



OWH eUpdate

www.fda.gov/womens

Winter 2008

In This Issue

- OWH Research
- Outreach Initiatives
- Hot Topics
- Update Extras

OWH Highlights

Heart Health

Free Publications

Spanish Fact Sheets

Birth Control

e-Update Archive

FDA Highlights

Cold Medicines & Kids
*Info on use of cough & cold
meds by kids under age 2*

Report a Problem
*Report problems with
medical products,
cosmetics, food, etc.*

FDA Newsroom
*Public notices, safety alerts,
media contacts and more*

Chantix Advisory
New safety warnings

Wrinkle Fillers
Info for consumers

Contact Us

5600 Fishers Lane
Room 16-65
Rockville, MD 20857
301-827-0350 (phone)
301-827-0926 (fax)
owh@fda.gov

Message from the Director

The FDA Office of Women's Health is pleased to bring you the first eUpdate of 2008. This year the recurring theme for the eUpdate and for the Office as a whole will be "safety". In this issue, you will find information on recent FDA actions related to the safe use of contraceptive products, as well as links to the new OWH birth control guide for consumers. This update also highlights information on outreach partnerships to promote safe medication use and OWH research projects on clinical trials safety data. OWH strives to provide our partners with greater access to the latest scientific, regulatory, and consumer safety information from the Agency.

Kathleen Uhl, MD

Assistant Commissioner for Women's Health

OWH Research

Tracking Women In Clinical Trials

In 2007, OWH conducted several projects related to the participation of women in clinical trials. OWH completed a pilot project that created a standardized review template to capture demographic data from clinical drug reviews. The aim of this project was to provide a consistent data format that would improve the ability to track safety and efficacy information for women and other demographic subgroups. In addition, OWH recently completed projects that addressed the planning of subgroup analysis specifically for sex differences, contraception requirements for women enrolling in clinical trials, and the enrollment of women and minorities in clinical trials for diabetes drugs. A list of projects funded by OWH and conducted by OWH staff can be found on our updated Women in Clinical Trials webpage, <http://www.fda.gov/womens/trials.html>.

Outreach Initiatives

New Birth Control Information Available

OWH has developed a new Birth Control booklet and poster. The booklet features illustrations of the 18 contraceptive products currently approved by the FDA and on the market, along with risk and effectiveness data. It also includes a handy tear-out chart for comparing all the products at a glance.

To View and Download the Birth Control booklet, visit:

<http://www.fda.gov/womens/healthinformation/birthcontrolguide.pdf>

To Order Bulk Copies from the Federal Clearinghouse, go to:

<http://www.pueblo.gsa.gov/results.tpl?id1=16&startat=1&--woSECTIONSdatarq=16&--SECTIONSword=ww>

Pharmacy Choice Web Portal Features OWH Publications

Pharmacy Choice, Inc. and the FDA OWH are collaborating to make it easier for pharmacists, pharmacy technicians, and students to keep up with the latest consumer health information from the FDA. Pharmacy Choice has created a special web portal just for OWH consumer health education materials. The portal will provide easy access to all OWH fact sheets and medication guides.

Pharmacy Choice web portals provide a comprehensive suite of web-based tools and information, including drug information, industry news, and education programs. OWH and Pharmacy Choice, Inc. invite you to collaborate in distributing the information to women and their families across the country.

Check out the new website at:

<http://www.pharmacychoice.com/resources/fda/index.cfm>

Hot Topics

FDA Takes Action on "Bio-Identical" Hormone Products

FDA issued several warning letters notifying certain compounding pharmacies about unlawful practices related to their so-called "bio-identical hormone replacement therapy" ("BHRT") drugs, a form of menopausal hormone therapy. FDA's letters warned the pharmacies that the claims they make about the safety and effectiveness of their

"BHRT" products are unsupported by medical evidence, and are considered false and misleading by the agency. These false claims include statements that compounded "BHRT" drugs are safer or more effective than FDA approved hormone therapy drugs and claims that compounded "BHRT" drugs can prevent or treat serious illnesses such as Alzheimer's disease and certain forms of cancer.

In addition, FDA warned a number of pharmacies that they may not compound products using the hormone estriol, without a valid investigational new drug application. No drug product containing estriol has ever been approved by FDA and the safety and effectiveness of estriol are unknown.

FDA's action will not limit women's access to compounded hormone therapies prescribed by her physician to meet her specific medical needs. However, because compounded drugs are not reviewed by the FDA for safety and effectiveness, FDA encourages patients to use FDA-approved drugs whenever possible. All patients who use compounded hormone therapy drugs should discuss the various options for menopausal hormone therapy with their health care provider.

