

(NEAP) of 1969, and the President's Council on Environmental Quality Regulations (40 CFR parts 1500-1508), as implemented by General Services Administration (GSA) Order PBS P 1095.4C, GSA announces its Notice of Intent (NOI) to prepare an EIS for the proposed disposal of the Volunteer Army Ammunition Plant. The proposed action includes the disposal of all of real property associated with this government owned facility. The property consists of about 6,500 acres of land including buildings, industrial facilities and equipment, roadways, utilities, specialized facilities, easements, rights of way, and natural undeveloped land.

The EIS will address the potential impacts of two alternatives: the Proposed Action (Disposal Alternative), and No-Action Alternative (Continued Federal Ownership). The EIS will examine the short and long term impacts to both natural environment and impacts to the surrounding community. The Disposal Alternative will be further refined into a series of alternative proposed land use scenarios. These will be developed with the input from the local community through the scoping process. As the scoping proceeds, land use and development scenarios will be presented to the community for comment and will be addressed in the Draft EIS. GSA will solicit community input throughout this process, and will incorporate community comments into the decision process.

After the scoping is completed, GSA will present potential land use plans to the community in the Draft Environmental Impact Statement for comment. GSA will hold a Public Meeting during the Draft EIS 45-day comment period to solicit comments from the community. Although this schedule is tentative, GSA anticipates this will occur in April 1999. After the Draft, GSA will issue a Final EIS. A decision on the Disposal and land use development will not be made until 30 days after the release of the Final EIS. GSA anticipates this decision will be rendered by August 1999.

The EIS will seek to disclose the reasonable and foreseeable impacts that will result from this proposed Disposal Alternative, as well as the No Action Alternative, will seek to minimize these impacts and mitigate them where practical. As part of the Public Scoping process, GSA solicits comments in writing at the following address: Mr. Phil Youngberg, Regional Environmental Officer, (4PT), General Services Administration (GSA), 401 West Peachtree Street, NW, Suite 3010,

Atlanta, GA 30365, or FAX: Mr. Phil Youngberg at 404-331-4540. Comments should be submitted in writing.

GSA will conduct a Public Scoping Meeting to solicit comments, and to address general questions concerning the proposed action and NEPA. The first Scoping Meeting will be held at Central High School on Thursday November 19th at 6:30 PM. GSA will place a Public Notice of this and all subsequent public meetings in the Chattanooga Free Press approximately two weeks prior to the event. GSA will also notify persons and organizations by direct mail.

Dated: October 21, 1998.

**Phil Youngberg,**

*Regional Environmental Officer (4PT).*

[FR Doc. 98-28991 Filed 10-28-98; 8:45 am]

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## GENERAL SERVICES ADMINISTRATION

### President's Commission on the Celebration of Women in American History; Meeting

**AGENCY:** General Services Administration.

**ACTION:** Meeting notice.

**SUMMARY:** Notice is hereby given that the President's Commission on the Celebration of Women in American History will hold an open meeting from 9 a.m. to 4 p.m. on Monday, November 12, 1998, from 9 a.m. to 4 p.m. on Tuesday, November 13, 1998, at the State Department East Auditorium, 2201 C Street, NW, Washington DC 20520.

**PURPOSE:** The meeting is called to update members on committee operations and activities. Guest speakers will address known events or celebrations of women (past or present) in their local community and/or nationally. Participants may wish to make a statement covering personal interests in the history of women in America or share thoughts on appropriate commemorative events.

**FOR FURTHER INFORMATION CONTACT:** Martha Davis (202) 501-0705, Assistant to the Associate Administrator for Communications, General Services Administration. Also, inquiries may be sent to [martha.davis@gsa.gov](mailto:martha.davis@gsa.gov). Under 41 CFR 101-6.1015(b)(2) less than 15 days notice of the meeting is provided due to delays in organizing schedules.

Dated: October 23, 1998.

**Beth Newburger,**

*Associate Administrator for Communications.*

[FR Doc. 98-28913 Filed 10-28-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Health Care Policy and Research

### Meeting of the National Advisory Council for Health Care Policy, Research, and Evaluation

**AGENCY:** Agency for Health Care Policy and Research, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the National Advisory Council for Health Care Policy, Research, and Evaluation.

**DATES:** The meeting will be held on Friday, November 20, 1998, from 8:30 a.m. to 4:00 p.m.

**ADDRESSES:** The meeting will be held at 6010 Executive Boulevard, Fourth Floor, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Nancy Foster, Coordinator of the Advisory Council at the Agency for Health Care Policy and Research, 2101 East Jefferson Street, Suite 502, Rockville, Maryland 20852, (301) 594-1349, ext. 1307.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Linda Reeves, Assistant Administrator for Equal Opportunity, AHCPH, on (301) 594-6662 no later than November 13, 1998.

