product receives marketing exclusivity, FDA will not approve (or, in limited cases, even receive) an ANDA for the drug product during that time period.

Respondents to this collection of information are new drug and abbreviated new drug applicants.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
314.50(i)	8	1	8	2	16
314.50(j)	50	1	50	2	100
314.52	8	1	8	8	64
314.53	200	1	200	1	200
314.54(a)(1)(vii)	8	1	8	1	8
314.70(f)	43	1	43	1	43
314.94(a)(12)	395	1	395	2	790
314.95	30	1	30	16	480
314.107(c)(4), (e)(2)(iv), (f)(2), (f)(3)	30	1	30	1	30
Total					1,731

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

This estimate is based on FDA's experience over the last 3 years in receiving this information, and the familiarity by FDA reviewers with the amount of time it takes to prepare and submit the information to FDA.

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32553 Filed 12–11–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0320]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Filing Objections and Requests for a Hearing on a Regulation or Order'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 6, 1997 (62 FR 42257 to 42258), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0184. The approval expires on September 30, 2000.

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32583 Filed 12–11–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0443]

Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide'' (compliance guide). This compliance guide is intended to help small entities comply with the final rule requiring label warnings and unit-dose packaging for iron-containing supplements and drug products. This action is being taken under the Small Business Regulatory Enforcement Fairness Act of 1996 (the SBREFA).

DATES: Written comments on the compliance guide may be submitted at any time.

ADDRESSES: An electronic version of the compliance guide entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide'' is available on the Internet at ''http://vm.cfsan.fda.gov/~dms/secqiron.html''. Printed copies may be obtained from the Iron Labeling and Packaging, Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Submit written comments on the compliance guide to the contact person below.

FOR FURTHER INFORMATION CONTACT: Linda S. Kahl, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3101.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 15, 1997 (62 FR 2218), FDA issued a final rule requiring: (1) Label warning statements on products taken in solid oral dosage form to supplement the dietary intake of iron or to provide iron for therapeutic purposes and (2) unit-dose packaging for iron-containing products that contain 30 milligrams or more of iron per dosage unit. This final rule became effective July 15, 1997.

FDA is announcing the availability of a compliance guide entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide'' under the SBREFA (Pub. L. 104–121). This compliance guide is intended to help small businesses comply with the requirements of the new rule, and it restates in plain language the legal requirements set forth in the current regulation for labeling and packaging of iron-containing supplements and drug products. Any statement in this compliance guide that goes beyond merely restating the applicable legal requirements represents the agency's current thinking on this subject. The regulation is binding and has the force and effect of law; however, this compliance guide does not, itself, create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Dated: November 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32552 Filed 12–11–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: Acute Infection and Early Disease Research Network (AIEDRN).

Date: January 9, 1998.

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

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815, (301) 656–1500.

Contact Person: Dr. Allen C. Stoolmiller, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C05, Bethesda, MD 20892, (301) 496–7966.

Purpose/Agenda: To evaluate contract proposals.

The meeting will be closed in accordance with the provisions set forth in secs. 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.

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health.)

Dated: December 5, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–32470 Filed 12–11–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Promotion of Homologous Recombination DNA Pairing by RecA And RecA Peptides

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This notice is accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(I) that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to practice the inventions embodied in U.S. Patents No. 5,460,941, entitled, ''Method of Targeting DNA'' and 5,510,473, entitled, ''Cloning of the RecA Gene From Thermus Aquaticus YT–1'', U.S. Patent Applications Serial Numbers 08/446,413, entitled, ''Cloning of the RecA Gene From Thermus Aquaticus YT–1'', 08/483,115 entitled, ''Promotion of Homologous Recombination DNA Pairing By Rec-A-Derived Peptides'', 60/001,384 and 08/682,305, ''Rec A Assisted Cloning of DNA'', and corresponding U.S. and foreign patent applications to the Pangene Corporation of Menlo Park, California. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or applications for a license which are received by NIH on or before February 10, 1998 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: Raphe Kantor, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804. Telephone: (301) 496–7735 ext. 247; Facsimile: (301) 402–0220. A signed Confidentially Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: This technology covers methodology for inducing sequence-specific homologous recombination between an exogenous DNA sequence and the corresponding genomic DNA sequence by use of the *E. coli* RecA protein. The RecA protein brings together an exogenous DNA sequence and a corresponding genomic DNA sequences for homologous recombination. A peptide of RecA can be substituted for the entire *E. Coli* RecA protein to target a double-strand of DNA or to inhibit transcription of a given gene. The ability of a RecA peptide to induce homologous recombination gives this technology broad commercial applicability. The peptide can be used in site-specific targeting of DNA sequences for purposes of cleavage, protection or enrichment as a research reagent, a diagnostic tool or for use in gene therapy.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use of this exclusive license may be limited to human therapeutics.

Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated licenses. Comments and objections submitted to this notice will not be available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 1, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–32469 Filed 12–11–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4263–N–62]

Submission for OMB Review: Comment Request

AGENCY: Office of Administration, HUD.