guidance document will serve as the special control for *Plasmodium* species antigen detection assays. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on ''*Plasmodium* species antigen detection assays.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: *Plasmodium* Species Antigen Detection Assays'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1646 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: April 30, 3008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–11261 Filed 5–19–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: June 5, 2008, 12 p.m. to 5 p.m. EDT. June 6, 2008, 9 a.m. to 12:30 p.m. EDT.

Place: Parklawn Building (and via audio conference call), Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Thursday, June 5 from 1 p.m. to 5 p.m. (EDT) and Friday, June 6 from 9 a.m. to 12:30 p.m. (EDT). The public can join the meeting via audio conference call by dialing 1–888–593–8429 on June 5 & 6 and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: The agenda items for the June meeting will include, but are not limited to: updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics Evaluation and Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Michelle Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail: *mherzog@hrsa.gov.* Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Michelle Herzog, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–6593 or e-mail: *mherzog@hrsa.gov.*

Dated: May 14, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–11237 Filed 5–19–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Office of Liaison, Policy and Review; Meeting of the NTP Board of Scientific Counselors: Amended Notice

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

ACTION: Availability of a Public Telephone Call-In Line.

SUMMARY: This notice announces the availability of a public telephone call-in line for the June 11–12, 2008 meeting of the NTP Board of Scientific Counselors. The meeting will be held at the Radisson Hotel Research Triangle Park, 150 Park Drive, Research Triangle Park, NC 27709 and videocast through the Internet at *http://www.niehs.nih.gov/news/video/live*. Information regarding the meeting was announced in the **Federal Register** (73FR20289) published on April 15, 2008. The guidelines published in the April 15 **Federal Register** notice for submitting written public comments or making an oral presentation at the meeting still apply. In response to the public interest in the peer review of the Draft NTP Brief on Bisphenol A, the NTP will provide a telephone call-in line for public comments. The line will be open from 8:30 a.m. until 3 p.m. on June 11, although public comments will be received only during the formal public comment period on the draft brief. The exact time for the presentation of public comments is not set, but will follow the overview presentation on the draft brief and the talk on biomonitoring of bisphenol A exposures (the preliminary agenda is available at (*http://ntp.niehs.nih.gov/go/165*) or by contacting Dr. Barbara Shane, see **FOR FURTHER INFORMATION CONTACT** below).

ADDRESSES: Public comments on all agenda topics and any other correspondence should be submitted to Dr. Barbara Shane, Executive Secretary for the NTP BSC, NTP Office of Liaison, Policy and Review, NIEHS, P.O. Box 12233, MD A3–01, Research Triangle Park, NC 27709; telephone: 919–541–4253; fax: 919–541–0295; or e-mail: *shane@niehs.nih.gov*. Courier address: NIEHS, 111 T.W. Alexander Drive, Room A322, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. Barbara Shane (telephone: 919–541–4253 or e-mail: *shane@niehs.nih.gov*).

Telephone Call-in Line

The following information is required for telephone access:

- USA Toll Free Number: 877–915–2768.
- Passcode: NTP.
- Leader Name: Barbara Shane.

The NTP has reserved 50 telephone lines for this call and access availability will be on a first come first served basis. Telephone comments should not exceed three minutes in length and each organization is allowed only one oral slot (in person at the meeting or by telephone) per agenda topic. Calls will be taken as time permits and at the discretion of the BSC chairperson. Every effort will be made to accommodate callers, but the total time allotted for comments and the time allotted per speaker via the telephone will depend on how many people register online to speak. Registration to present oral public comments or to submit written comments can be completed online at the BSC meeting site (*http://ntp.niehs.nih.gov/go/165*). Details about the meeting, Internet access, and telephone call-in are also available at this site. The public telephone call-in is a new remote access option for the BSC, thus its technical quality cannot be guaranteed.

Persons who register online to make oral comments by telephone are asked, if possible, to send a copy of their statement to the Executive Secretary for the NTP BSC (see **ADDRESSES** above) by June 4, 2008, to enable review by the NTP BSC prior to the meeting. Written statements can supplement and may expand the oral presentation.

Dated: May 8, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E8–11206 Filed 5–19–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Report on Carcinogens (RoC); Availability of the Draft Background Document for Styrene; Request for Comments on the Draft Background Document for Styrene; Announcement of the Styrene Expert Panel Meeting

AGENCY: National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Availability of Background Documents; Request for Comments; and Announcement of a Meeting.

SUMMARY: The NTP announces the availability of the draft background document for styrene on May 22, 2008, on the RoC Web site (*http://ntp.niehs.nih.gov/go/29679*) or in printed text from the RoC (see **ADDRESSES** below). The NTP invites the submission of public comments on the draft background document for styrene. The expert panel will meet on July 21–22, 2008, at the Radisson Hotel Research Triangle Park, 150 Park Drive, Research Triangle Park, NC 27709 to peer review the draft background document for styrene and, once completed, make a recommendation regarding the listing status for styrene (i.e., *known to be a human carcinogen, reasonably anticipated to be a human carcinogen*, or not to list) in the 12th Edition of the RoC (12th RoC). The RoC expert panel meeting is open to the public with time scheduled for oral public comments. Attendance is limited only by the available meeting room space. Following the expert panel meeting and completion of the expert panel report, the NTP will post the final version of the background document and the expert-panel peer review report on the RoC Web site.

DATES: The expert panel meeting for styrene will be held on July 21–22, 2008. The draft background document for styrene will be available for public comment on May 22, 2008. The deadline to submit written comments is July 07, 2008, for pre-registration to attend the meeting is July 14, 2008, and for pre-registration to provide oral comments at the meeting is July 14, 2008.

ADDRESSES: The RoC expert panel meeting on styrene will be held at Radisson Hotel Research Triangle Park, 150 Park Drive, Research Triangle Park, NC 27709. Access to on-line registration and materials for the meeting are available on the RoC Web site (*http://ntp.niehs.nih.gov/go/29679*). Comments