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 AGRYLIN (anagrelide), ARGATROBAN (argatroban), CLOLAR (clofarabine), and MERIDIA (sibutramine). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (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. 6489, Silver Spring, MD 20993–0002, 301–796–2200, e-mail: *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 AGRYLIN (anagrelide), ARGATROBAN (argatroban), CLOLAR (clofarabine), and MERIDIA (sibutramine). 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 at *http://www.fda.gov/cder/pediatric/index.htm* summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for AGRYLIN (anagrelide), ARGATROBAN (argatroban), CLOLAR (clofarabine), and MERIDIA (sibutramine). Copies are also available 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: April 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–6706 Filed 5–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0385]

Guidance for Industry on Using Electronic Means to Distribute Certain Product Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Guidance for Industry: Using Electronic Means to Distribute Certain Product Information'' dated March 2006. The final guidance explains that persons can distribute certain product information, such as for recalls and product safety, by electronic means. We encourage the use of electronic communications for conveying all such important product safety information. We are making clear in this guidance that manufacturers and others may disseminate communications by electronic means, including e-mail or other electronic methods.

DATES: Submit written or electronic comments on agency guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 301–827–3360. Submit written comments concerning the 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

On September 30, 2005, we published a notice of availability for a draft guidance entitled ''Guidance for Industry: Using Electronic Means to Distribute Certain Product Information'' (70 FR 57300). The draft guidance requested comments by November 29, 2005. We received comments from individuals, associations, companies that provide safety and drug notices, and the pharmaceutical industry. We have reviewed these comments and have modified the guidance in response to those comments.

The timely dissemination of communications about recalls of FDA-regulated products, important drug safety information, and other important product safety information is essential for the protection of the public health. We encourage manufacturers to provide such information in a timely manner to distributors, doctors, and others. Over the years, we have worked with manufacturers and distributors to promote the use of electronic methods of communication and encourage the

use of innovative technologies to disseminate safety information, particularly when doing so can provide a public health benefit. We are making clear in the guidance that manufacturers and distributors may disseminate the communications discussed in §§ 7.49 and 200.5 (21 CFR 7.49 and 200.5) by various electronic methods, including e-mail. The guidance also applies to those instances, not addressed in any regulation, where we recommend that manufacturers and distributors voluntarily convey certain safety information about their products to members of the public.

The use of e-mail and other electronic communications has dramatically changed how we and the public convey information. Electronic communications have a number of advantages over paper-based communications. They can significantly shorten the time between an event and the public's knowledge of the event. When the event involves product safety, it is even more important that accurate safety information be transmitted rapidly. E-mail and other electronic communications can be more efficient and timelier than traditional mail. These communications involve considerably less cost to the sender than older, more traditional delivery services. Verification of receipt or delivery is less expensive and can be automatically accomplished through various means such as delivery or read receipt confirmation, or other electronic receipt acknowledgement mechanisms. Any necessary followup (such as when receipt of the e-mail is not acknowledged in some fashion) also can be accomplished electronically. If receipt of the electronic communication is not acknowledged appropriately by the recipient (as determined by the sender) or the electronic communication is undeliverable, the sender can resort to more traditional notification methods to ensure the communication is received.

We interpret the provisions of §§ 7.49 and 200.5 to allow the use of e-mail and other electronic communication methods, such as fax or text messaging, to accomplish any recall notification or distribution of important safety information. Section 7.49(b) provides that, ''A recall communication can be accomplished by telegrams, mailgrams, or first class letters* * *'' Given the use of the term ''can,'' we read the three examples as being illustrative rather than the sole means of accomplishing recall communications. Electronic notification, with appropriate safeguards and the use of acknowledgement mechanisms, is a viable alternative to more traditional methods.

II. Comments/Responses

We received a number of comments on the guidance and have modified the guidance to address some of the comments. Other comments are outside the scope of the guidance and thus are not addressed in the guidance. We have made changes on our own initiative to provide clarity to certain statements and recommendations.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance. Submit a single copy of electronic comments or 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.

III. The 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 (the PRA) (44 U.S.C 3501–3520). The collection of information in this guidance has been approved under OMB control number 0910–0249 which expires October 18, 2008.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/oc/guidance/electronic.html* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–6705 Filed 5–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Information Resources for Radiation Science.

Date: June 8, 2006.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6130 Executive Blvd., Conference Room C, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Kenneth L. Bielat, PhD, Scientific Review Administrator, Division Of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892, (301) 496–7576, *bielatk@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel, Innovations in Cancer Sample Preparation.

Date: June 13, 2006.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6130 Executive Blvd, Conference Room F, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: C. Michael Kerwin, PhD, MPH, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm. 8057, Bethesda, MD 20892–8329, (301)–496–7421. *kerwinm@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel, Discover and Development.

Date: June 19–21, 2006.

Time: 6 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Peter J. Wirth, PhD, Scientific Review Administrator, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8131, Bethesda, MD 20892–8328, 301–496–7565, *pw2q@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel, RFA CA–06–014, ''Tumor Microenvironment Network''.

Date: August 2–4, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.