animal drug user fees and fee waivers and reductions.

DATES: Submit either electronic or written comments on the collection of information by January 31, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.Vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Animal Drug User Fees and Fee Waivers and Reductions—(OMB Control Number 0910–0540—Extension)

Enacted on November 18, 2003, the Animal Drug User Fee Act (ADUFA) (Pub. L. 108–130) amended the Federal Food, Drug, and Cosmetic Act and requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. It also requires the Agency to grant a waiver from, or a reduction of those fees in certain circumstances. Thus, to implement this statutory provision of ADUFA, FDA developed a guidance entitled "Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions." It provides guidance on the types of fees FDA is authorized to collect under ADUFA, and on how to request waivers and reductions from FDA's animal drug user fees. The guidance also describes the types of fees and fee waivers and reductions, the information FDA recommends respondents submit in support of a request for a fee waiver or reduction, how respondents may submit such a request, and FDA's process for reviewing requests.

Respondents to this collection of information are new animal drug sponsors. Requests for waivers or reductions may be submitted by a person paying any of the animal drug user fees assessed—application fees, product fees, establishment fees, or sponsor fees.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
740(d)(1)(A) Significant barrier to innovation	22	1	22	2	44
740(d)(1)(B) Fees exceed cost	0	1	0	2	0
740(d)(1)(C) Free choice feeds	2	1	2	2	4
740(d)(1)(D) Minor use or minor species	52	1	52	2	104
740(d)(1)(E) Small business	0	1	0	0	0
Request for reconsideration of a decision	5	1	5	2	10
Request for review—(user fee appeal officer)	2	1	2	2	4
Total					166

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA's database system, there are an estimated 250 sponsors of products subject to ADUFA. However, not all sponsors will have any submissions in a given year and some may have multiple submissions. The total number of waiver requests is based on the number of submission types received by FDA in fiscal year 2008.

Dated: November 24, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30264 Filed 12–1–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Gastrointestinal Drugs 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: Gastrointestinal Drugs 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 January 12, 2011, from 8 a.m to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, Bldg. 31, the Great Room, White Oak Conference Center (rm. 1503). Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading "Resources for You," click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings." Please note that visitors to the White Oak Campus must have a valid driver's license or other picture ID, and must enter through Building 1.

Contact Person: Kristine T. Khuc, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, *FAX:* 301–847–8533, *e-mail: kristine.khuc@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512538. 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 January 12, 2011, the committee will discuss the safety and efficacy of new drug application (NDA) 022–486, for Solpura (liprotamase) Capsules, by Alnara Pharmaceuticals, for the proposed indication (use) in the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy (surgical removal of all or part of the pancreas), or other conditions that may impair or limit function of the pancreas. The pancreas is an organ involved, in part, in the digestion of food through the use of specialized proteins called enzymes. Exocrine pancreatic insufficiency is a decreased ability to digest food due to deficient enzyme production by the pancreas.

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 December 28, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Those individuals interested in making 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 December 17, 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 December 20, 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 Kristine T. Khuc 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: November 26, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30274 Filed 12–1–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Novel Compositions and Methods To Treat Glioblastoma and Other Cancers

Description of Technology: There remains a significant unmet need for therapeutics to treating glioblastoma multiforme, a very aggressive type of brain tumor. Glioblastoma is difficult to treat with conventional surgery, chemical, and radiation therapies. With approximately 18,000 new glioblastoma cases in the U.S. each year, and a comparable market in Europe, the global market for such products forecast to be over $300 million. In light of the high unmet need in malignant astrocytoma and little in the way of pipeline competition, this indication represents a potential easy route to market for new drugs.