section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before July 11, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 22, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–15167 Filed 6–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Product, Establishment, and Biologics License Applications, Refusal to File; Meeting of Oversight Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the remaining 1997 meetings of its standing oversight committee in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's), establishment license applications (ELA's), and biologics license applications (BLA's). CBER's RTF oversight committee examines all RTF decisions which occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions.

DATES: The next meetings will be held on July 8, 1997, and October 14, 1997.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–5), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 15, 1995 (60 FR 25920), FDA announced the establishment and first meeting of CBER's standing oversight committee. As explained in the notice, the importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority. CBER's managed review process focuses on specific milestones or intermediate goals to ensure that a quality review is conducted within a specified time period. CBER's RTF oversight committee continues CBER's effort to promote the timely, efficient, and consistent review of PLA's, ELA's, and BLA's.

FDA regulations on filing PLA's, ELA's, and BLA's are found in 21 CFR 601.2 and 601.3. A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter may ask that the application be filed over protest, similar to the procedure for drugs described under 21 CFR 314.101(a)(3).

CBER's standing RTF oversight committee consists of senior CBER officials, a senior official from FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and Ombudsman. Meetings will ordinarily be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions. If there are no RTF decisions to review, however, the meeting may be cancelled. FDA intends to post any meeting cancellation on the CBER home page at http://www.fda.gov/cber/confmeet.htm. Publication of any meeting cancellation will be made only as time permits.

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all such confidential commercial information omitted, may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If, following the committee's review, an RTF decision changes, the appropriate division within CBER will notify the sponsor.

Dated: June 4, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–15165 Filed 6–10–97; 8:45 am]

BILLING CODE 4160–01–F

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 35, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to 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, 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: The Health Education Assistance Loan (HEAL) Program Regulations—42 CFR part 60—0915–0108—Extension, No Change

This clearance request is for extension of approval for the notification, reporting and recordkeeping requirements in the HEAL program to insure that the lenders, holders and schools participating in the HEAL program follow sound management procedures in the administration of federally-insured student loans. While the regulatory requirements are approved under this OMB number, much of the burden associated with the regulations is cleared under the OMB numbers for the HEAL forms used to report required information (listed below). The table listed at the end of this notice contains the estimate of burden for the remaining regulations.

Annual Response Burden for the following regulations is cleared by OMB when the reporting forms are cleared:

OMB Approval No. 0915–0034, Lender's Application, Borrower Status, Manifest, Loan Transfer, Contract for Loan Insurance:

Reporting
- 42 CFR 60.7(c)(3), Employer certification of nonstudent status
- 42 CFR 60.31(a), Lender annual application
- 42 CFR 60.38(a), Loan reassignment

Notification
- 42 CFR 60.12(c)(1), Borrower deferment

OMB Approval No. 0915–0036, Lender's Application for Insurance Claim:

Reporting
- 42 CFR 60.35(a)(2), Lender skip-tracing activities
- 42 CFR 60.40(a), Lender documentation to litigate a default
- 42 CFR 60.40(c)(1) (i), (ii), and (iii), Lender default claim
- 42 CFR 60.40(c)(2), Lender death claim
- 42 CFR 60.40(c)(3), Lender disability claim
- 42 CFR 60.40(c)(4), Lender report of student bankruptcy

OMB Approval No. 0915–0038, Student Application

Reporting
- 42 CFR 60.7(a)(1)(ii), Student application
- 42 CFR 60.7(a)(3), School section of the application
- 42 CFR 60.51(a), School section of the application

Notification
- 42 CFR 60.7(a)(2), Federal debt collection policies—student
- 42 CFR 60.33(c), Creditworthiness of applicant

OMB Approval No. 0915–0043, Promissory Note, Repayment Schedule, Call Report

Notification
- 42 CFR 60.7(c)(2) Federal debt collection policies—nonstudent
- 42 CFR 60.11(e), Establishment of repayment terms—borrower
- 42 CFR 60.11(f)(5), Borrower notice of supplemental repayment agreement
- 42 CFR 60.33(e), Executed note to borrower
- 42 CFR 60.34(b)(1), Establishment of repayment terms—lender

OMB Approval No. 0915–0204, Physician's Certification of Permanent and Total Disability

Reporting
- 42 CFR 60.39(b)(2), Holder request to Secretary to determine borrower disability

The estimate of burden for the regulatory requirements of this clearance are as follows:

