at higher risk.

Health care professionals may be able to reduce the potential negative impact of the most common interactions, for example, by co-prescribing gastroprotective agents with aspirin and other NSAIDs. In older patients, the total body clearance of commonly used cardioselective beta blockers may be reduced and higher blood concentrations may result in loss of cardioselective properties. Thus, caution, more vigorous monitoring, and perhaps lower doses are advised.

(Source: *Ann Pharmacother* 2005;39:412–417.)

Amiodarone with Beta Blocker Aids Patients with Defibrillators

Amiodarone (e.g., Pacerone®) plus a beta blocker can make life easier for patients with an implantable cardioverter defibrillator (ICD), according to the Optimal Pharmacological Therapy in Implantable Cardioverter Defibrillator Patients (OPTIC) trial, sponsored by St. Jude Medical, Inc., St. Paul, Minnesota. The researchers said that the combination drug treatment cut the risk of delivered shocks by 73% over one year.

After a St. Jude Medical dual-chamber ICD was implanted in 412 patients with life-threatening arrhythmia, the annual risk of shock dropped to only 10% with the amiodarone combination treatment, compared with a rate of 24% with sotalol (Betapace®, Bristol-Myers Squibb) and a rate of 39% with beta blockers alone.

Sotalol was less well tolerated than the amiodarone/beta-blocker combination; 24% of patients taking it stopped, compared with 18% of those taking amiodarone.

The dramatically reduced shock rates with the dual-drug regimen may alleviate some of the anxieties that plague many patients with ICDs. Another researcher said that between 64% and 69% of patients reported "daily preoccupation" with their

device during the first couple of months after implantation. The emotional toll can include depression, fears about the device going off, and preoccupation with body image.

(Source: American College of Cardiology, www.theheart.org.)

Aspirin Safer Than Warfarin For Blocked Brain Arteries?

To reduce the risk of stroke, physicians have treated partially blocked arteries in the brain with drugs such as aspirin and warfarin, which reduce blood clotting. A double-blind, randomized clinical trial has shown that aspirin works as well as warfarin with fewer side effects. The Warfarin Aspirin Symptomatic Intracranial Disease (WASID) trial was funded by the National Institute of Neurological Disorders and Stroke, part of the National Institutes of Health (NIH).

Investigators at 59 U.S. medical centers compared warfarin with 1,300 mg/day of aspirin in 569 patients for 1.8 years. All of the patients had a greater than 50% blockage of a major intracranial artery and had experienced a nondisabling stroke within the 90 days prior to their enrollment in the study.

Approximately 22% of the patients had a subsequent ischemic stroke (caused by blockage of an artery), brain hemorrhage, or death from other blood vessel-related causes, whether they received aspirin or warfarin. However, the rates of major hemorrhage and death from all causes were higher with warfarin. Enrollment was terminated early because of safety concerns about warfarin.

Because warfarin therapy is more expensive and complicated than aspirin therapy, not using warfarin and preventing the bleeding complications associated with it would save more than $20 million per year in the U.S. The results are relevant only for patients with intracranial stenosis, the study authors noted. People who take warfarin for other conditions, such as an irregular heart rhythm or clots in the legs or lung, should not stop taking it, because it is the best option in those circumstances.

The aspirin dose used in the study (1,300 mg) was much higher than the usual daily doses prescribed (81–325 mg).

Even with treatment, the rates of ischemic stroke in this clinical trial were higher than in stroke-prevention trials that have evaluated aspirin and warfarin in patients with other causes of stroke. This underscores the fact that patients with intracranial stenosis are at particularly high risk for stroke and that better therapies are needed.

(Sources: *N Engl J Med* 2005;352:1305–1316; National Institutes of Health.)

Preventing Pain After Rocuronium Injection

Half or more of patients have pain after rocuronium bromide (Zemuron®, Organon) injection, say the authors of a study comparing the efficacy of intravenous (IV) fentanyl with IV lidocaine as pretreatment. In fact, they noted withdrawal responses to rocuronium injection even after patients lost consciousness during induction of anesthesia.

