

application. Based on information available to FDA, we estimate that approximately 24 sponsors will prepare approximately 1 breakthrough therapy designation submission in accordance with the draft guidance and that the added burden for each submission will be approximately 70 hours to prepare and submit (totaling 1,680 hours).

*Promotional Materials for Accelerated Approval Under Part 314.* The draft guidance describes section 506(c)(2)(B) of the FD&C Act and FDA's accelerated approval regulations (§§ 314.550 and 601.45). These provisions authorize FDA to require sponsors to submit copies of all promotional materials to the Agency for consideration prior to

their dissemination. The regulations provide that copies of all promotional materials including promotional labeling as well as advertisements intended for dissemination or publication within 120 days following marketing approval must be submitted to FDA during the preapproval period. The regulations further provide that after 120 days following marketing approval, unless otherwise informed by the Agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement. Currently, FDA has OMB approval for

the submission of copies of all promotional materials under part 601 (OMB control number 0910-0338) but does not have approval for the submission of copies of all promotional materials under part 314.

Based on information from FDA's databases and information available to FDA, we estimate that approximately 20 sponsors will submit promotional materials for accelerated approval 7 times annually in accordance with § 314.550 and that the burden for each submission will be approximately 120 hours (a total of 16,800 hours).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Draft guidance on expedited programs	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Designation Request .....	47	1	47	30	1,410
Breakthrough Therapy Designation Request .....	24	1	24	70	1,680
Promotional Materials for Accelerated Approval Under § 314.550 .....	20	7	140	120	16,800
Total .....					19,890

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

### III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>.

### IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: June 20, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0001]

### Blood Products 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). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Blood Products 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 August 2, 2013, from 10 a.m. to approximately 1:30 p.m.

*Location:* National Institutes of Health, Building 29, Conference Room A/B, 9000 Rockville Pike, Bethesda, MD 20892. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room.

*Contact Person:* Bryan Emery or Pearlina Muckelvene, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, HFM-71, Rockville, MD 20852, 301-827-0314, email: [Bryan.Emery@fda.hhs.gov](mailto:Bryan.Emery@fda.hhs.gov) or [Pearline.Muckelvene@fda.hhs.gov](mailto:Pearline.Muckelvene@fda.hhs.gov) or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 advisory committee information line, or visit our Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> to learn about possible modifications before coming to the meeting.

*Agenda:* On August 2, 2013, the Committee will meet in open session to hear updates on the research programs of the Laboratory of Molecular Virology, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA.

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 meeting link.

**Procedure:** On August 2, 2013, from 10 a.m. to approximately 1 p.m., the meeting is open to the public. 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 July 26, 2013. Oral presentations from the public will be scheduled between approximately 12 noon and 1 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 July 18, 2013. 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 July 19, 2013.

**Closed Committee Deliberations:** On August 2, 2013, from approximately 1 p.m. to 1:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the site visit report of the intramural research programs and make recommendations regarding personnel staffing decisions.

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 Bryan Emery or Pearl Muckelvene 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: June 21, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-15239 Filed 6-25-13; 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, 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. 209 and 37 CFR part 404 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.

**FOR FURTHER INFORMATION CONTACT:** 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.

#### Predicting Age of Onset of Niemann-Pick Disease

**Description of Technology:** Niemann-Pick disease (NPD) refers to a group of fatal inherited metabolic disorders. Children with type A or B NPD usually die within the first few months or years of life, while NPD type C progresses more slowly, and affected individuals may survive into their seventies. The lifespan of patients with NPD is related to the age of onset. At present, however,

there is no effective diagnostic method to predict the age of NPD disease onset.

The instant invention presents diagnostic compositions and efficient methods for predicting the age of onset of a lysosomal storage disease (e.g., NPD) and of diseases associated with lysosomal or autophagic defects (e.g., Parkinson's disease and Alzheimer's disease) in patients. It can also be used to screen for agents useful in treating NPD patients.

#### Potential Commercial Applications:

- Predicting the age of disease onset in patients with Niemann-Pick disease, and other diseases associated with lysosomal or autophagic defects.

- Identifying agents for treating NPD patients.

**Competitive Advantages:** A new method for predicting the age of NPD disease onset.

#### Development Stage:

- Early-stage.
- Pre-clinical.
- In vitro data available.

**Inventors:** William J. Pavan, et al. (NHGRI).

**Intellectual Property:** HHS Reference No. E-060-2013/0—U.S. Provisional Application No. 61/781,807 filed 14 Mar 2013.

**Licensing Contact:** Betty B. Tong, Ph.D.; 301-594-6565; [tongb@mail.nih.gov](mailto:tongb@mail.nih.gov).

**Collaborative Research Opportunity:** The National Human Genome Research Institute (NHGRI) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize diagnostic methods for predicting the age of onset of lysosomal disorders, such as NPD and Parkinson's. For collaboration opportunities, please contact Dr. William J. Pavan at [bpavan@nhgri.nih.gov](mailto:bpavan@nhgri.nih.gov).

#### Rat Model for Alzheimer's Disease

**Description of Technology:** The present invention is directed to a transgenic rat model of Alzheimer's Disease (AD) termed TgF344-19+/- . The invention rat overexpresses two human genes (APP<sup>swe</sup> and PS1<sup>ΔE9</sup> genes), each of which are believed to be independent dominant causes of early-onset AD. The hemizygote exhibits major features of AD pathology (i.e., dense and diffuse amyloid plaques, neurofibrillary tangles, cerebral amyloid angiopathy, hyperphosphorylated tau, paired-helical filaments, Hirano bodies, granulovacuolar degeneration, cognitive impairment, and cortical neuronal loss).

The invention rat is superior to AD mice models because the rat has a larger sized brain to accommodate *in vivo* imaging studies and complex behavioral