TABLE OF REGULATORY SECTIONS AND RESPONDENT BURDEN

Type of burden	Transactions per year	Estimated time per transaction	Annual response burden (hours)
REPORTING			
Subpart D: Lender—32 Participating Lenders			
60.32(b) Application for Loan	[1]0	0.00	0
60.40(c)(1)(iv) Bankruptcy Report to the Secretary	140	12 min.	28
60.42(d) Audit	32	240 min. (4 hrs.)	128
60.42(e) Evidence of Fraud	3	120 min. (2 hrs.)	6
60.43(b) Evidence of Cause for Administrative Hearing	2	180 min. (3 hrs.)	6
Subtotal	177		168
Subpart E: School—190 Participating Schools			
60.56(c) Biennial Audit	190	240 min. (4 hrs.)	760
60.60(b) Evidence of Cause for Administrative Hearing	3	180 min. (3 hrs.)	9
60.61(b) Evidence of Fraud	0.00	0.00	0.00
60.61(d) Bankruptcy Documentation	140	10 min.	23
Subtotal	333		792
Total Reporting			960
NOTIFICATION			
Subpart B: Borrower—20,640 Borrowers			
60.0(a)(5) Sale or Transfer of Loan		Burden included in 60.38a	
60.8(b)(3) Status change	20,500	10 min.	3,417
60.61(d)* Bankruptcy	140	10 min.	23
Subtotal	20,640		3,440

TABLE OF REGULATORY SECTIONS AND RESPONDENT BURDEN—Continued

Type of burden	Transactions per year	Estimated time per transaction	Annual response burden (hours)
Subpart C: Loan/Lender—32 Participating Lenders			
60.18 Loan Consolidation	5,000	40 min.	3,333
60.21(b)(2) Refund Check Transfer	1,000	30 min.	500
60.21(b)(2) Refund Check Notification	1,000	15 min.	250
Subpart D: Lender—32 Participating Lenders			
60.33(g) Denial of Loan	133	14 min.	31
60.33(h) Borrower Indebtedness	15,227	1 min.	254
60.34(c) Biannual Debt Status	250,000	10 min.	41,667
60.35(a)(1) Delinquent Payment Notice to Borrower	9,500	30 min.	4,750
60.35(c)(2) Delinquent Notice to Credit Reporting Agency	1,300	15 min.	325
60.35(e) Demand Letter	1,300	10 min.	217
60.37(a) Right to Forbearance	2,400	5 min.	200
60.37(c)(3) Reminder of obligation to pay	1,200	10 min.	200
60.38(a) Notification to Borrower of Loan Reassignment	7,500	5 min.	625
60.40(c)(1)(iv) and (c)(4) Default Notification to Courts	140	25 min.	58
Subtotal	295,700		51,915
Subpart E: School—190 Participating Schools			
60.53 Change in Student Status	Burden included with 60.61(a)(7)		
60.54 Notice of Refund Payment	190	25 min.	79
60.57 Borrower Identifying Information	1,240	8 min.	165
60.61(a)(1) Entrance Interview	6,818	35 min.	3,977
60.61(a)(2) Exit Interview	6,818	50 min.	5,682
60.61(a)(2) Student Departure Notification to Lender	190	35 min.	111
60.61(a)(3) Unresolved Discrepancies to Lender	204	12 min.	41
60.61(a)(7) Change in Student Address to Lender	10,227	10 min.	1,705
Subtotal	25,687		11,760
Total Notification			67,115
RECORDKEEPING			
Subpart B: Borrower			
60.7(a)(2) Student Signed Stmt.-Gov. Debt Collection Procedures	Burden included in 60.34(b)(2) and 60.61(a)(1)&(2)		
60.7(c)(2) Non-Student signed Stmt.-Gov. Debt Collection	0.00		0.00
Subpart D: Lender—32 Participating Lenders			
60.31(c) Procedures for Servicing & Collecting Loans	32	240 min. (4 hrs.)	128
60.33(e) Promissory Note	Burden included in 60.42(a)(2)		
60.34(b)(2) Terms of Repayment Schedules	15,227	5 min.	1,269
60.35(a)(1) Attempts to Collect Delinquent Payment	10,000	5 min.	833
60.35(a)(2) Documentation of Skip-tracing	2,500	10 min.	417
60.37(a)(1) Documentation of Borrower's Inability to Pay	2,500	15 min.	625
60.37(c) Renewals of Forbearance	1,200	10 min.	200
60.37(c)(1) Basis for Belief of Borrower Itent to Default	300	10 min.	50
60.40(a) Documentation of Insurance Claims	978	70 min.	1,141
60.42(a)(1) Loan Records	Burden included in 60.42(a)(2)		
60.42(a)(2) Borrower's Payment History	133,500	15 min.	33,375
Subtotal	166,237		38,038
Subpart E: School—190 Participating Schools			
60.51(f)(1) Documentation of Needs Analysis Adjustment	Burden included in 60.61(a)(5)		
60.51(f)(2) Documentation of Standard Student Budget Adjustments	Burden included in 60.61(a)(5)		
60.56(a) Required Retention of HEAL Borrower Records	Burden included in 60.61(a)(5)		
60.56(b) Five year Retention of Student Records	Burden included in 60.61(a)(5)		
60.57 Retention of Reports to the Secretary	190	45 min.	143
60.61(a)(1) Entrance Interview	6,8185 min.	568.	
60.61(a)(2) Exit Interview	6,818	5 min.	568
60.61(a)(4) HEAL Check Receipt	190	300 min. (5 hrs.)	950
60.61((a)(5) Complete Records of HEAL Borrowers	133,500	15 min.	33,375
60.61(a)(6) Criteria for Student Budgets	10,227	2 min.	341
Subtotal	154,743		35,945
Total Recordkeeping			73,983

TABLE OF REGULATORY SECTIONS AND RESPONDENT BURDEN—Continued

Type of burden	Transactions per year	Estimated time per transaction	Annual response burden (hours)
Total Annual Burden			142,058

[1] No new HEAL loans.
[2] Burden is from Subpart E—School.

