shown that a few respondents will go out of business (§ 822.26) or cease marketing the device subject to PS (§ 822.28) each year. In addition, manufacturers must certify transfer of records when ownership changes § 822.34.

FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically-based PS plan, using three investigators. These estimates are based on FDA's knowledge and experience with limited implementation of section 522 under the Safe Medical Devices Act of 1990. Therefore, FDA would expect that the recordkeeping requirements would apply to a maximum of 10 manufacturers (3 to 4 added each year) and 30 investigators (three per PS plan). After 3 years, FDA would expect these numbers to remain level as the PS plans conducted under the earliest orders reach completion and new orders are issued.

Dated: September 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–16231 Filed 9–29–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting and Nonvoting Consumer Representative Members on Public Advisory Committees and Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting and nonvoting consumer representatives to serve on its advisory committees/panels that are under the purview of the Office of the Commissioner, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the National Center for Toxicological and Research (NCTR).

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on its advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2006. Because vacancies occur on various dates throughout the year, there is no cutoff date for the receipt of nominations.

ADDRESSES: Send all nominations and curricula vitae to the following contact persons listed in table 1 of this document:

TABLE 1.

Contact Person	Committee/Panel
Jan Johannessen, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, rm. 14B–08, Rockville, MD 20857, 301–827–6687, e-mail: *jan.johannessen@fda.hhs.gov*	Pediatric Advisory Committee
Igor Cerny, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301–827–6763, e-mail: *igor.cerny@fda.hhs.gov*	Arthritis Advisory Committee
Collin L. Figueroa, Center for Devices and Radiological Health (HFZ–342), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850	Device Good Manufacturing Practice Advisory Committee
Geretta Wood, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., rm. 110D, Rockville, MD 20850, 301–594–2022, x 133, e-mail: *geretta.wood@fda.hhs.gov*	General Hospital and Personal Use Devices Panel, Gastroenterology-Urology Devices Panel, General and Plastic Surgery Devices Panel, and the Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee
Leonard M. Schechtman, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, rm. 16–85, Rockville, MD 20857, 301–827–6696, e-mail: *leonard.schechtman@fda.hhs.gov*	Science Advisory Board to NCTR

FOR FURTHER GENERAL INFORMATION CONTACT: Doreen Brandes, Office of the Commissioner (HF–4), Food and Drug Administration, 5600 Fishers Lane, rm. 15A–12, Rockville, MD 20853, 301–827–1220, e-mail *doreen.brandes@fda.hhs.gov*.

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

TABLE 2.

Committee/Panel Expertise Needed	Current and Upcoming Vacancies	Approximate Date Needed
Pediatric Advisory Committee—knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics	1—Voting Consumer Representative	Immediately
Arthritis Advisory Committee—knowledgeable in the fields of arthritis, rheumatology, orthopedics, epidemiology or statistics, analgesics, and related specialties	1—Voting Consumer Representative	Immediately

TABLE 2.—Continued

Committee/Panel Expertise Needed	Current and Upcoming Vacancies	Approximate Date Needed
Certain Panels of the Medical Devices Advisory Committee		
Anesthesiology and Respiratory Therapy Devices Panel—anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, pharmacology, physiology, or the effects and complications of anesthesia	1—Nonvoting Consumer Representative	Immediately
General Hospital and Personal Use Devices Panel—internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, bio-medical engineers, or microbiologists/infection control practioners or experts	1—Nonvoting Consumer Representative	Immediately
Gastroenterology-Urology Devices Panel—gastroenterologists, urologists, and nephrologists	1—Nonvoting Consumer Representative	January 1, 2007
General and Plastic Surgery Devices Panel—surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic, and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians	1—Nonvoting Consumer Representative	Immediately
Science Advisory Board to NCTR—toxicologists, chemists, or public health background as it relates to foods, drugs, etc.	1—Voting Consumer Representative	July 1, 2007

I. Functions

A. Pediatric Advisory Committee

The Committee advises and makes recommendations to the Commissioner of Food and Drugs (the Commissioner) regarding the following topics: (1) Pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act (42 U.S.C. 262, 284m, and 290b) and sections 501, 502, 505, 505A, and 505B of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351, 352, 355, 355a, and 355c); (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics; (4) pediatric labeling disputes as specified in section 3 of the Best Pharmaceuticals for Children Act (BPCA) (Public Law 107–109); (5) pediatric labeling changes as specified in section 5 of the BPCA; (6) adverse event reports for drugs granted pediatric exclusivity and any safety issues that may occur as specified in section 17 of the BPCA; (7) any other pediatric issue or pediatric labeling dispute involving FDA regulated products; (8) research involving children as subjects as specified in 21 CFR 50.54; and (9) any other matter involving pediatrics for which FDA has regulatory responsibility.

B. Arthritis Advisory Committee

The committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases and makes appropriate recommendations to the Commissioner.

C. 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. The panels engage in a number of activities to fulfill the functions the act envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner regarding recommended 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 application of portions of the 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 on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

D. NCTR

The Science Advisory Board to the committee is responsible for examining the biological effects of potentially toxic substances found in the environment through fundamental investigations aimed at understanding the mechanisms of actions of those substances in animals and developing a better understanding of what these data in animals mean for man.

II. Criteria for Members

Persons nominated for membership as consumer representatives on the committees/panels must 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 representatives must be able to represent the consumer perspective on issues and actions before the advisory committee, serve as liaisons 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 consumer advocacy groups. The organizations have the responsibility of recommending candidates of the agency's selection.

IV. Nomination Procedures

All nominations must include a cover letter, a curriculum vitae or resume (that includes the nominee's office address, telephone number, and e-mail address), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation. Nominations will specify the advisory panel(s) or committee(s) for which the nominee is recommended. Nominations will include confirmation that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee if selected, and appears to have no conflict of interest that would preclude membership.

Any interested person or organization may nominate one or more qualified persons for membership as consumer representatives on one or more of the advisory committees/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 a conflict of interest. The nomination should specify the committee(s)/panel(s) of interest. The term of office is up to 4 years, depending on the appointment date.

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: September 25, 2006.

Randall Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–16216 Filed 9–29–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0050]

Determination of Regulatory Review Period for Purposes of Patent Extension; BYETTA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BYETTA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions 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*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product BYETTA (exenatide injection). BYETTA is indicated as adjunctive therapy to improve glycemic control in patients with type 2 diabetes mellitus who are taking metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea but have not achieved adequate glycemic control. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BYETTA (U.S. Patent No. 5,424,286) from Amylin Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 24, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BYETTA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for BYETTA is 2,271 days. Of this time, 1,968 days occurred during the testing phase of the regulatory review period, while 303 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: February 10, 1999. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 10, 1999.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: June 30, 2004. The applicant claims June 29, 2004, as the date the new drug application (NDA) for BYETTA (NDA 21–773) was initially submitted. However, FDA records indicate that NDA 21–773 was submitted on June 30, 2004.

3. *The date the application was approved*: April 28, 2005. FDA has verified the applicant's claim that NDA 21–773 was approved on April 28, 2005.

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 1,286 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**) written or electronic comments and ask for a redetermination by December 1, 2006. 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