

amended the Federal Food, Drug, and Cosmetic Act, Congress directed EPA to develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have hormonal effects in humans. In 1996, EPA chartered a scientific advisory committee, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), under the authority of the Federal Advisory Committee Act (FACA) to advise it on establishing a program to carry out Congress' directive. EDSTAC recommended a multi-step approach including a series of screens (Tier I screens) and tests (Tier II tests) for determining whether a chemical substance may have an effect in humans similar to that produced by naturally occurring hormones. EPA adopted almost all of EDSTAC's recommendations in the program that it developed, the Endocrine Disruptor Screening Program (EDSP), to carry out Congress' directive.

EDSTAC also recognized that there currently are no validated test systems for determining whether a chemical may have an effect in humans that is similar to an effect produced by naturally occurring hormones. Consequently, EPA is in the process of developing and validating the screens and tests that EDSTAC recommended for inclusion in the EDSP. In carrying out this validation exercise, EPA is working closely with, and adhering to the principles of the Interagency Coordinating Committee for the Validation of Alternate Methods (ICCVAM). EPA also is working closely with the Organization for Economic Cooperation and Development's (OECD) Endocrine Testing and Assessment Task Force to validate and harmonize endocrine screening tests of international interest.

Finally, to ensure that EPA has the best and most up-to-date advice available regarding the validation of the screens and tests in the EDSP, EPA formed the Endocrine Disruptor Methods Validation Subcommittee (EDMVS) of the National Advisory Council for Environmental Policy and Technology (NACEPT). EDMVS provides independent advice and counsel to the Agency through NACEPT, on scientific and technical issues related to validation of the EDSP Tier I screens and Tier II tests, including advice on methods for reducing animal use, refining procedures involving animals to make them less stressful, and replacing animals where scientifically appropriate.

The EDMVS has held six meetings since its establishment in September 2001.

The objectives of the first meeting, which was held in October 2001, (docket control number OPPT-42212D) were for EPA to provide:

1. An overview of EPA's Endocrine Disruptor Program.
2. Background information on test protocol validation and approaches.
3. For the EDMVS to develop a clear understanding of their scope, purpose, and operating procedures.

4. The EDMVS and the EDSP to determine the next steps.

The objectives of the December 2001 meeting (docket control number OPPT-42212E) were for the EDMVS to provide input and advice on:

1. EDMVS's mission statement and work plan.
2. The *in utero* through lactation assay detailed review paper.
3. The pubertal assay study design for the multi-dose and chemical array protocols.
4. The mammalian one-generation study design.

The objectives of the March 2002 meeting (docket control number 42212F) were for the EDMVS to provide input and advice on:

1. EPA's implementation process and practical aspects of validation.
2. The *in utero* through lactation assay protocol.
3. The fish reproduction assay detailed review paper.
4. Special studies, the fathead minnow assays, vitellogenin assay, and avian dosing protocol.
5. The steroidogenesis detailed review paper.
6. The aromatase detailed review paper.
7. A proposed standard suite of chemicals for testing in the Tier I screening assays.
8. The current efforts related to evaluating the relevance of animal data to human health.
9. EPA's approach to addressing low dose issues.

The objective of the June 2002 teleconference meeting (docket ID number OPPT-2002-0020) was for the EDMVS to provide input and advice on the steroidogenesis detailed review paper.

The objectives of the July 2002 meeting (docket ID number OPPT-2002-0029) were:

1. To review the screening criteria, recommended by EDSTAC and adopted by EDSP for screens.
2. To receive an update of the NICEATM estrogen and androgen receptor binding efforts.

3. To discuss and provide advice on general dose setting issues; and to provide comments and advice on:

- A pubertal--special study--restricted feeding.
- A mammalian 2-generation draft PTU special study.
- An amphibian metamorphosis detailed review paper.
- An invertebrate detailed review paper.

The objective of the December 2002 teleconference meeting (docket ID number OPPT-2002-0059) was for the EDMVS to provide input and advice on the Tier II fish life cycle assay detailed review paper.

### III. Meeting Objectives for the June 5-6, 2003 Meeting

The objectives of the June 5-6, 2003 (docket ID number OPPT-2003-0016) are for EDMVS to provide input and advice on:

1. The Tier II Mammalian 2-generation special study on the one-generation extension results.
2. The Tier I steroidogenesis (sliced testes) study results.
3. To provide the status of the Tier I study results of the aromatase placental tissue study.

A list of the EDMVS members and meeting materials are available on our web site (<http://www.epa.gov/scipoly/oscpendo/edmvs.htm>) and in the public docket.

### List of Subjects

Environmental protection, Endocrine system, Endocrine disruptors, Endocrine disruptor screening program.

Dated: May 9, 2003.

**Joseph Merenda,**

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[FR Doc. 03-12484 Filed 5-20-03; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0142; FRL-7308-4]

### Fenhexamid; Notice of Filing Pesticide Petitions to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain