Application No.	Drug	Applicant
NDA 16–636	NARCAN (naloxone hydrocholoride (HCl)) Injection, 0.02 mg/mL, 0.4 mg/mL, and 1 mg/mL	Endo Pharmaceuticals, Inc., 100 Painters Dr., Chadds Ford, PA 19317
NDA 16–929	FUDR (floxuridine) Injection, 500 mg/vial	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045
NDA 18–538	LOZOL (indapamide) Tablets, 1.25 mg and 2.5 mg	Sanofi-Aventis U.S., 55 Corporate Blvd., P.O. Box 5925, Bridgewater, NJ 08807
NDA 18–821	REGLAN (metaclopramide HCl) Oral Solution, equivalent to (EQ) 5 mg base/5 mL	A.H. Robins Co., c/o Wyeth-Ayerst Research, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 18–831	TRACRIUM (atracurium besylate) Injection, 10 mg/mL	Hospira, Inc.
NDA 18–831	TRACRIUM (atracurium besylate) Preservative Free Injection, 10 mg/mL	Do.
NDA 19–080	PROSOM (estazolam) Tablets, 1 mg and 2 mg	Abbott Laboratories, 200 Abbott Park Rd., D–491, AP30–1E, Abbott Park, IL 60064–6157
NDA 20–397	ZANAFLEX (tizanidine HCL) Tablets, EQ 2 mg base	Acorda Therapeutics, 15 Skyline Dr., Hawthorne, NY 10532

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: May 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–11217 Filed 5–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0189]

Guidance for Industry: Animal Generic Drug User Fees and Fee Waivers and Reductions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (#199) entitled ''Animal Generic Drug User Fees and Fee Waivers and Reductions.'' The purpose of this document is to provide guidance to industry on the Animal Generic Drug User Fee Act of 2008 (AGDUFA). FDA is issuing this final guidance document for immediate implementation consistent with the agency's good guidance practices (GGPs). Interested persons may submit comments on agency guidances at any time.

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

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

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

FOR FURTHER INFORMATION CONTACT: David Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: *dnewkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On August 14, 2008, AGDUFA (Public Law 110–316) was enacted. AGDUFA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and requires FDA to assess and collect user fees for certain applications, products, and sponsors. It also requires the agency to grant a waiver from or a reduction of fees in certain circumstances. Under section 741(d) of the FD&C Act, when certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication.

The purpose of the guidance document is to provide guidance on the types of fees FDA is authorized to collect under AGDUFA and how to request waivers and reductions of these fees. It describes the types of fees, the type of fee waiver or reduction

available, what information FDA recommends you submit in support of a request for a fee waiver or reduction, how to submit such a request, and FDA's process for reviewing requests.

FDA is issuing this level 1 final guidance document for immediate implementation consistent with FDA's GGPs regulation (21 CFR 10.115). Prior public participation is not feasible because the guidance concerns statutory requirements that FDA must implement immediately. AGDUFA's user fee provisions are already in effect, and it is essential for the agency to provide guidance on how to request fee waivers and reductions as quickly as possible. If FDA receives comments on this final guidance, it will review the comments and revise the guidance if appropriate.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the fee waiver provisions of AGDUFA. It does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

FDA concludes that there are no collections of information under the Paperwork Reduction Act of 1995.

IV. Comments

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. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the internet may obtain the guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov*.

Dated: May 7, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–11218 Filed 5–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

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 meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting 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 Advisory Board Subcommittee on Cancer Centers.

Open: June 10, 2009, 6 p.m. to 7:30 p.m.

Agenda: Discussion on Cancer Centers.

Place: Bethesda Hyatt Regency Hotel, One Metro Center, Bethesda, MD 20814.

Contact Person: Dr. Linda K. Weiss, Executive Secretary, NCAB Subcommittee on Cancer Centers, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Suite 700, Bethesda, MD 20892–8345, (301) 496–8531.

Name of Committee: National Cancer Advisory Board.

Open: June 11, 2009, 8 a.m. to 4 p.m.

Agenda: Program reports and presentations; business of the Board.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327. (301) 496–5147.

Name of Committee: National Cancer Advisory Board.

Closed: June 11, 2009, 4 p.m. to adjournment.

Agenda: Review of grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Name of Committee: National Cancer Advisory Board.

Open: June 12, 2009, 8:30 a.m. to 12 p.m.

Agenda: Program reports and presentations; business of the Board.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/ncab.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 5, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–11236 Filed 5–13–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

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