guidelines concerning the provision of such information in 510(k) submissions? If not, what additional guidance might be helpful?

6. Section 513(f)(5) of the act (21 U.S.C. 360c(f)(5)) states that FDA may not withhold an initial classification determination based on "a failure to comply with any provision of the act unrelated to a substantial equivalence decision," including current good manufacturing practice (cGMP) requirements, unless there is a substantial likelihood that such failure will potentially present a serious risk to human health. Would it be beneficial for FDA to have greater authority to withhold an initial classification determination based on a failure to comply with cGMP requirements or other provisions of the act? Please explain.

7. Currently, some 510(k) submissions include as the "indication for use" a device function that is not associated with a specific clinical utility (e.g., treatment or diagnosis of a specific condition).

a. For new devices, should a requirement of the 510(k) program be that a device's "indication for use" be proven to FDA to provide clinical utility?

b. Please provide examples of devices whose "indications for use" statements do not describe a clinical utility, and whether this may be beneficial, harmful, or neither. Examples may include devices that are capable of monitoring or measuring a new physiologic parameter that has no standard clinical context, or tool-type devices such as scalpels or lasers that may be cleared to cut and coagulate tissue.

8. How effective is FDA's current implementation of section 513(i)(1)(E) of the act with respect to curbing off-label use that could cause harm? The current implementation is described in "Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff (Update to K98–1)" which is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082162htm*. Without regard to current law, should FDA consider modifying its approach? Please explain why or why not. If FDA should consider modifying its approach, how should FDA modify it?

C. Issues Related to Practices CDRH has Adopted in Response to a High Volume of 510(k) Submissions

FDA receives a very large number of 510(k) submissions each year. In response to this high volume of work, CDRH has adopted a number of practices to allow for less resource-intensive reviews, including the third party review program, the Special 510(k) under the 510(k) Paradigm, bundling of devices in 510(k) submissions, and reliance on 510(k) submitters' assertions of conformance to recognized standards (as in the Abbreviated 510(k) program). Due to resource constraints, CDRH often must rely on a single reviewer to assess each 510(k) submission. Please comment on the advantages and disadvantages of each of these practices, as related to the quality and timeliness of 510(k) reviews.

D. Issues Related to Postmarket Surveillance and New Information about Marketed Devices

1. FDA generally does not require postmarket surveillance studies as a condition of medical device 510(k) clearance. Without regard to current law, please comment on whether or not it might be beneficial for FDA to impose such studies as a condition of medical device 510(k) clearance.

2. Without regard to current law, should FDA allow for the rescission of 510(k) clearance decisions under a broad range of circumstances? If so, what specific criteria might justify the rescission of a 510(k) clearance decision?

3. FDA obtains a significant amount of postmarket information for 510(k)-cleared devices, including adverse event reports, recalls, and inspectional findings. Without regard to current law, should such information influence the premarket 510(k) review of similar devices? If so, how?

4. FDA regulations require the submission of proposed labeling (including indications for use, directions for use, precautions, warnings, and contraindications) in a 510(k) prior to clearance of a device. However, 510(k) holders sometimes alter the labeling after clearance, so that the final printed labeling is different from that submitted to FDA in the 510(k). Please comment on whether or not it might be beneficial for FDA to review and clear the final printed labeling for all 510(k) devices or for selected 510(k) devices prior to marketing.

5. FDA does not always know when there has been a purchase, sale, or transfer of ownership of a 510(k) for a particular device. Even though the new owner of the 510(k) is required to register and list, FDA may not be aware that the ownership of the 510(k) for the device has legally transferred. Should FDA exercise more authority in this area? If so, how?

IV. Transcripts

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public meeting at a cost of 10 cents per page. A transcript of the public meeting will be available on the Internet at *http://www.regulations.gov*.

Dated: January 22, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1620 Filed 1–22–10; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Occupational Safety and Health Training Projects Grants, Request for Applications (RFA) 06–484; and Occupational Safety and Health Educational Research Centers, RFA 06–485, Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Times and Dates:

8:30 a.m.–5 p.m., February 18, 2010 (Closed).
8:30 a.m.–5 p.m., February 19, 2010 (Closed).

Place: Marina Del Ray Marriott, 4100 Admiralty Way, Marina Del Ray, California 90292, Telephone (310) 301–3000.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the initial review, discussion, and evaluation of "Occupational Safety and Health Training Projects Grants, RFA 06–484; and Occupational Safety and Health Educational Research Centers, RFA 06–485."

There were site visits conducted at the University of California, Berkeley and San Francisco, October 12–14, 2009; the University of Massachusetts, Lowell, October 21, 2009; the University of West Virginia, October 27, 2009; the University of Colorado, November 2–4, 2009; the University of Minnesota, November 18–20, 2009; and the University of Washington, December 16–18, 2009 to advise and make recommendations to the Disease, Disability, and Injury Prevention and Control SEP: Occupational Safety and Health Training Projects Grants, RFA 06–484; Occupational Safety and Health Educational Research Centers, RFA 06–485.

Contact Person for More Information: Dr. M. Chris Langub, PhD, Scientific Review Administrator, 1600 Clifton Road, NE., Mailstop E74, Atlanta, GA 30333, Telephone (404)498–2543.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 19, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–1633 Filed 1–26–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Science Board to the Food and Drug Administration; 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: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues, as well as emerging issues within the scientific community in industry and academia. Additionally, the Science Board provides advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on Monday, February 22, 2010, from 8 a.m. to 3 p.m.

Addresses: Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact Person: Doreen Kezer, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, rm. 14–65, Rockville, MD 20857, 301–827–1249, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512603. 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 February 22, 2010, the Science Board will hear about and discuss an interim report from its subcommittee reviewing research at the Center for Food Safety and Applied Nutrition. The Science Board will also hear about and discuss plans to establish another subcommittee to review research programs at the Center for Drug Evaluation and Research. The Science Board will then hear and discuss updates on science programs at the Office of Regulatory Affairs and the National Center for Toxicological Research.

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 Monday, February 15, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make 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 Friday, February 5, 2010. 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 Monday, February 8, 2010.

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 Doreen Kezer 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: January 19, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–1520 Filed 1–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

The Neurological Devices Panel of the Medical Devices 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: Neurological Devices Panel of the Medical Devices 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 March 12, 2010, from 8 a.m. to 5 p.m.