

Dated: April 18, 2007.

**Maryam Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. E7-7732 Filed 4-23-07; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**President's Committee for People With Intellectual Disabilities; Notice of Meeting**

**AGENCY:** President's Committee for People with Intellectual Disabilities (PCPID), Administration for Children and Families, HHS.

**ACTION:** Notice of quarterly meeting.

**DATES:** Monday, May 14, 2007, from 9 a.m.–5 p.m. EST, and Tuesday, May 15, 2007, from 9 a.m.–2 p.m. EST. The meeting will be open to the public.

**ADDRESSES:** The meeting will be held in Room 800 of the Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC 20201. Individuals who will need accommodations for a disability in order to attend the meeting (e.g., interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify Kodie Ruzicka via e-mail at [kruzicka@acf.hhs.gov](mailto:kruzicka@acf.hhs.gov), or via telephone at 202-205-7989 no later than May 1, 2007. PCPID will attempt to meet requests made after that date, but cannot guarantee availability. All meeting sites are barrier free.

*Meeting Registration:* The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting Kodie Ruzicka at the e-mail address or telephone number listed in the **ADDRESSES** section of this notice by 12 p.m. EST on May 11, 2007. For those unable to participate in person, audio of the Monday, May 14 proceedings may be accessed via telephone. Please use the above contact information for Kodie Ruzicka to obtain telephone and passcode information.

*Agenda:* PCPID will meet to reappoint its members. They will also discuss possible content areas for the 2008 Report to the President and will divide into subcommittees for that purpose.

**FOR FURTHER INFORMATION CONTACT:**

Sally D. Atwater, Executive Director, President's Committee for People with Intellectual Disabilities, The Aerospace Center, Suite 701, 370 L'Enfant Promenade, SW., Washington, DC

20447. Telephone: 202-619-0634, fax: 202-205-9591. E-mail: [satwater@acf.hhs.gov](mailto:satwater@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. PCPID, by Executive Order, is responsible for evaluating the adequacy of current practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative proposals that impact the quality of life experienced by citizens with intellectual disabilities and their families.

Dated: April 17, 2007.

**Sally D. Atwater,**

*Executive Director, President's Committee for People with Intellectual Disabilities.*

[FR Doc. E7-7759 Filed 4-23-07; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for CELEBREX (celecoxib), COLAZAL (balsalazide), ELOXATIN (oxaliplatin), EMTRIVA (emtricitabine), SUPRANE (desflurane), and TOPROL-XL (metoprolol). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (the BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

**ADDRESSES:** Submit written requests for single copies of the summaries to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist

that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

**FOR FURTHER INFORMATION CONTACT:**

Grace Carmouze, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6460, Silver Spring, MD 20993-0002, 301-796-0700, e-mail: [grace.carmouze@fda.hhs.gov](mailto:grace.carmouze@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for CELEBREX (celecoxib), COLAZAL (balsalazide), ELOXATIN (oxaliplatin), EMTRIVA (emtricitabine), SUPRANE (desflurane), and TOPROL-XL (metoprolol). The summaries are being made available consistent with section 9 of the BPCA (Public Law 107-109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for CELEBREX (celecoxib), COLAZAL (balsalazide), ELOXATIN (oxaliplatin), EMTRIVA (emtricitabine), SUPRANE (desflurane), and TOPROL-XL (metoprolol). See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries. Copies are also available by mail (see **ADDRESSES**).

## II. Electronic Access

Persons with access to the Internet may obtain the summaries at <http://www.fda.gov/cder/pediatric/index.htm>.

Dated: April 16, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-7717 Filed 4-23-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0122]

#### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems.” This guidance document describes a means by which computerized labor monitoring systems may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify computerized labor monitoring systems into class II (special controls). This guidance document is being immediately implemented as the special control for computerized labor monitoring systems, but it remains subject to comment in accordance with the agency’s good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled “Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Picard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax

your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

Identify comments with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Glenn Bell, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4100.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying computerized labor monitoring systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for computerized labor monitoring systems. 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 time frames 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. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately implemented. 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 GGPs regulation

(§ 10.115). The guidance represents the agency’s current thinking on computerized labor monitoring systems. 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 “Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems,” you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto: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 1625 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 on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

## 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; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.