formal presentations from members of industry and FDA. Following the formal presentations, time will be allotted to hear from members of the public who have pre-registered as speakers. After the pre-registered speakers, there will be a moderated discussion open to all members of the audience.

FDA is considering issuing draft guidance on this issue and believes it is important to receive input from all interested parties through a public meeting.

V. Speakers

Members of the public who would like to make a short statement (approximately 5 minutes) should register with DIA (see **ADDRESSES**) by April 26, 2005. Requests to speak should include the speaker's name and affiliation, and should identify the appropriate panel (public health or legal issues). DIA will notify persons who register by April 26, 2005, of the approximate time of their turn to speak. Speakers will be scheduled in the order DIA receives the requests.

If you need special accommodations due to a disability, please contact, at least 7 days in advance: Amanda Carmody, Drug Information Association, at *Amanda.carmody@diahome.org* or 215–442–6176.

VI. Request for Comments and Transcripts

Regardless of attendance at the meeting, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the topics presented in this document. The agency welcomes comments before and after the meeting. Two paper copies of mailed comments are to be submitted, 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 are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments and a transcript of the public meeting will be made available on the Office of Combination Products Web site at *www.fda.gov/oc/combination*.

Dated: March 21, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–5978 Filed 3–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0103]

Draft Guidance for Industry on Using a Centralized Institutional Review Boards Process in Multicenter Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Using a Centralized IRB Process in Multicenter Clinical Trials.'' The draft guidance is intended to assist sponsors, institutions, institutional review boards (IRBs), and clinical investigators involved in multicenter clinical research in meeting the requirements of FDA's regulations by facilitating the use of a centralized IRB review process.

DATES: Submit written or electronic comments on the draft guidance by May 27, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Nancy Stanisic, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1660; or

Steve Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210, 301–827–7975; or

Dave Lepay, Good Clinical Practice Program, Office of Science and Health Coordination (HF–34), Office of the Commissioner, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Using a Centralized IRB Review Process in Multicenter Clinical Trials.'' The draft guidance is intended to assist sponsors, institutions, IRBs, and clinical investigators involved in multicenter clinical research in meeting the requirements of 21 CFR part 56 by facilitating the use of a centralized IRB review process. The draft guidance: (1) Describes the roles of the participants in a centralized IRB review process; (2) offers guidance on how a centralized IRB review process might address local aspects of IRB review; (3) makes recommendations about documenting agreements between a central IRB and the IRBs at institutions involved in the centralized IRB review process concerning their respective responsibilities; and (4) makes recommendations concerning written procedures for implementing a centralized review process. Finally, the draft guidance discusses using a central IRB at clinical trial sites not already affiliated with an IRB.

This draft guidance applies to clinical investigations conducted under 21 CFR part 312 (investigational new drug application or IND regulations).

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on this topic. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any mailed comments are to be submitted, 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–5977 Filed 3–25–05; 8:45 am]

BILLING CODE 4160–01–S

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 PARAPLATIN (carboplatin), TRUSOPT (dorzolamide), CAMPTOSAR (irinotecan), PREVACID (lansoprazole), TAMIFLU (oseltamivir), VIOXX (rofecoxib), FERRLECIT (sodium ferric gluconate), IMITREX (sumatriptan), DETROL and DETROL LA (tolterodine). 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.

In addition, the agency is also announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies for the following antidepressants: CELAXA (citalopram), REMERON (mirtazapine), SERZONE (nefazodone), PAXIL (paroxetine), and ZOLOFT (sertraline). Studies for these drugs were submitted before the BPCA was implemented. Therefore, they are not subject to its requirements. However, due to the public's interest in these pediatric studies, FDA asked the sponsors to consent to the public disclosure of a summary of the medical and clinical pharmacology reviews for these studies. Based on sponsors' consent, FDA is making the summaries publicly available.

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 (HFD–960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, e-mail: *carmouzeg@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies. As discussed in greater detail in the following paragraphs, section 9 of the BPCA (Public Law 107–109) requires the disclosure of certain summaries of pediatric study reviews. In addition, based on the sponsors' consent, FDA is making available summaries of medical and clinical pharmacology reviews for pediatric studies of antidepressants submitted in response to a written request.

The summaries of medical and clinical pharmacology reviews of pediatric studies conducted for PARAPLATIN (carboplatin), TRUSOPT (dorzolamide), CAMPTOSAR (irinotecan), PREVACID (lansoprazole), TAMIFLU (oseltamivir), VIOXX (rofecoxib), FERRLECIT (sodium ferric gluconate), IMITREX (sumatriptan), DETROL and DETROL LA (tolterodine) are being made available consistent with section 9 of the BPCA. 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 (*http://www.fda.gov/cder/pediatric/index.htm*) summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for PARAPLATIN (carboplatin), TRUSOPT (dorzolamide), CAMPTOSAR (irinotecan), PREVACID (lansoprazole), TAMIFLU (oseltamivir), VIOXX (rofecoxib), FERRLECIT (sodium ferric gluconate), IMITREX (sumatriptan), DETROL and DETROL LA (tolterodine). Copies are also available by mail (see **ADDRESSES**).

In addition, the agency is also announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies for the following antidepressants: CELAXA (citalopram), REMERON (mirtazapine), SERZONE (nefazodone), PAXIL (paroxetine), and ZOLOFT (sertraline). Section 9 of the BPCA does not require the disclosure of these summaries. However, due to the public's interest in these studies, FDA asked the sponsors to consent to the public disclosure of the summaries of the medical and clinical pharmacology reviews. Based on the sponsors' consent, FDA is making the reviews publicly available on the Internet (*http://www.fda.gov/cder/pediatric/index.htm*) and by mail (see **ADDRESSES**).

II. Electronic Access

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

Dated: March 18, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–5974 Filed 3–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the