

*...Protecting & Advancing the Health of Women*

## **UPDATE**

**March 2006**

### **“ASK FDA”: Public Session at FDA Science Forum**

The Food and Drug Administration (FDA) will conduct a free public session called **"ASK FDA"** on April 18, 2006 from 1:30-5:30 p.m. at the Washington, DC Convention Center. The session will allow the public to get answers from top FDA scientists on important health questions. Dr. Janet Woodcock, FDA Deputy Commissioner for Operations, will moderate a panel of FDA scientists who will answer, in plain language, consumer questions on FDA-regulated products. The session is free but attendees should register.

The **"ASK FDA"** session will be a part of the FDA's annual 2-day Science Forum. The theme for the 2006 Science Forum is **A Century of FDA Science: Pioneering the Future of Public Health**. OWH staff will have several poster presentations displayed during the Science Forum. Visit the posters to learn more about OWH sponsored research and outreach initiatives.

To register for the free public session, visit:

<http://www.accessdata.fda.gov/scripts/oc/scienceforum/sf2006/rsvp.html>

For FDA Science Forum information, visit:

<http://www.fda.gov/scienceforum/>

### **OWH Issues Progress Report: “10 Years and Beyond”**

FDA OWH has issued a report detailing our achievements for the first ten years and plans for the current decade. In addition to providing historical information about the office, the report highlights OWH funded and published research and award-winning outreach campaigns, as well as, updates the status of our new Demographic Information and Data Repository (DIDR). The report also includes opportunities for groups to partner with OWH to advance our mission to protect and advance women's health. Log on to <http://www.fda.gov/womens/reports/report0306.pdf> to read a copy of the report.

## Approvals

**February 28, 2006**

### **Emsam (Selegiline) – First Drug Patch for Depression**

FDA approved Emsam (Selegiline) for treatment of major depression. Emsam is a transdermal patch that delivers selegiline through the skin into the bloodstream. The patch is available at three dosages. At the lowest dose (6mg per 24 hour period), Emsam can be used without the strict dietary restrictions that are required for other MAO Inhibitors. For more information on Emsam, visit:

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01326.html>

## Recalls and Safety Alerts

**December 2005**

### **Climara Pro Safety Label Changes Approved**

FDA posted its MedWatch summary of a new Black Box warning for Berlex's Climara Pro (estradiol/levonorgestrel) transdermal system. The warning is related to the Women's Health Initiative and reported increased risks of stroke and deep vein thrombosis in postmenopausal women and an increased risk of developing probable dementia. For additional information on safety labeling changes, go to:

[http://www.fda.gov/medwatch/safety/2005/dec05\\_quickview.htm](http://www.fda.gov/medwatch/safety/2005/dec05_quickview.htm)

## FDA Advisory Committee Meetings and Public Meetings

### **Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee**

**Topic:**

**Date and Time:** March 27, 2006 10:00 a.m. – 5:45 p.m.

March 28, 2006 9:00 a.m. – 3:00 p.m.

**Location:** Hilton, Salons A, B, and C  
620 Perry Pkwy, Gaithersburg, MD

On March 27, 2006, the committee will discuss, make recommendations, and vote on a premarket approval application for a post surgical adhesion prevention device for use in patients undergoing gynecological laparoscopic surgical procedures.

On March 28, 2006, the committee will have a general topic discussion of clinical trial design issues for new devices intended to treat symptomatic uterine fibroids.

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

**Advisory Committee Meeting Calendar:**

<http://www.fda.gov/oc/advisory/accalendar/2006/default.htm>

## **FDA Public Workshop**

**Topic:** Hand-Held, Doppler Ultrasound Prenatal Listening Devices  
**Date and Time:** March 29, 2006 9:00 a.m. – 3:30 p.m.  
**Location:** Hilton, 620 Perry Pkwy, Gaithersburg, MD

This public meeting will address whether the hand-held Doppler monitors should be made available without a prescription.

## **Conferences**

*Visit the OWH booth at the following conferences:*

**Joint Conference on Aging, March 16-19** – Anaheim, CA  
**Anxiety Disorders Association of America, March 23-25** – Miami, FL  
**National Hispanic Medical Association, March 24-26** – Washington, DC  
**FDA Science Forum, April 18-20** – Washington, DC  
**Priester National Extension Health Conference, April 25-27** – Louisville, KY

## **March Observances**

Did you know that March 28<sup>th</sup> is **American Diabetes Alert Day**? On this day, people are encouraged to find out their risk for diabetes. Over 6 million Americans have diabetes but don't know it.

Check out the FDA OWH **Take Time to Care About Diabetes** website at <http://www.fda.gov/womens/taketimetocare/diabetes/default.htm>.

Click on "Materials" to find OWH information on Diabetes in English, Spanish, and 11 different Asian languages.



U.S. Food and Drug Administration

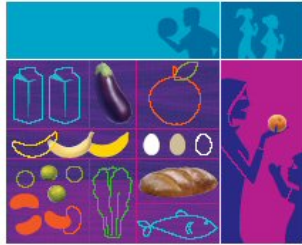
*Take Time To Care ... About Diabetes*

*Office of Women's Health*

For up-to-date information on FDA-approved diabetes medicines and medical devices, go to: <http://www.fda.gov/diabetes/>

## **NUTRITION**

March is also **National Nutrition Month®**, sponsored by the American Dietetic Association. The FDA Center for Food Safety and Applied Nutrition (CFSAN) has food labeling and nutrition information at: <http://vm.cfsan.fda.gov/label.html>



Dietary Guidelines  
for Americans  
2005

The latest federal government Dietary Guidelines can be found at: <http://www.health.gov/dietaryguidelines/>

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

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