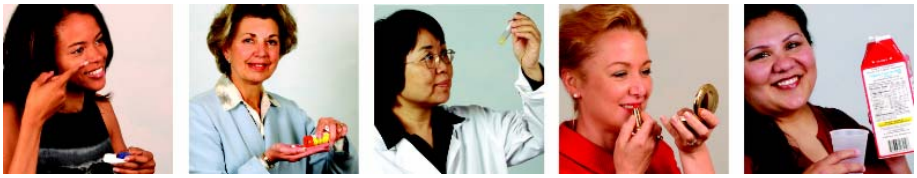

...Protecting & Advancing the Health of Women

UPDATE

August/September 2005

FDA Commissioner Confirmed

On July 18, 2005, Lester M. Crawford D.V.M., Ph.D. was confirmed by the Senate as Commissioner of the FDA. Dr. Crawford has served as the Acting Commissioner for the past year. Previously, he served as Deputy Commissioner of the FDA and as Director of the Center for Food and Nutrition Policy at Georgetown University and Virginia Tech. Dr. Crawford has demonstrated a continued commitment to working with OWH. In one of his first acts in his new position, Dr. Crawford announced the establishment of a new women's health award at the FDA. OWH congratulates Dr. Crawford on his confirmation, and we look forward to future successful collaborations.

OWH – BlueCross/ BlueShield Partnership

OWH has partnered with BlueCross/ BlueShield (BC/BS) to bring the latest health information to women and their families. OWH supplied each of the 20 BC/BS regional directors with a CD containing our most popular fact sheets, ranging from mammography to diabetes. Each region will print and distribute copies to members across the country.

Recalls / Safety Alerts / Approvals

July 19, 2005
Mifeprex Safety Alert
The Food and Drug Administration (FDA) issued a public health advisory on Mifepristone (trade name Mifeprex, also known as RU-486). The advisory noted that from September 2003 to June 2005 four women in California died from sepsis (blood infection) following medical abortion with mifepristone and misoprostol. The bacteria that caused the sepsis in two of the cases have been identified as *Clostridium sordelli*. No causal relationship between these events and the use of Mifeprex and misoprostol has been established. Sepsis is a known risk associated with any type of abortion. *Clostridium sordelli* is a bacterium that in very rare cases produces toxins that are rapidly fatal. The patients in whom *Clostridium sordelli* was identified had no fever but had a rapid pulse, low blood pressure, and very high red and white blood cell counts. They also had symptoms that included weakness, nausea, vomiting or diarrhea with or without abdominal pain.

The public health advisory called for advising patients to contact their health care professional immediately if they develop any of these symptoms with or without fever. A dear health care provider letter was written and sent by the manufacturer, Danco Laboratories. Label changes also were made to alert physicians and patients to the possibility of this rare infection. For more information, go to:
http://www.fda.gov/cder/drug/infopage/mifepristone/default.htm

July 29, 2005
Recall of Counterfeit "Lipitor" Sold in the United Kingdom
The Food and Drug Administration (FDA) alerted U.S. residents to the recent recall of a batch of counterfeit "Lipitor" (atorvastatin) sold in the United Kingdom (U.K.). The medicine is used to treat high cholesterol. The counterfeit Lipitor 20mg tablets were recalled in the U.K. on July 28, 2005. The affected product is sold in packages of 28 tablets. The drug packages are marked with batch number 004405K1 and an expiration date of 11 2007.

Complications from Metallic Tracheal Stents in Patients with Benign Airway Disorders
The Food and Drug Administration (FDA) alerted health care practitioners of serious complications associated with the use of metallic tracheal stents in patients with benign airway disorders. The notification includes all covered and uncovered metallic tracheal stents. This notification focuses on patients with benign airway disorders because use of metallic stents in this patient population may preclude them from receiving future alternative therapies (such as tracheal surgical procedures or placement of silicone stents) after a metallic stent is removed. This patient population has a greater risk of serious complications than those with malignant disorders since the metallic tracheal stent is left in place longer.

July 28, 2005
Approvable Letter to Mentor Corporation
The Food and Drug Administration (FDA) issued an approvable letter to Mentor Corporation for their application for silicone gel-filled breast implants. Federal law and regulations prohibit the government from discussing the specific contents of the letter. However, an approvable letter is one of several intermediate steps in the FDA review process of new products. Previously at their April 2005 meeting, the General and Plastic Surgery Devices Advisory Committee voted 7-2 that Mentor's application was "approvable with conditions." This letter does not mean that the device is approved for marketing in the United States at this time.

FDA Advisory Committee Meetings

National Mammography Quality Assurance Advisory Committee
Topic: Mammography Quality Standards and Procedures
Date: September 26-27, 2005
Location: Holiday Inn, Gaithersburg, MD
Advisory Committee Meeting Information:
http://www.fda.gov/oc/advisory/accalendar/2005/default.htm
Advisory Committee Telephone Information Line: 1-800-741-8138, code 3014512397.

FDA Advisory Committees web page: http://www.fda.gov/oc/advisory/default.htm

Conferences

Visit the OWH booth at the following conferences:

American Association of Diabetes Educators, August 11-13 – Washington, DC
National Association of Community Health Centers, September 18-20 – Miami Beach, FL
North American Menopause Society, September 28 – October 2 – San Diego, CA
National Association of Nurse Practitioners in Women's Health, September 28 – October 1 – Naples, FL
AARP, September 29 – October 1 – New Orleans, LA

We endeavor to provide timely information for your use.
Feel free to share this with your network, members, constituents, and community.

Food and Drug Administration
Office of Women's Health
5600 Fishers Lane, Room 16-65
Rockville, MD 20857
301-827-0350
website: www.fda.gov/womens
