IND effective date was July 24, 1992, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 8, 2000. The applicant claims December 7, 2000, as the date the new drug application (NDA) for Symlin (NDA 21–332) was initially submitted. However, FDA records indicate that NDA 21–332 was submitted on December 8, 2000.

3. *The date the application was approved*: March 16, 2005. FDA has verified the applicant's claim that NDA 21–332 was approved on March 16, 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 1,586 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 August 15, 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 December 13, 2006. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–9414 Filed 6–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Response to Solicitation on Organ Procurement and Transplantation Network (OPTN) Living Donor Guidelines

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Response to solicitation of comments.

SUMMARY: A notice was published in the **Federal Register** on January 23, 2006 (Vol. 71, No. 14, pages 3519–3520). The purpose of this notice was to solicit comments to assist HRSA in determining whether criteria developed by the Organ Procurement and Transplantation Network (OPTN) concerning organs procured from living donors, including those concerning the allocation of organs from living donors, should be given the same status, and be subject to the same enforcement actions, as other OPTN policies.

FOR FURTHER INFORMATION CONTACT: James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 12C–06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov*.

SUPPLEMENTARY INFORMATION: Congress has provided specific authority under sections 372 of the Public Health Service (PHS) Act, as amended, 42 U.S.C. 274 for the creation of a national OPTN, which is, among other things, to facilitate a donor and recipient matching system; establish membership criteria and medical criteria for allocating donated organs; and provide opportunities to members of the public to comment with respect to proposed criteria.

The OPTN Final Rule (42 CFR part 121) governs the operations of the OPTN and is intended to help achieve the most equitable and medically effective use of human organs that are donated in trust for transplantation. Under the final rule, the OPTN is to develop policies on a variety of issues, including ''[p]olicies for the equitable allocation of cadaveric organs [now referred to as deceased donor organs].'' 42 CFR 121.4(a)(1). Under the final rule, allocation policies developed by the OPTN under section 121.8 of the final rule will be considered enforceable when and if the Secretary approves the policies as such. Enforceable OPTN policies are subject to the sanctions described in section 121.10(c)(1) of the final rule. Non-enforceable OPTN policies may still be subject to lesser sanctions by the OPTN (*e.g.*, an OPTN member being designated a Member Not in Good Standing).

Although the authorizing statute does not distinguish between transplants using organs from living donors and those using organs from deceased donors, the final rule does not include a requirement that the OPTN develop policies concerning the equitable allocation of living donor organs. Until recently, OPTN policies have predominantly focused on issues related to organ donation and transplantation of deceased donor organs.

However, several widely publicized living donor deaths have caused the OPTN to implement new practices of reviewing and approving, on an advisory basis, the qualifications of living donor transplant programs. Additionally, the increased incidence of altruistic living donations has prompted the OPTN to consider policies that are patient-focused yet address the unique circumstances pertaining to the recovery and transplantation of living donor organs. Section 121.4(a)(6) of the final rule provides that the OPTN shall be responsible for developing policies on a variety of topics, including ''[p]olicies on such matters as the Secretary directs.'' In accordance with that authority, the Healthcare Systems Bureau directed the OPTN to develop allocation guidelines for organs from living donors and other policies necessary and appropriate to promote the safety and efficacy of living donor transplantation for the donor and recipient. It further advised the OPTN that all living donation policies (other than data reporting policies) should be considered as best practices or voluntary guidelines and not subject to regular OPTN sanctions (even those available with respect to violation of non-enforceable policies) until the public has had an opportunity to comment on the matter.

In the January 23, 2006, **Federal Register** notice, comments were requested to assist HRSA in determining whether OPTN living donor guidelines should be given the same status of other OPTN policies, *i.e.*, be treated as policies developed in accordance with 42 CFR 121.8, and be subject to the same enforcement actions. The Secretary explained that if he decided these questions in the affirmative, OPTN policies relating to living donors would be treated the same as other OPTN policies developed in accordance with section 121.8 of the final rule. In other words, OPTN policies concerning living

donors would not be considered enforceable policies under section 121.10 of the final rule, and violations of such policies would not be subject to the sanctions described in section 121.10(c)(1), unless and until the Secretary approved such policies as enforceable.

During the comment period, HRSA received 29 comments from individuals affiliated with or representing universities, hospitals, professional associations, and living donation advocacy organizations; a healthcare accreditation organization; transplant recipients; and family members of donors, recipients and candidates. Twenty of these comments explicitly referenced changing the status of OPTN living donor guidelines. The remaining nine comments expressed views about various aspects of the national transplant system not directly related to the solicitation of comments.

HRSA thanks the respondents for the quality and thoroughness of their comments. The comments and HRSA's decision are discussed below.

I. Living Donor OPTN Policies Consistent With Other OPTN Policies

The majority of respondents indicated that OPTN living donor guidelines should be given the same status of other OPTN policies. Of the 20 comments that explicitly referenced changing the status of OPTN living donor guidelines, 17 were supportive of giving OPTN living donor guidelines the same status, and subjecting these to the same enforcement actions, as other OPTN policies. Supportive comments were received from representatives of academia, transplant surgeons, living donors who had positive donation experiences, living donors who had negative donation experiences, family members of living donors who died or who experienced complications as a result of the donation, living donation advocacy organizations, transplant administrators, the professional societies representing transplant surgeons and transplant physicians, transplant candidate/recipient advocacy organizations, the organization serving as the current OPTN contractor, and an organization that accredits hospitals.

Supportive comments cited the appropriateness of OPTN involvement in policies relating to living donors, including donor evaluation, informed consent, evaluation of surgical outcomes and complications, protection of living donors, peri-operative care, organ allocation, qualifications of transplant programs, and transplant program compliance with living donor policies.

