FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SAPIEN TRANSCATHETER HEART VALVE is 2,473 days. Of this time, 2,106 days occurred during the testing phase of the regulatory review period, while 367 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* January 26, 2005. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on March 24, 2003. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on January 26, 2005, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* November 1, 2010. The applicant claims October 29, 2010, as the date the premarket approval application (PMA) for SAPIEN Transcatheter Heart Valve (PMA P100041) was initially submitted. However, FDA records indicate that PMA P100041 was submitted on November 1, 2010.

3. *The date the application was approved:* November 2, 2011. FDA has verified the applicant's claim that PMA P100041 was approved on November 2, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,757 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by April 23, 2013. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 21, 2013. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04016 Filed 2–21–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Request for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels and Request for Notification From Consumer Organizations Interested in Participating in the Selection Process for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may either be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for current vacancies and for those that will or may occur through December 2013.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA by March 25, 2013, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by March 25, 2013.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be sent electronically to *CV@OC.FDA.GOV,* by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993–0002, or by fax to 301–847–8640. Information about becoming a member of an FDA advisory committee can be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Dornette Spell-LeSane, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993–0002, 301–796–8224, *dornette.spelllesane@fda.hhs.gov.*

For questions relating to specific advisory committees or panels, contact the appropriate person listed in table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION:

For questions relating to specific advisory committees or panels, contact the appropriate person listed in table 1 of this document.

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Diane Goyette, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2408, Silver Spring, MD 20993–0002, 301–796–9014, FAX: 301–847–8533, *Diane.Goyette@fda.hhs.gov*.	Anti-Infective Drugs.

TABLE 1—ADVISORY COMMITTEE CONTACTS—Continued

Contact person	Committee/panel
Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2408, Silver Spring, MD 20993–0002, 301–796–0063, FAX: 301–847–8533, *Kristina.Tolliver@fda.hhs.gov*.	Cardiovascular and Renal Drugs.
Diem-Kieu Ngo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2408, Silver Spring, MD 20993–0002, 301–796–9001 X9021, FAX: 301–847–8533, *Diem.Ngo@fda.hhs.gov*.	Endocrinologic and Metabolic Drugs.
Glendolynn Johnson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *Glendolynn.Johnson@fda.hhs.gov*.	Nonprescription Drugs and Peripheral and Central Nervous System Drugs.
Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2528, Silver Spring, MD 20993–0002, 301–796–0889, FAX: 301–847–8533, *Cindy.Hong@fda.hhs.gov*.	Pulmonary Allergy Drugs.
Karen Strambler, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., Rm. 1C016, College Park, MD 20740, 240–402–2589, FAX: 301–436–2657. *FoodAdvisoryCommittee@fda.hhs.gov*.	Food Advisory Committee.
Donald Jehn, Center for Biologics Evaluation and Research, 1401 Rockville Pike (HFM–71), Rockville, MD 20852, 301–827–1293, FAX: 301–827–0294, *Donald.Jehn@fda.hhs.gov*.	Vaccines and Related Biological Products.
Jamie Waterhouse, Center for Devices and Radiological Devices, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1611, Silver Spring, MD 20993–0002, 301–796–3063, FAX: 301–847–8116, *Jamie.Waterhouse@fda.hhs.gov*.	Circulatory System Devices and Ear, Nose and Throat Devices Panel.
Shanika Craig, Center for Devices and Radiological Devices, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993–0002, 301–796–6639, FAX: 301–847–8121, *Shanika.Craig@fda.hhs.gov*.	Microbiology Devices Panel.
Sara J. Anderson, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1544, Silver Spring, MD 20903, 301–796–7047, FAX: 301–847–8121, *Sara.Anderson@fda.hhs.gov*.	Orthopaedic and Rehabilitation Devices Panel.

