

request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Seldon received the proposal on May 27, 2011, and failed to respond within the timeframe prescribed by regulation. She therefore has waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)), under authority delegated to him (Staff Manual Guide 1410.35), finds that Deborah Martinez Seldon has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Seldon is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**), (see section 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Ms. Seldon in any capacity during Ms. Seldon's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Seldon provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act) (21 U.S.C. 335b(a)(7)). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Deborah Martinez Seldon during her period of debarment (section 306(c)(1)(A) of the FD&C Act (21 U.S.C. 335a(c)(1)(A))).

Any application by Deborah Martinez Seldon for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA-2011-N-0165 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 6, 2011.

**Armando Zamora,**

*Acting Director, Office of Enforcement, Office of Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Pediatric Oncology Subcommittee of the Oncologic Drugs 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 Oncology Subcommittee of the Oncologic Drugs 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 1, 2011, from 8 a.m. to 5:30 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "Public Meetings at the FDA White Oak Campus". Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, e-mail: [ODAC@fda.hhs.gov](mailto:ODAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product 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 November 1, 2011, information will be presented regarding pediatric development plans for four products that were either recently approved by FDA, are in late stage development for an adult oncology indication, or in late stage development in pediatric patients with cancer. The subcommittee will consider and discuss issues relating to the development of each product for pediatric use and provide guidance to facilitate the formulation of Written Requests for pediatric studies, if appropriate. The four products under consideration are: (1) Sodium thiosulfate injection, application submitted by Adherex Technologies, Inc.; (2) vismodegib (GDC-0449), application submitted by Genentech, Inc.; (3) pazopanib, application submitted by Glaxo Wellcome Manufacturing Pte Ltd., Singapore doing business as GlaxoSmithKline; and (4) Medi-573 (fully human antibody to IGF-I and IGF-II), application submitted by MedImmune, LLC.

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 October 18, 2011. Oral presentations from the public will be scheduled between approximately 9:15 a.m. to 9:30 a.m., 11:15 a.m. to 11:30 a.m., 2:05 p.m. to 2:20 p.m., and 4:10 p.m. to 4:25 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 October 7, 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 October 11, 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 Caleb Briggs 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/ucm111462.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: September 30, 2011.  
**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*  
 [FR Doc. 2011-25684 Filed 10-4-11; 8:45 am]  
**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request; STAR METRICS (Science and Technology for America's Reinvestment: Measuring the Effects of Research on Innovation, Competitiveness and Science)**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director of the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* STAR METRICS (Science and Technology for America's Reinvestment: Measuring the Effects of Research on Innovation,

Competitiveness and Science). *Type of Information Collection Request:* Reinstatement of OMB number 0925-0616, expiration date 01/31/2011. *Need and Use of Information Collection:* The aim of STAR METRICS is twofold. The goal of STAR METRICS is to continue to provide mechanisms that will allow participating universities and Federal agencies with a reliable and consistent means to account for the number of scientists and staff that are on research institution payrolls, supported by Federal funds. In subsequent generations of the program, it is hoped that STAR METRICS will allow for measurement of science impact on economic outcomes (such as job creation), on knowledge generation (such as citations and patents) as well as on social and health outcomes. *Frequency of Response:* Quarterly. *Affected Public:* Universities and other research institutions. *Type of Respondents:* University administrators. The annual reporting burden is as follows: *Estimated Number of Respondents:* 100. *Estimated Number of Responses per Response:* 4. *Average Burden Hours per Response:* 2.5. *Estimated Total Annual Burden Hours Requested:* 1,315. The annualized cost to respondents is estimated to be \$65,750. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

**A.12-1 ESTIMATES ANNUAL BURDEN HOURS**

Form	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
Stage 1: One time data input .....	7	1	45	315
Stage 2: Ongoing quarterly data input .....	100	4	2.5	1000
Total .....				1,315

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic,

mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Julia Lane, e-mail: [julia.lane@nih.gov](mailto:julia.lane@nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: September 27, 2011.  
**Stefano Bertuzzi,**  
*Office of the Director, Office of Science Policy Analysis, Office of Science Policy, National Institutes of Health.*  
 [FR Doc. 2011-25732 Filed 10-4-11; 8:45 am]  
**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, HHS  
**ACTION:** Notice.