

reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of this product from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 28, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-16101 Filed 7-3-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0596]

#### Lung Cancer Patient-Focused Drug Development; Extension of Comment Period

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

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the comment period for the public docket on lung cancer patient-focused drug development. In the **Federal Register** of June 5, 2013 (78 FR 33581), FDA announced an opportunity for public comment on this topic and explained that the comment period would close on July 29, 2013. The Agency is taking this action to allow interested persons additional time to submit comments.

**DATES:** Submit either electronic or written comments to the docket by August 28, 2013.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1199, Silver Spring, MD 20993-0003, 301-796-5003, email: [graham.thompson@fd.hhs.gov](mailto:graham.thompson@fd.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of June 5, 2013 (78 FR 33581), FDA announced an opportunity for public comment on lung cancer patient-focused drug development and explained that the comment period would close on July 29, 2013. The Agency is extending the comment period to allow interested persons additional time to submit comments.

As part of Patient-Focused Drug Development, FDA is gathering patient and patient stakeholder input on symptoms of lung cancer that matter most to patients and on current approaches to treating lung cancer. FDA is interested in patients' perspectives for the two main types of lung cancer (small-cell and non-small cell lung cancer) on the importance of disease symptoms, benefits of treatment approaches, and possible cancer treatment side effects. FDA is interested in receiving patient input that addresses the following questions.

##### *Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients*

1. For context, how long ago was your diagnosis of lung cancer? Is your cancer currently in only one area of the lung or has it spread to other parts of the lung or outside of the lungs?

2. Of all the symptoms that you experience because of your lung cancer, which one to three symptoms have the most significant impact on your daily life? (Examples may include pain, cough, shortness of breath, fatigue, voice hoarseness.)

3. Are there specific activities that are important to you but that you cannot do at all, or as fully as you would like, because of lung cancer? (Examples may

include sleeping through the night, climbing stairs, household activities.)

##### *Topic 2: Patients' Perspectives on Current Approaches To Treating Lung Cancer*

1. Are you currently undergoing any cancer treatments to help reduce or control the spread of your lung cancer? Please describe.

1.1 What do you consider to be the most significant downsides of these treatments? (Examples of downsides may include side effects, going to the hospital for treatment, frequent blood tests, etc.)

1.2 How do these downsides affect your daily life?

2. What supportive care treatments, if any, are you taking to help improve or manage the symptoms you experience because of your lung cancer? Please include any prescription medicines, over-the-counter products, and other therapies including non-drug therapies (such as breathing techniques).

2.1 What specific symptoms do your treatments address?

2.2 How well do these treatments manage these symptoms?

2.3 Are there symptoms that your current treatment regimen does not address at all, or does not treat as well as you would like?

3. When thinking about your overall goals for treatment, how do you weigh the importance of prolonging your life versus improving the symptoms you experience because of your lung cancer?

4. What factors do you take into account when making decisions about using treatments to help reduce or control the spread of your lung cancer? In particular:

4.1 What information on the potential benefits of these treatments factors most into your decision? (Examples of potential benefits from treatments may include shrinking the tumor, delaying the growth of the tumor, prolonging life, etc.)

4.2 How do you weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include nausea, loss of appetite, fatigue, diarrhea, rash.)

4.3 How do you weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are developing a hole in the stomach or intestine, liver failure, kidney failure, lung inflammation, blood clot, stroke, heart attack, serious infections, etc.)

## II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 28, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-16102 Filed 7-3-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel, ZHD1 DSR-L 41 1.

*Date:* July 15, 2013.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Dennis E. Leszczynski, Ph.D., Scientific Review Officer, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-2717, [leszcyd@mail.nih.gov](mailto:leszcyd@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel, ZHD1 DRG-D 42 1.

*Date:* July 10, 2013.

*Time:* 2:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Sherry L. Dupere, Ph.D., Director, Division of Scientific Review, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5b01, Bethesda, MD 20892, 301-451-3415, [duperes@mail.nih.gov](mailto:duperes@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel, ZHD1 DRG-D 41 1.

*Date:* July 16, 2013.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Sherry L. Dupere, Ph.D., Director, Division of Scientific Review, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-451-3415, [duperes@mail.nih.gov](mailto:duperes@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel, ZHD1 DRG-D 43 1.

*Date:* August 1, 2013.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Sherry L. Dupere, Ph.D., Director, Division of Scientific Review, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-451-3415, [duperes@mail.nih.gov](mailto:duperes@mail.nih.gov).

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel, ZHD1 DSR-H 50.

*Date:* July 30-31, 2013.

*Time:* 9:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Washington, 1515 Rhode Island Avenue NW., Washington, DC 20005.

*Contact Person:* Marita R. Hopmann, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6911, [hopmannm@mail.nih.gov](mailto:hopmannm@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 28, 2013.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-16083 Filed 7-3-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Arthritis and Musculoskeletal and Skin Diseases Clinical Trials Conflict Review Meeting.

*Date:* July 26, 2013.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Helen Lin, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301-594-4952, [linh1@mail.nih.gov](mailto:linh1@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: June 28, 2013.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-16082 Filed 7-3-13; 8:45 am]

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