FDA is requesting nominations for voting and/or nonvoting consumer representatives for the vacancies listed in table 2 of this document:

TABLE 2—COMMITTEE/PANEL VACANCIES

Committee/panel/areas of expertise needed	Current and upcoming vacancies	Approximate date needed
Anti-Infective Drugs	1-Voting	December 1, 2013.
Knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties		
Cardiovascular and Renal Drugs	1-Voting	July 1, 2013.
Knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics.		
Endocrinologic and Metabolic Drugs	1-Voting	July 1, 2013.
Reviews and evaluates data concerning the safety and efficacy of marketed and investigational human drugs products for use in the treatment of endocrine and metabolic disorders.		
Nonprescription Drugs	1-Voting	July 1, 2013.
Knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties.		
Peripheral and Central Nervous System Drugs	1-Voting	Immediately.
Knowledgeable in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology or statistics, and related specialties		
Pulmonary Allergy Drugs	1-Voting	June 1, 2013.
Knowledgeable in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics		
Food Committee	1-Voting	July 1, 2013.
Knowledgeable in the areas of food technology, pediatric development, nutrition, food microbiology and toxicology		
Vaccines and Related Biological Products	1-Voting	Immediately.
Knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry		
Circulatory System Devices Panel	1-Nonvoting	July 1, 2013.
Knowledgeable in the safety and effectiveness of marked and investigational devices for use in the circulatory and vascular systems.		
Ear, Nose, and Throat Devices Panel	1-Nonvoting	Immediately.
Knowledgeable in the safety and effectiveness of marketed and investigational ear, nose and throat devices		
Microbiology Devices Panel	1-Nonvoting	Immediately.

TABLE 2—COMMITTEE/PANEL VACANCIES—Continued

Committee/panel/areas of expertise needed	Current and upcoming vacancies	Approximate date needed
Knowledgeable in data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine including microbiology, virology, and infectious disease and makes appropriate recommendations		
Orthopaedic and Rehabilitation Devices Panel	1-Nonvoting	September 1, 2013.
Knowledgeable in data concerning the safety and effectiveness of marketed and investigational orthopaedic and rehabilitation devices		

I. Functions

A. Anti-Infective Drugs

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

B. Cardiovascular and Renal Drugs

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

B. Endocrinologic and Metabolic Drugs

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

C. Nonprescription Drugs

The Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner of Food and Drugs either on the issuance of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee will serve as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of Agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

D. Peripheral and Central Nervous system Drugs

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases and makes appropriate recommendations to the Commissioner of Food and Drugs.

E. Pulmonary Allergy Drugs

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes appropriate recommendations to the Commissioner of Food and Drugs.

F. Food Advisory Committee

The Committee provides advice to the Commissioner of Food and Drugs and other appropriate officials, on emerging food safety, food science, nutrition, and other food-related health issues that FDA considers of primary importance for its food and cosmetics programs. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food or cosmetic related issues, (2) the safety of new foods and food ingredients, (3) labeling of foods and cosmetics, (4) nutrient needs and nutritional adequacy, and (5) safe exposure limits for food contaminants. The Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

G. Vaccines and Related Biologic Products

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which FDA has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs.

H. Certain Panels of the Medical Devices Advisory Committee

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area; advises on the classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding

the safety and effectiveness of marketed and investigational devices.

II. Criteria for Members

Persons nominated for membership as consumer representatives on the committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing three to five qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Potential candidates will be required to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

All nominations should include: a cover letter; a curriculum vitae or resume that includes the nominee's office address, telephone number, and email address; and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations also should specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination and is willing to serve as a member of the advisory committee or panel if selected.

The term of office is up to 4 years. FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: February 15, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–04059 Filed 2–21–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System Data Access Request

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Neurological Disorders and Stroke (NINDS), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project, obtain a copy of the data collection plans and instruments, or to submit written comments, contact Rebecca L. Frederick, Office of Science Policy and Planning, OSPP, NINDS, NIH, 31 Center Drive, Building 31, Room 8A03, Bethesda, MD 20892; call 301–496–9271; or Email: *rebecca.frederick@nih.gov.*

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Proposed Collection: Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System Data Access Request.

Need and Use of Information Collection: The FITBIR Informatics System Data Access Request form is necessary for ''Recipient'' Principal