

reading the news article, participants will complete a questionnaire assessing their emotional response, appraisals, attribution of responsibility, perceptions about the safety of the affected produce, intentions to grow, sell, or buy the affected produce, perceived probability of a repeat event, and a measure of their innate ability to effectively respond to the information in the article.

To help design and refine the questionnaire, we will recruit 25 participants in order to conduct 10 cognitive interviews. We estimate cognitive interview recruitment will

take 5 minutes (0.083 hours), for a total of 2 hours. The cognitive interviews are estimated at 1 hour per response for a total of 10 hours for the cognitive interview activities. We expect to send screeners to 800 members of a consumer panel, each taking 2 minutes (0.03 hours) to complete, for a total of 24 hours for the consumer panel screener activity. We also expect to administer 360 screeners to growers and retailers, each taking 2 minutes (0.033 hours) to complete, for a total of 24 hours (11 + 11 = 22). Twenty-four participants (20 consumers, 2 growers, 2 retailers) will

complete the pre-test. Each pre-test will take 10 minutes (0.17 hours) for a total of 5 hours for the pre-test activity. We estimate that 900 individuals (540 consumers, 180 growers, and 180 retailers) will complete the questionnaire for the experiment, each taking 10 minutes (0.17 hours) for a total of 153 hours for the experimental study activities. The estimated total hour burden of the collection of information is 215 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) <sup>2</sup>	Total hours
Cognitive Interview Recruitment .....	25	1	25	5/60	2
Cognitive Interviews .....	10	1	10	1	10
Consumer Panel Screener .....	800	1	800	2/60	24
Grower Screener .....	360	1	360	2/60	11
Retailer Screener .....	360	1	360	2/60	11
Pre-tests .....	24	1	24	10/60	5
Experiment .....	900	1	900	10/60	153
Total .....					216

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format “[number of minutes per response]/60”.

## II. References

- Olsen, S., L. MacKinnon, *et al.*, “Surveillance for Foodborne Disease Outbreaks—United States, 1993 to 1997,” *Morbidity and Mortality Weekly Report* 49(SS01), pp. 1 through 51, 2000.
- FDA 101: Product Recalls—From First Alert to Effectiveness Checks, Available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm>.
- Calvin, L., “Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices,” *Amber Waves* 5(3), pp. 24 through 31, 2007.
- Lucier, G. and R. Dettmann, “Vegetables and Melons Outlook,” A Report From the United States Department of Agriculture, Economic Research Service, VGS-327, June 26, 2008.

Dated: April 11, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-9155 Filed 4-14-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-E-0241]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; ATRYN; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 21, 2011 (76 FR 15323). The document announced the determination of the regulatory review period for ATRYN. The document was published with an incorrect docket number. This document corrects that error.

#### FOR FURTHER INFORMATION CONTACT:

Joyce Strong, Office of Policy, Planning and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3208, Silver Spring, MD 20993-0002, 301-796-9138.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2011-6509, appearing on page 15323, in the **Federal Register** of Monday, March

21, 2011, the following correction is made:

1. On page 15323, in the first column, in the Docket No. heading, “[Docket No. FDA-2010-E-0241]” is corrected to read “[Docket No. FDA-2009-E-0241]”.

Dated: April 8, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-9153 Filed 4-14-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Pediatric 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). The meeting will be open to the public.

*Name of Committee:* Pediatric 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 Monday, May 16, 2011, from 8 a.m. to 3 p.m.

*Location:* Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel's telephone number is 301-589-5200.

*Contact Person:* Walter Ellenberg, Office of Pediatric Therapeutics, Office of the Commissioner, Food and Drug Administration, Bldg. 32, rm. 5154, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-0885, e-mail: [Walter.Ellenberg@fda.hhs.gov](mailto:Walter.Ellenberg@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On May 16, 2011, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act (Pub. L. 110-85) for Bepreve (bepotastine besilate), Besivance (besifloxacin hydrochloride), Cetraxal (ciprofloxacin hydrochloride), Patanase Spray (olopatadine hydrochloride), Astepro Spray (azelastine hydrochloride), Crestor (rosuvastatin calcium), Welchol (colesevelam hydrochloride), Intuniv (guanfacine), Lexapro (escitalopram oxalate), Actonel (risedronate), Hiberix [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)], and Valcyte (valganciclovir). The committee will also receive further followup on Topical Calcineurin Inhibitors: Elidel (pimecrolimus) and Protopic (tacrolimus).

The Pediatric Advisory Committee will hear and discuss the recommendation of the Pediatric Ethics Subcommittee from its meeting on May 11, 2011, regarding the Institutional Review Board process for clinical investigations that involve both an FDA regulated product and research involving children as subjects that is conducted or supported by HHS. The

announcement of the May 11, 2011, Pediatric Ethics Subcommittee of the Pediatric Advisory Committee meeting can be found elsewhere in this issue of the **Federal Register**.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 2, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 25, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 26, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.htm> for procedures on

public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 11, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-9150 Filed 4-14-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0184]

#### Pediatric Ethics Subcommittee; 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). The meeting will be open to the public.

*Name of Committee:* Pediatric Ethics Subcommittee of the Pediatric Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Pediatric Advisory Committee on FDA and certain Department of Health and Human Services regulatory issues.

**DATES:** The meeting will be held on Wednesday, May 11, 2011, from 8 a.m. to 3 p.m.

FDA is opening a docket to allow for additional public comments to be submitted to the Agency on the issues before the Pediatric Ethics Subcommittee. Submit either electronic or written comments by May 5, 2011.

**ADDRESSES:** The meeting will be held at the North Marriott Hotel & Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852.

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.

*Contact Person:* Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993-0002, 301-796-0885, or by e-mail: [Walter.Ellenberg@fda.hhs.gov](mailto:Walter.Ellenberg@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the