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: June 3, 1997.

James J. Corrigan,

Acting Associate Administrator for Management and Program Support.

[FR Doc. 97–15278 Filed 6–10–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Methods for Detecting Cervical Cancer

T Ried et al. (NHGRI)
U.S. Patent Serial No. 08/781,424 filed 10 Jan 97
Licensing Contact: Mary Savagner, 301/496–7735 ext. 205

Last year, nearly 16,000 women in the United States were diagnosed with invasive cervical carcinoma and nearly 5,000 women died from the disease. While the widespread promotion and use of the Pap smear has contributed to the reduced mortality rate associated with the disease over the last 30 years, there is still a need for improvement and optimization of the screening process. Despite tremendous efforts, the automated analysis of cervical PAP smears based on cytopathological stains has not been achieved. Also, cytopathological analyses reveal insufficient information to predict disease progression.

This invention provides a method of detecting the presence of invasive cervical carcinoma by detecting in a cervical cell taken from a patient the presence of a chromosomal aberration indicating the presence of invasive cervical carcinoma. The invention also provides a method of diagnosing advanced-stage cervical carcinoma in a patient as well as a method of classifying the progression of dysplastic cervical cells from non-invasive to invasive cervical carcinoma. In addition, the invention provides kits comprising nucleic acids that specifically hybridize in chromosome 3q and specifically hybridize to another chromosome, and to compositions comprising nucleic acids. (portfolio: Cancer—Diagnostics, in vitro, other)

Chimeric Nucleic Acid Sequences Encoding attenuated Hepatitis A Viruses and the Use of These Sequences and Viruses as Vaccines

SU Emerson, SA Harmon, E Ehrenfeld, DF Summers (NIAID)
Serial No. 08/547,482 filed 24 Oct 95
Licensing Contact: Gloria Richmond, 301/496–7056 ext. 268

This invention is directed to chimeric hepatitis A viruses, containing mutations in the 2A gene, which will be used as the basis for an attenuated vaccine for humans. The mutations in the 2A gene are unusual because they are not naturally occurring mutations but were engineered into an infectious cDNA clone. These mutations in 2A are able to decrease pathology substantially and offer the opportunity of constructing a virus that will induce effective immunity without causing disease. Sales of the inactivated vaccine in Europe have demonstrated the commercial importance of a vaccine for hepatitis A. An attenuated vaccine would be more economical and easier to administer. (portfolio: Infectious Diseases—Vaccines, viral, non-AIDS)

Vaccine for Dengue Virus

C–J Lai, M Bray, AG Pletnev, R Men, Y–M Zhang, KH Eckels (NIAID)
Serial No. 08/250,802 filed 27 May 94
Licensing Contact: Gloria H. Richmond, 301/496–7056 ext 268

The claimed invention relates to recombinant modified or viable chimeric dengue viruses for use as vaccines against dengue and other flavivirus disease, including tick-borne encephalitis. Dengue is a mosquito-transmitted viral disease which occurs in tropical and subtropical regions throughout the world. Inactivated whole dengue virus vaccines have been shown to be insufficiently immunogenic and live dengue virus vaccines prepared by serial passage in cell culture have not been shown to be consistently attenuated. A dengue vaccine is still not available. The present invention represents a technical breakthrough, which provides new approaches to dengue vaccines by construction of chimeric dengue viruses of all four serotypes and strategic modification to produce attentuated virus strains. Several fields of use remain available for licensing. (portfolio: Infectious Diseases—Vaccines, viral, non-AIDS)

Parvovirus B19 Receptor and Parvovirus B19 Detection

N Young, K Brown (NHLBI)
Serial No. 08/034,132 filed 22 Mar 93; U.S. Patent 5,449,608 issued 12 Sep 95
Licensing Contact: Gloria H. Richmond, 301/496–7056 ext 268

The claimed invention provides a method of detecting the presence of a parvovirus in a sample. Parvoviruses infect animals and man. In man, the only known pathogenic member of this family is parvovirus B19. The inventors have identified the parvovirus B19 receptor which provides for a method to diagnose, prevent, and treat parvovirus infection utilizing the binding affinity for the receptor. (portfolio: Infectious