Researchers from Malaysia randomly assigned 90 patients, 18 to 65 years of age, to three groups: one group of patients received 2 ml of IV fentanyl 50 mcg/ml, one group received 2 ml of preservative-free lidocaine 2%, and one group received placebo.

The incidence of withdrawal response after the rocuronium injection was 57% with placebo, 30% with lidocaine, and 7% with fentanyl. The researchers say the fact that fentanyl was better than lidocaine in this context is interesting, considering that other trials have found the opposite. The difference, they believe, is in timing. They administered fentanyl two minutes before induction, followed by the rocuronium injection, thus allowing adequate time for the onset of drug effect.

Pretreatment with opioids is effective only if adequate time is allowed for the onset of analgesia, whereas pretreatment with drugs with local anesthetic properties is effective when it is administered immediately before or with a venous occlusion technique.

The authors suggest combining IV fentanyl 2 mcg/kg and lidocaine 0.5–1 mg/kg, administering fentanyl (for its central analgesic action) two minutes before and lidocaine (for its peripheral analgesic action) immediately before the rocuronium.

(Source: *Anesth Analg* 2005;100:987–990.)

Do Drugs for Impotence Cause Blindness?

The FDA said that it was looking into cases of impaired vision among men with erectile dysfunction who took sildenafil (Viagra®, Pfizer). Other cases have been reported in men taking tadalafil (Cialis®, Eli Lilly ICOS) and vardenafil (Levitra®, GlaxoSmithKline/Schering-Plough/Bayer AG).

The warning labels for these drugs already mention the possibility of temporary changes in color vision (such as trouble distinguishing blue from green or seeing blue-tinged objects), sensitivity to light, and blurred vision. At issue is the sudden loss of vision when blood flow to the optic nerve is blocked. This condition is called non-arteritic anterior ischemic optic neuropathy ("Naion"). (The blue vision is caused by a reaction in the retina and is not related to Naion.)

The FDA has received 43 reports of Naion: 38 for sildenafil, four for tadalafil, and one for vardenafil.

Naion is considered a common cause

of sudden vision loss in older Americans. Risk factors include diabetes and heart disease, two of the leading causes of impotence.

Naion is sometimes referred to as a stroke of the eye. The optic nerve is a conduit for blood and oxygen to the eye and visual signals to the brain. In Naion patients, the optic nerve narrows suddenly, which cuts off blood and oxygen flow, usually resulting in impaired vision and in rare cases, permanent blindness.

These drugs dilate the arteries, causing increased blood flow in the penis. It isn't clear whether this action affects blood flow to the eye.

Earlier this year, a report in an ophthalmology journal mentioned seven patients who experienced Naion vision loss within 36 hours of a sildenafil dose.

Despite the reports, the link between the drugs and Naion is not clear. There appears to be little evidence that the drugs increase the risk of blindness.

(Sources: Associated Press, May 28, 2005; *The Wall Street Journal,* June 2, 2005.)

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: Tag-It™ Cystic Fibrosis DNA Kit

Manufacturer: Tm Bioscience Corporation, Toronto, Ontario, Canada

Approval Date: May 9, 2005

Use Classification: This DNA-based test is used to detect and simultaneously identify mutations and variants in the cystic fibrosis (CF) transmembrane conductance regulator gene in human blood specimens in order to determine CF carrier status in adults, as an aid in newborn screening, and in diagnostic testing of newborns and children.

Description: The precision of the kit was tested via synthetic positive controls representing all potential genotyping calls for 43 mutations and variants. Overall, all genotyping calls that can be made by the kit were made correctly and were reproducible under the evaluated conditions with a precision of greater than 99.9%. The kit's accuracy was established in a comparison study using DNA sequencing as reference methods.

Purpose: This is the first multiplexed human disease genotyping test to be cleared by the FDA as an *in vitro* device for the diagnosis of cystic fibrosis.

Benefit: CF is the most common autosomal recessive disorder in Caucasians, with an incidence of approximately 1 in 3,200 live births. The kit simultaneously screens for 23 CF transmembrane conductance regulator gene mutations and four variants, as recommended by the American College of Medical Genetics and the American College of Obstetricians and Gynecologists.

