TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Form No.	No. of Recordkeepers	Annual Frequency per Recordkeeping	Hours per Recordkeeper	Total Hours
361.1(c)(2)	FDA 2914 and 2915	100	1 per qtr = 4 per yr	10	1,000
Total					1,000

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

Dated: April 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–9705 Filed 4–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0109]

Determination of Regulatory Review Period for Purposes of Patent Extension; LEVAQUIN™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LEVAQUIN™ 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 drug 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 Commissioner 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 LEVAQUIN™ (levofloxacin). LEVAQUIN™ is indicated for the treatment of adults (≥ 18 years of age) with mild, moderate, and severe infections caused by susceptible strains of the designated microorganisms in the conditions: Acute maxillary sinusitis due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis*; Community-acquired pneumonia due to *Staphylococcus aureus, S. pneumoniae, H. influenzae, H. parainfluenzae, Klebsiella pneumoniae, M. catarrhalis, Chlamydia pneumoniae, Legionella pneumophila,* or *Mycoplasma pneumoniae*; Uncomplicated skin and skin structure infections (mild to moderate) including abscesses, cellulitis, furuncles, impetigo, pyoderma, wound infections, due to *S. aureus* or *S. pyrogenes*; Complicated urinary tract infections (mild to moderate) due to *Enterococcus faecalis, Enterobacter cloacae, Escherichia coli, K. pneumoniae, Proteus mirabilis,* or *Pseudomonas aeruginosa*; Acute pyelonephritis (mild to moderate) caused by *E. coli.* Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LEVAQUIN™ (U.S. Patent No. 5,053,407) from Daiichi Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 18, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LEVAQUIN™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LEVAQUIN™ is 2,059 days. Of this time, 1,693 days occurred during the testing phase of the regulatory review period, 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) became effective*: May 4, 1991. The applicant claims May 3, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 4, 1991, 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 of the Federal Food, Drug, and Cosmetic Act*: December 21, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for LEVAQUIN™ NDA 20–634 was initially submitted on December 21, 1995.

3. *The date the application was approved*: December 20, 1996. FDA has verified the applicant's claim that NDA 20–634 was approved on December 20, 1996.

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 811 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 15, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 13, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 31, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–9703 Filed 4–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: April 21, 1998.

Time: 3 p.m.

Place: Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Rehana A. Chowdhury, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–6470.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: April 27, 1998.

Time: 2 p.m.

Place: Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Phyllis D. Artis, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–6470.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: May 1, 1998.

Time: 8:30 a.m.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Richard Johnson, Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1340.

The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: April 8, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–9715 Filed 4–13–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of meetings of the National Institute of Neurological Disorders and Stroke (NINDS).

The National Advisory Neurological Disorders and Stroke Council meeting will be open to the public as indicated below. Attendance by the public will be limited to space available.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of meetings, rosters of committee members, and other information pertaining to the meetings can be obtained from the Executive Secretary or the Scientific Review Administrator indicated. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary or the Scientific Review Administrator listed for the meeting.

Name of Committee: The Planning Subcommittee of the National Advisory Neurological Disorders and Stroke Council.

Date: May 27, 1998.

Place: National Institutes of Health, Building 31, Conference Room 8A28, 9000 Rockville Pike, Bethesda, MD 20892.

Closed: 1:30 p.m. to recess.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.

Date: May 28–29, 1998.

Place: National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

Open: May 28, 8:30 a.m. to recess.

Agenda: A report by the Acting Director, NINDS; a report by the Director, Division of Extramural Activities, NINDS; a report by the Director, Office of Extramural Research, OD; and a scientific presentation by an NINDS grantee.

Closed: May 29, 8:30 a.m. to adjournment.

Executive Secretary: Constance W. Atwell, Ph.D., Director, Division of Extramural Activities, NINDS, National Institutes of Health, Bethesda, MD 20892, Telephone: (301) 496–9248.

The following meetings will be totally closed to review and evaluate grant applications:

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group (Neurological Sciences and Disorders A).

Date: June 18–19, 1998.

Time: June 18, 8:30 a.m. to recess; June 19, 8:30 a.m. to adjournment.

Place: Wyndham Bristol Hotel, 2430 Pennsylvania Avenue, N.W., Washington, DC 20037.

Contact Person: Dr. Katherine Woodbury, Scientific Review Administrator, Scientific Review Branch, NINDS, National Institutes of Health, Federal Building, Room 9C–10, Bethesda, MD 20892, (301) 496–9223.

Name of Committee: Training Grant and Career Development Review Committee.

Date: June 19, 1998.

Time: 8:00 a.m. to adjournment.

Place: Wyndham Bristol Hotel, 2430 Pennsylvania Avenue, N.W., Washington, DC 20037.

Contact Person: Dr. Alfred W. Gordon, Scientific Review Administrator, Scientific Review Branch, NINDS, National Institutes of Health, Federal Building, Room 9C–10, Bethesda, MD 20892, (301) 496–9223.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group (Neurological Sciences and Disorders B).