OWH eUpdate

www.fda.gov/womens

Summer 2007

In This Issue

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

OWH Highlights

Pregnancy Registry

Medicine Booklets

Spanish Fact Sheets

Sex and Gender Course

e-Update Archive

FDA Highlights

FDA Consumer Website
Links to agency-wide info for consumers

Avandia (Rosiglitazone)
Information for health professionals and patients

Safety Information
Recalls, withdrawals, and safety alerts

New Fibromyalgia Drug
Press release and consumer article

Upcoming Meetings
FDA Advisory Committee Meetings

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

OWH continues to seek innovative scientific and outreach opportunities to promote and advance the health of women nationwide. On the research front, OWH recently selected the recipients of the FY07 intramural funding awards. OWH is also embarking on a new partnership with the Agency for Healthcare Research and Quality (AHRQ) and the FDA Center for Devices and Radiological Health (CDRH) to study the long term health outcomes in patients receiving drug eluting stents for cardiovascular disease. The projects announced in this issue will help to advance the understanding of the impact of sex differences on disease diagnosis and treatment.

In addition, OWH continues to translate what we learn from science into reliable, easy-to-understand health information for women from diverse cultures and regions. For the first time, OWH has made all of our consumer fact sheets available in Spanish. Read more about how to access these publications and about the results of our creative outreach through the “Dear Abby” newspaper column.

Kathleen Uhl, MD

Assistant Commissioner for Women’s Health

OWH Research

Intramural Research Funding

OWH recently announced FY 2007 funding for nine new projects through the OWH Intramural Research and Development Program. These projects were selected through a highly competitive process from a pool of 50 applications. We congratulate the FDA scientists listed below for their outstanding submissions and look forward to learning more from them about their research.

Indira Hewlett, Ph.D. - CBER
Evaluation of gender differences in detection, replication and transmissibility of emerging HIV-1 Variants

Deborah Taylor, Ph.D. - CBER
The Role of Estrogen in Enhancing Innate Immunity during Viral Infection

Yongsheng Yang, Ph.D. - CDER
Identification of Sex Differences in Adverse Outcomes for New Molecular Entities (NMEs) Approved from 2000-2002

Soma Kalb, Ph.D. - CDRH
Factors Accelerating the Progression of Heart Failure (HF) in Women: Implications for Drug Interactions with Medical Devices

Dinesh Patwardhan, Ph.D. - CDRH
The Impact of Sex-Based Differences in Atherosclerotic Plaque on the Response to Drug Eluting Stent Implantation

Neera Gopee, Ph.D. - NCTR
Sex differences in Systemic Lupus Erythematosus (SLE): Effects of a single nucleotide polymorphism (SNP) in the prolactin (PRL) gene on individual response to prasterone therapy

Baitang Ning, Ph.D. - NCTR
Mechanisms of Gender Differences in Aspirin Effects: Metabolizing Enzymes and Therapeutic Targets

Lesley Kerr - ORA
Development of a Rapid Version of the Tampon Test Method Based on 21CFR801.430

Phyllis Wilson - ORA
Development and Validation of an HPLC method for the Simultaneous Determination of Estradiol, Estriol, Estrone and Progesterone in Pharmaceutical Preparations

****

OWH Supports Coronary Stents Research via FDA Critical Path Initiative

OWH is collaborating on several projects that are part of FDA's Critical Path Initiative. Critical Path is an Agency effort to address challenging product development issues and identify novel solutions through collaboration among FDA, industry, and academia.

OWH is collaborating with the Agency for Healthcare Research and Quality (AHRQ) and the FDA Center for Devices and Radiological Health (CDRH) on a retrospective study to assess long term health outcomes in patients receiving drug eluting stents and to identify risk factors for late thrombosis.

Drug eluting coronary stents are frequently used to treat heart disease - the number one killer of women. These stents have been known to clot (called thrombosis) immediately or soon after insertion into a coronary artery. The occurrence of late thrombosis - happening months to years after insertion - is a recently discovered problem. The new AHRQ/ FDA funded research project will advance our understanding of how late thrombosis may affect women.

For More Information on Drug Eluting Stents, visit:
http://www.fda.gov/hearthealth/treatments/medicaldevices/stentqa.html

Check the OWH website for future updates on the status of this research.

Outreach Initiatives

FREE – Consumer Health Information in Spanish

For the first time, all OWH consumer fact sheets are available in Spanish. OWH recently released 42 new Spanish-language publications on a range of topics including depression, generic drugs, heart disease, cosmetics, arthritis, mammography, HIV, and food safety. These easy-to-read fact sheets complement OWH's other Spanish language materials on diabetes, menopause, and safe medication use.