### SUPPLEMENTARY INFORMATION:

#### I. Purpose

Section 921 of the Public Health Service Act (42 U.S.C. 299c) establishes the National Advisory Council for Health Care Policy, Research and Evaluation. The Council provides advice to the Secretary and the Administrator, Agency for Health Care Policy and Research (AHCPH), on matters related to AHCPH activities to enhance the quality, appropriateness, and effectiveness of health care services and access to such services through scientific research and the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services. The Council is composed of members of the public appointed by the Secretary and Federal ex-officio members. Harold S. Luft, Ph.D., the Council chairman, will preside.

#### II. Agenda

On Friday, November 20, 1998, the meeting will begin at 8:30 a.m., with the call to order by the Council Chairman.

The Administrator, AHCPR, will present the status of current Agency programs and initiatives. Tentative agenda items include the strategic directions for the Agency's research on access, cost and use of health care services, children's health issues, cultural competency and the implementation and evaluation of evidence based practice centers. Agenda items are subject to change as priorities dictate. The meeting will adjourn at 4:00 p.m.

Dated: October 22, 1998.

**John M. Eisenberg,**  
*Administrator.*

[FR Doc. 98-28909 Filed 10-28-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 98N-0718 and 76N-0377; DESI 7661]

#### **Eli Lilly & Co. and Bristol-Myers Squibb Co.; Withdrawal of Approval of Three New Drug Applications for Estrogen-Androgen Combination Drugs**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of three new drug applications (NDA's) for estrogen-androgen combination drugs. The NDA's are held by Eli Lilly & Co. and Bristol-Myers Squibb Co. The products are no longer marketed. Both companies requested that the NDA's be withdrawn and waived their opportunity for a hearing. The products will be removed from the list of drug products with effective approvals.

**EFFECTIVE DATE:** OCTOBER 29, 1998.

#### **FOR FURTHER INFORMATION CONTACT:**

David T. Read, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** Previous **Federal Register** notices regarding the regulatory status of the three applications named below, as well as two others (NDA's 10-597 and 11-267), were published on September 8, 1972 (37 FR 18225), and September 29, 1976 (41 FR 43112). (The approvals of NDA 10-597 (Tace with Androgen Capsules containing chlorotrianisone and methyltestosterone) and NDA 11-267 (Halodrin Tablets containing

fluoxymesterone and ethinyl estradiol) were withdrawn in **Federal Register** notices of June 25, 1993 (58 FR 34466), and March 2, 1994 (59 FR 9989), respectively; see also 43 FR 49564 (October 24, 1978), which was a proposal to withdraw approval of estrogen-containing drug products labeled for use in postpartum breast engorgement.)

By letter dated June 5, 1998, Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543, requested that FDA withdraw approval of NDA 9-545 (Deladumone OB Injection and Deladumone Injection, each containing testosterone enanthate and estradiol valerate), stating that the marketing of Deladumone OB Injection was discontinued in 1989 when the indication for postpartum breast engorgement was withdrawn (noting that this was the only indication for Deladumone OB Injection), and that the marketing of Deladumone Injection was discontinued in 1991 because there was no longer a significant patient population requiring the concurrent therapy of an estrogen and an androgen in a fixed dose.

By letters dated July 15, 1998, and July 30, 1998, Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, requested that FDA withdraw approval of NDA 7-661 (Tylosterone Tablets) and NDA 8-099 (Tylosterone Injection), both containing diethylstilbestrol and methyltestosterone, stating that the marketing of both products was discontinued in 1988 because there was no longer a significant patient population requiring the concurrent therapy of an estrogen and an androgen in a fixed dose.

Both applicants waived their opportunity for a hearing. The agency concurs in the applicants' finding that there is not a significant patient population requiring the concurrent therapy of an estrogen and an androgen in a fixed dose.

Approval of a new drug application will be withdrawn if there is a lack of substantial evidence that the drug product covered by the application has the clinical effect that it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling (21 U.S.C. 355(e)). For fixed combination prescription drugs, such substantial evidence exists only if each component makes a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such

concurrent therapy, as defined in the labeling for the drug (21 CFR 300.50). Estrogen and androgen fixed-dose combination products, therefore, lack substantial evidence of effectiveness due to the fact that there is not a significant patient population requiring the concurrent therapy of an estrogen and an androgen in a fixed dose.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.70 and 5.82), approval of NDA's 7-661, 8-099, and 9-545 and all amendments and supplements thereto, is hereby withdrawn for the reasons stated above, effective October 29, 1998. Under 21 CFR 314.161 and 314.162(a)(1), four of the estrogen and androgen fixed-dose combination products named above (NDA's 7-661, 8-099, 9-545, and 11-267) will be removed from the list of drug products with effective approvals published in FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations." FDA will not approve or accept ANDA's that refer to these drug products.

Dated: October 22, 1998.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### **Biological Response Modifiers Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

**Name of Committee:** Biological Response Modifiers Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on November 13, 1998, 8 a.m. to 5 p.m.

**Location:** Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.