A few comments indicated opposition to giving OPTN living donor guidelines the same status as other OPTN policies. A family member of two kidney transplant candidates who died on the waiting list is now an advocate of potential living donors and recipients meeting on the Internet and is opposed to the OPTN's involvement in living donor policy making because of the perception that the OPTN discourages living donor transplants resulting from such meetings. Another opponent of OPTN involvement is waiting for a liver transplant and does not trust the OPTN policymaking process because of the perception that wealthier candidates receive priority for donor organs. One data manager from a large transplant program commented that mandating data collection on living donors was unlikely to increase donor follow-up form completion rates unless the donors' insurance companies can be persuaded to pay for follow-up visits. HRSA appreciates each of these comments.

II. OPTN Living Donor Policy Making Authority—Organ Allocation

Comments supportive of OPTN involvement in living donor policy making expressed varying views regarding the scope of policies the OPTN should consider. Of the 17 comments that were supportive of OPTN involvement, five suggested areas in which the OPTN should not become involved. One comment did not advocate an intrusive role for the OPTN in the allocation of living donor organs or ethical review of local living donor practices. A transplant administrator offered the similar caution that altruistic living donors may feel a sense of connection to their local transplant center and may not want their organs allocated to a distant center. A representative of the professional society for transplant surgeons offered a comment to HRSA that the OPTN Final Rule does not authorize the OPTN to establish policies for living donor organ allocation. In response to this, HRSA emphasizes that its authority to direct the OPTN to develop living donor organ allocation policies is granted in § 121.4(a)(6) of the OPTN Final Rule which permits the Secretary to develop policies on such other matters as the Secretary directs. The wording in § 121.8(a) of the final rule referring to policies ''for the equitable allocation of cadaveric organs'' should not be construed as a limitation of the Secretary's policy making authority over living donation.

A representative of a living donor advocacy organization commented that OPTN policies should not interfere with the right of an altruistic living donor to direct their organ to a specific individual. We agree. Section 121.8(h) of the OPTN Final Rule permits the allocation of an organ to a recipient named by those authorized to make the donation. Because we are directing the OPTN to develop living donor allocation policies under section 121.8 of the final rule, section 121.8(h) will apply to living donation equally as it applies to deceased donation.

III. OPTN Living Donor Policy Making Authority—Donor Evaluation

Supportive comments varied in their level of support for OPTN involvement in developing policies for living donor evaluation. Of the 17 comments that were supportive, two were opposed to OPTN policymaking in this area. One comment from a representative of the professional organization for transplant surgeons and another from a transplant surgeon asserted that the OPTN should not develop policy in the area of donor evaluation because there is no clear clinical consensus regarding the policies or standards that should be followed. HRSA believes it is very likely that should the OPTN consider policy making in the area of living donor evaluation that members of OPTN committees and the Board of Directors will consider this perspective and abandon policy making in the absence of clear clinical consensus. Additionally, through its public comment process transplant professionals also have the opportunity to advise the OPTN of the lack of clear clinical consensus, should it exist.

IV. OPTN Living Donor Policy Making—Living Donor Follow-up

Several comments stated greater attention should be given to understanding the impact of donation on living donors. One commenter who represents the professional organization for transplant professionals recommended more Federal funding for a live organ donor database. A comment from a living donor who is a healthcare professional and living donor advocate asserted that there should be mandatory policies to protect living donors and a central source of outcome data via a living donor registry. A comment from a transplant surgeon supports more OPTN involvement in living donor data collection and monitoring living donor outcomes. A comment from a representative of a healthcare accreditation organization stated it is appropriate for the OPTN to establish additional policies to promote the safety of living donor transplantation. A

comment from the mother of a living donor and recipient who both experienced post-transplant complications asserted that stronger policies should be developed to ensure living donor safety.

Conclusion

HRSA has reviewed and considered each aspect of each comment and has determined that OPTN living donor guidelines should be given the same status of other OPTN policies as discussed in the **Federal Register** Notice published on January 23, 2006. Under 42 CFR 121.4(a)(6), the Secretary directs the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule. Thus, the OPTN shall develop such policies in the same manner, and with the same public comment process, that it does for policies on deceased organ donors and deceased organ donor recipients. Non-compliance with such policies shall subject OPTN members to the same consequences as noncompliance with policies concerning deceased organ donors and deceased organ donor recipients developed under the final rule.

Dated: June 9, 2006.

Elizabeth M. Duke,

Administrator.

[FR Doc. E6–9401 Filed 6–15–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed 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 following meeting.

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 Human Genome Research Institute Special Emphasis Panel; Sequencing Centers Review.

Date: July 13, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Hotel Rouge, 1315 16th Street, NW., Washington, DC 20036.

Contact Person: Rudy O. Pozzatti, PhD, Scientific Review Administrator, Office of Scientific Review, National Human Geonome Research Institute, National Institutes of Health, Bethesda, MD 20892. 301–402–0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: June 12, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–5471 Filed 6–15–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meetings

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 following meetings.

The meetings 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 Institute of Child Health and Human Development Special Emphasis Panel; Gonadotropin Inhibitors: A Structural Biology Approach To Immunocontraception.

Date: July 6, 2006.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892. (301) 435–6884. *ranhandj@mail.nih.gov*.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Global Profiling of Molecular Errors Associated With Human Spermatogenic Disorder.

Date: July 6, 2006.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892. (301) 435–6884. *ranhandj@mail.nih.gov*.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Immunodominant Ovarian Antigens Involved in Premature Ovarian Failure.

Date: July 7, 2006.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892. (301) 435–6884. *ranhandj@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 12, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–5470 Filed 6–15–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5U.S.C. Appendix 2), notice is hereby given of the following meeting.

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