OWH invites organizations and consumers to collaborate with us to distribute these free publications to women and their families.

To download copies of the new Spanish fact sheets, visit:
http://www.fda.gov/womens/getthefacts/Spanish/default.htm

To order free copies in bulk, visit:
http://www.pueblo.gsa.gov/rc/owhspanish.htm

****

Dear Abby Features OWH Health Information Kit

In celebration of Mother's Day and National Women's Health Week, Dear Abby encouraged women to be proactive in their health care by ordering the OWH Health Information Kit. Abby readers responded by ordering over 1.5 million OWH publications. The kit features several OWH medicine booklets, first-of-their kind pamphlets with information about all medications to treat depression, high blood pressure, high cholesterol and smoking. The kit also includes fact sheets on heart disease, food safety, and more.

The Health Information Kits are available online at:
http://www.pueblo.gsa.gov/rc/d57.htm

Hot Topics

FDA Issues Rules for Dietary Supplements

On June 22, 2007, FDA announced a final rule establishing regulations to require current good manufacturing practices (cGMP) for dietary supplements. Under the final rule, manufacturers are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or do not contain the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

The aim of the final rule is to prevent inclusion of the wrong ingredients, too much or too little of a dietary ingredient, contamination by substances such as natural toxins, bacteria, pesticides, glass, lead and other heavy metals, as well as improper packaging and labeling.

For More Information

Full Press Release:
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01657.html
Backgrounder: http://www.cfsan.fda.gov/~dms/dscgmps7.html
Fact Sheet: http://www.cfsan.fda.gov/~dms/dscgmps6.html

****

Continuous Use Contraceptive

On May 22, 2007, FDA approved Lybrel, the first continuous use product for prevention of pregnancy. Lybrel comes in a 28 day-pill pack with low-dose combination tablets that contain 90 micrograms of a progestin, levonorgestrel, and 20 micrograms of an estrogen, ethinyl estradiol, which are active ingredients available in other approved oral contraceptives. Other contraceptive pill regimens have placebo or pill-free intervals lasting four to seven days that stimulate a menstrual cycle. Lybrel is designed to be taken without the placebo or pill-free time interval. Women who use Lybrel would not have a scheduled menstrual period, but will most likely have unplanned, breakthrough, unscheduled bleeding or spotting. The occurrence of unscheduled bleeding decreases over time in most women who continue to take Lybrel for a full year.

Like other available oral contraceptives, Lybrel is effective for prevention of pregnancy when used as directed. The risks of using Lybrel are similar to the risks of other conventional oral contraceptives and include an increased risk of blood clots, heart attacks, and strokes. The labeling also carries a warning that

cigarette smoking increases the risk of serious cardiovascular side effects from the use of combination estrogen and progestin-containing contraceptives.

Because Lybrel users will eliminate their regular periods, it may be difficult for women to recognize if they have become pregnant. Women should take a pregnancy test if they believe they may be pregnant. Women should also discuss contraceptive use, and the precautions and warnings for use of the drug product, with their doctors or other health care professional.

For more information, look up Lybrel at **Drugs@FDA**

****

New FDA Consumer Website and E-Newsletter

FDA launched a new consumer webpage and e-newsletter. The webpage provides easy-to-read, product safety news and links to useful health information from the FDA and other U.S. government agencies. The e-newsletter, entitled "FDA Consumer Health Information", will alert consumers to product approvals, safety warnings, and other health news. The e-newsletter replaces the agency's print magazine FDA Consumer.

Consumers are invited to provide comments about the new website and newsletter. Email comments to fdaconsumerlist@oc.fda.gov or mail to FDA Consumer Health Information, Food and Drug Administration, HFI-40, Room 15-A29, Fishers Lane, Rockville, MD 20857.

Consumer Website: www.fda.gov/consumer

Free Monthly E-Newsletter:
www.fda.gov/consumer/consumerenews.html

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:

[redacted]

American Association of Diabetes Educators, August 1-4 – St. Louis, MO

National Medical Association, August 5-7 – Honolulu, HI

NACDS Pharmacy & Technology Conference, August 11-15 – Boston, MA

Minority Women's Health Summit, August 23-26 – Washington, DC

National Assoc. of Community Health Centers, August 27-28 – Dallas, TX

AARP, September 6-8 – Boston, MA

****

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