The warning letters and additional information can be viewed at:
<http://www.fda.gov/cder/pharmcomp/default.htm>

A consumer article called "Bio-Identicals: Sorting Myths from Facts" can be viewed at:
<http://www.fda.gov/consumer/updates/bioidenticals010908.html>

OWH Menopause Publications for Consumers:
<http://www.fda.gov/womens/pubs.html>

Label Changes for Birth Control Patch

The FDA approved additional changes to the label for the Ortho Evra Contraceptive Transdermal (Skin) Patch. The new label includes the results of a new epidemiology study that found that women who used the birth control patch were at higher risk of developing serious blood clots, also known as venous thromboembolism (VTE), than women using birth control pills.

Ortho Evra is a prescription patch that releases hormones through the skin into the blood stream. Because the hormones are processed by the body differently than hormones from birth control pills, women using the patch can be exposed to about 60 percent more estrogen than if they were using typical birth control pills. Increased levels of estrogen may increase the risk of side effects, including serious blood clots.

For more information of Ortho Evra, visit:

<http://www.fda.gov/cder/drug/infopage/orthoevra/default.htm>

New Warning for Products Containing Nonoxynol 9 (N9)

On December 18, 2007, FDA issued a final rule that requires new warning statements and other information on the labels of over-the-counter (OTC) stand-alone vaginal contraceptive and spermicidal products containing nonoxynol 9 (N9).

The new labels must include a warning that N9 does not provide protection against infection from HIV (the virus that causes AIDS) or other sexually transmitted diseases (STDs).

In addition, FDA is requiring that the labels warn consumers that N9 in stand-alone vaginal contraceptives and spermicides can irritate the vagina and rectum, which may increase the risk of contracting HIV/AIDS from an infected partner.

Stand-alone spermicides include gels, foams, films, or inserts that are used by themselves for contraception.

The new warnings can be viewed at:

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01758.html>

The full text of the final rule is posted at:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6111.htm>

Update Extras

Conferences

The OWH Outreach Team is busy exhibiting at conferences across the country to increase awareness and dissemination of the over 50 OWH health education fact sheets and brochures available for consumers.

Visit the OWH exhibit booth at these upcoming conferences:

Sister-2-Sister Women's Heart Day, [February 1](#) – Washington, DC

Natl. Conf. on African Americans and AIDS, [February 25-26](#) – Philadelphia

Anxiety Disorders Association of America, [March 6-9](#) – Savannah, GA

American Pharmacists Association, [March 14-17](#) – San Diego, CA

NCOA-ASA Aging in America Conference, [March 27-29](#) – Washington, DC

Women's Health 2008, [March 28-30](#) – Williamsburg, VA

Presentations

Conference: National Birth Defects Prevention Network Annual Meeting
Poster: Medical Product Exposure during Pregnancy: An Update on the OWH Pregnancy Exposure Registry Website
Authors: [Pellavi Sharma](#), Ameeta Parekh, Elizabeth Duvall-Miller, Connie O'Leary, Kathleen Uhl
Date: February 11-13, 2008
Location: Washington, DC

Conference: Uniformed Services Academy of Family Physicians
Presentation: FDA & Drug Development
Speaker: [Kathleen Uhl](#)
Date: March 16, 2008
Location: Portland, OR

Conference: Uniformed Services Academy of Family Physicians
Presentation: FDA & Drug Use by Pregnant & Lactating Women
Speaker: [Kathleen Uhl](#)
Date: March 18, 2008
Location: Portland, OR

Conference: Society for Gynecologic Investigation
Presentation: "Women's Health on Critical Path"
Speaker: [Ameeta Parekh](#)
Date: March 26-29, 2008
Location: San Diego, CA

Conference: American Society for Clinical Pharmacology & Therapeutics
Presentation: Women's Health: At the Intersection of Science, Policy & Politics
Speaker: [Kathleen Uhl](#)
Date: April 3, 2008
Location: Orlando, FL

Publications

Title: Outpatient Use of cardiovascular drugs during pregnancy
Journal: Pharmacoepidemiology and Drug Safety. 2008 Jan 16
Authors: Andrade SE, Raebel MA, Brown J, Lane K, Livingston J, Boudreau D, Rolnick SJ, Roblin D, Smith DH, Dal Pan GJ, Scott PE, Platt R
PubMed ID: [18200619](#)

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