approximately $6,250 (25 submissions per year x 2 pages = 50 pages x $125 per page = $6,250).

Dated: February 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2489 Filed 2–13–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N -0431]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substantial Evidence of Effectiveness of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 16, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR 514.4(a) (OMB Control Number 0910–0356)—Extension

Section 512(d)(1)(E) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(d)(1)(E)), requires FDA to issue an order refusing to approve a new animal drug application (NADA), if there is a lack of substantial evidence that a new animal drug will have the effect it is purported or represented to have under the conditions of use prescribed in the proposed labeling. Therefore, substantial evidence must be submitted to us as part of the NADA to establish effectiveness of a drug. Section 21 CFR 514.4(a) specifies requirements for submitting adequate and well-controlled studies to provide substantial evidence of effectiveness for a new animal drug. This information collection requirement provides for submissions of substantial evidence of effectiveness information via electronic submissions to the Center for Veterinary Medicine (CVM).

CVM is continuously seeking ways through advances in information technology to reduce the burden on the government and sponsors. The Center continues to look at what information can be submitted electronically and will permit electronic submission of data to NADA files as technology and resources permit.

In the **Federal Register** of November 2, 2006 (71 FR 64535), FDA published a 60-day notice in the **Federal Register** soliciting public comment on the proposed collection of information collection requirements. In response to that notice, no comments were received.

The likely respondents for this collection of information are sponsors of NADA applications.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.4(a)	190	4,546	860	632.6	544,036

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

The estimate for the annual reporting burden for this collection of information was derived from discussion with industry and agency records.

Dated: February 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2497 Filed 2–13–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Bureau of Primary Health Care (BPHC) Uniform Data System (OMB No. 0915–0193) Revision

The Uniform Data System (UDS) contains the annual reporting requirements for the cluster of primary care grantees funded by the Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Public Housing Primary Care, and other grantees under Section 330.

The authorizing statute is Section 330 of the Public Health Service Act, as amended.

HRSA collects data in the UDS which is used to ensure compliance with legislative mandates and to report to Congress and policy makers on program accomplishments. To meet these objectives, BPHC requires a core set of data collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Universal Report	1,002	1	1002	27	27,054
Grant Report	234	1	234	18	4,212
Total	1,002	.....	1,326	.....	31,266

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 2, 2007.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

[FR Doc. E7–2553 Filed 2–13–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Field of Use: Development of a Live Microbicide for Preventing Sexual Transmission of HIV

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

ACTION: Notice.

SUMMARY: This is notice, in 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 license to practice the invention embodied in:

(1) U.S. Patent No. 5,821,081, filed April 26, 1996, issued Oct. 13, 1998, entitled ''Nucleic Acids Encoding Antiviral Proteins and Peptides, Vectors and Host Cells Comprising Same, and Methods of Producing the Antiviral Proteins and Peptides'' (E–117–1995/1–US–01) (Inventors: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker, and James B. McMahon) (NCI);

(2) U.S. Patent No. 5,843,882, filed April 27, 1995, issued Dec. 01, 1998, entitled ''Antiviral Proteins and Peptides, DNA, DNA-coding Sequences Therefore, and Uses thereof '' (E–117–1995/0–US–01) (Inventors: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker, and James B. McMahon) (NCI);

(3) U.S. Patent No. 5,998,587, filed Nov. 13, 1997, issued Dec. 7, 1999, entitled ''Anti-cyanovirin Antibody'' (E–117–1995/1–US–02) (Inventors: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker, and James B. McMahon) (NCI);

(4) U.S. Patent No. 6,015,876, filed Oct. 27, 1999, issued Jan. 18, 2000, entitled ''Method of Using Cyanovirins'' (E–117–1995/0–US–02) (Inventor: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker, and James B. McMahon) (NCI);

(5) U.S. Patent No. 6,780,847, filed March 22, 2001, issued August 24, 2004, entitled ''Glycosylation-Resistant Cyanovirins and Related Conjugates, Compositions, Nucleic Acids, Vectors, Host Cells, Methods of Production and Methods of Using Nonglycosylated Cyanovirins'' (E–074–1999/3–US–01) (Inventors: Michael R. Boyd, Barry O'Keefe, Toshiyuki Mori (NCI) and Angela Gronenborn (NIDDK));

(6) U.S. Patent No. 7,048,935, filed July 1, 2002, issued May 23, 2006, entitled ''Cyanovirin Conjugates and Matrix-Anchored Cyanovirin and Related Compositions and Methods of Use'' (E–074–1999/1–US–03) (Inventor: Michael R. Boyd (NCI);

(7) U.S. Patent No. 7,105,169, filed September 12, 2001, issued September 12, 2006, entitled ''Cyanovirins Conjugates and Matrix-Anchored Cyanovirins and Methods of Use'' (E–074–1999/1–US–02) (Inventor: Michael R. Boyd (NCI);

(8) U.S. Patent No. 6,743,577, filed October 27, 1999, issued June 1, 2004, entitled '' Methods of Using Cyanovirins to Inhibit Viral Infection'' (E–074–1999/0–US–03) (Inventor: Michael R. Boyd (NCI);

(9) U.S. Patent No. 6,420,336, filed October 27, 1999, issued July 16, 2002, entitled ''Methods Of Using Cyanovirins Topically To Inhibit Viral Infection'' (E–074–1999/3–US–01) (Inventor: Michael R. Boyd (NCI)

to Osel, Inc. (Hereafter Osel), having a place of business in Santa Clara of California. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before April 16, 2007 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Sally Hu, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; E-mail: *hus@od.nih.gov*; Telephone: (301) 435–5606; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: 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 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.

Cyanovirin-N (CV-N) is a novel, naturally occurring anti-HIV protein that was originally isolated from *Nastoc ellipipsosporum,* a blue-green algae. Cyanovirin is a protein with potent neutralizing activity against HIV1 and 2 by blocking the fusion reaction between HIV and CD4 target cells. Cyanorvirin is in the pre-IND development phase with several animal toxicology and irritation studies completed; initial chemical purification processes developed; and no human data to date. Dr. Boyd and his colleagues have demonstrated that a simple aqueous gel formulation of CV-N completely protected macaques against intravaginally or intarectally transmitted SHIV 89–9P (a chimeric simian/human immunodeficiency virus that causes ''AIDS'' in simians). Also importantly, there was no indication of any toxicity or other adverse effects of the CV-N to the macaques in these