Precautions: The kit is not intended for fetal diagnostic, pre-implantation testing, or stand-alone diagnostic purposes.

Sources: http://press.arrivenet.com; www.fda.gov

Name: Taxus® Express2™ Paclitaxel-Eluting Coronary Stent System

Manufacturer: Angiotech Pharmaceuticals, Inc., corporate partner of Boston Scientific, Natick, MA

Approval Date: May 8, 2005

Use Classification: Enhanced directions indicate that patients may safely undergo magnetic resonance imaging (MRI) examination immediately after the stent is implanted.

Description: The stent system has been found safe for patients undergoing MRI at a high level of magnetic field strengths, with minimal effects on rising temperatures and release of the drug.

Purpose: MRI is an effective method of providing detailed diagnosis for many types of injuries and conditions, including cardiovascular disease. Because of the use of intense magnetic fields in MRI examinations, implanted medical devices that contain metal may be subject to potential migration and heating within the body. As a result, the instructions for the use of stent systems containing metal usually recommend a waiting period of approximately two months from the time of implantation until an MRI can be performed safely.

Benefit: This is the first drug-eluting stent to receive approval for immediate post-procedure MRI.

Source: www.pharmacyonesource.com

Name: Decapinol™ Oral Rinse

Supplier: Sinclair Pharmaceuticals, Ltd., Surrey, UK

Approval Date: April 25, 2005

Use Classification: This dental rinse is a new prescription treatment for gingivitis, a common gum disease that affects many adults. Gingivitis is manifested by inflamed or bleeding gums.

Description: The rinse treats gingivitis by reducing the number of bacteria that attach to tooth surfaces and that cause dental plaque. Decapinol™ decreased gingivitis by up to 60%, compared with no treatment, when it was used as instructed with recommended toothbrushing and flossing.

Purpose: The surfactant in this rinse has the potential to result in a substantial reduction in gingivitis. The rinse is considered a medical device, not a drug, because its primary mode of action is to create a physical barrier rather than to act chemically, making it more difficult for bacteria to stick to tooth surfaces.

Benefits: This product is an adjunct to toothbrushing and flossing in the treatment of gingivitis. Scientists believe that plaque-forming bacteria within the mouth and on the tooth surfaces are a cause of gingivitis. Substances released by the bacteria cause gum inflammation.

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Reducing plaque bacteria can decrease the inflammatory substances and thus reduce gingivitis.

Precautions: The product is not recommended for pregnant women.

Sources: www.fda.gov; www.sinclairpharma.com; www.decapinol.com

Name: ColActive™

Manufacturer: Covalon Technologies Ltd., Mississauga, Ontario, Canada

Approval Date: April 29, 2005

Use Classification: ColActive™ is a collagen scaffold used as a wound dressing.

Description: This device is composed of cultured cells on its collagen-based scaffold (matrix).

Purpose: The successful growth of animal cells on a cellular scaffold demonstrates that the matrix is well accepted by cells. The cells adhere and grow well on the matrix, and the matrix is used as a wound dressing.

Benefit: The matrix is biocompatible with human tissue and is biodegradable.

Sources: www.pharmacyonesource.com; www.stockjunction.com

Name: V-BAG™ Vacuum-Assisted Soft Shell Venous Reservoir

Manufacturer: Gish Biomedical, Inc., Rancho Santa Margarita, CA, a subsidiary of CardioTech International, Inc., Ridgeland, MS

Approval Date: March 28, 2005

Use Classification: The device represents a disposable vacuum-assisted reservoir that uses Gish's proprietary GBS™ heparin-bonded coating.

Description: The reservoir facilitates air removal during surgical procedures in which extracorporeal support is necessary for up to six hours.

Purpose: The vacuum-assisted venous drainage is designed to minimize overall prime volume and surface area of the extracorporeal circuit during open-heart surgery.

Benefit: The polymer-based, heparin-bonded coating provides a hemocompatible and biocompatible surface for cardiopulmonary bypass via protein and platelet preservation.

Sources: www.pharmacyonesource.com; www.amex.com