Dated: August 19, 2003.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–21733 Filed 8–25–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0361]

Anti-counterfeit Drug Initiative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a docket to receive information and comments on the agency's initiative against counterfeit drugs. Many individuals, vendors, trade and professional associations, consumer groups, and other stakeholders have offered to assist FDA. This action is intended to ensure that there is a venue for information and comments to be submitted to the agency regarding the anti-counterfeit initiative.

DATES: The agency encourages interested parties to submit information by November 30, 2003.

ADDRESSES: Submit written comments and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* All comments submitted to the public docket are public information and may be posted to FDA's Web site (*http://www.fda.gov*) for public viewing. Please include the docket number listed in the heading of this document on all correspondence related to this docket.

FOR FURTHER INFORMATION CONTACT: Poppy Kendall, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, *e-mail: pkendall@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Counterfeit drugs pose potentially serious public health and safety concerns. They may contain only inactive ingredients, incorrect ingredients, improper dosages, or even dangerous subpotent or superpotent ingredients. In the United States, drug counterfeiting is a relatively rare event. Although FDA believes domestic counterfeiting is not widespread, the agency has recently seen an increase in counterfeiting activities as well as a more sophisticated ability to introduce finished dosage counterfeits into the otherwise legitimate drug distribution channels. FDA has seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about 5 per year through the late 1990's.

In an effort to protect against the rising occurrence of potentially unsafe counterfeit drugs reaching consumers, on July 16, 2003, FDA announced an initiative to more aggressively protect American consumers from the risks posed by counterfeit drugs. As part of this effort, FDA established an internal task force that will develop recommendations for steps FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs getting into the supply chain. Some of the areas that FDA's task force will explore include the following topics:

- *Technology:* Assess the extent to which new technologies can help assure the authenticity of drugs;
- *Regulatory/Legislative Issues:* Will evaluate potential regulatory and legislative changes that could be made to strengthen the nation's protections against counterfeiting;
- *Public Education:* Recommend ways to educate consumers and health providers on steps they can take to minimize risks associated with counterfeit drugs; will also educate consumers and health professionals about what to look for and what to do if they suspect they have received a counterfeit drug;
- *Industry and Health Professional Issues:* Identify actions industry and health professionals can take to prevent, detect, and respond to counterfeit drugs;

The task force has the following deliverables:

- Interim task force report to be released in September 2003. It will include draft recommendations on which interested persons may comment.
- Public meeting to be held in mid-October 2003. The meeting announcement will be published in a forthcoming **Federal Register** and will pose issues for discussion at the meeting.
- Final task force report to be released in January 2004.

Many individuals, vendors, trade and professional associations, consumer groups, and other stakeholders have offered to assist the agency and provide information that may be helpful in the agency's anti-counterfeit drug efforts. The agency requests that all persons or organizations that would like to provide such information submit it to this docket number.

FDA expects to place submissions it receives on this initiative in the public docket. Therefore, submitters should recognize that information submitted to this docket is public information and can be viewed and accessed by the general public.

Note that, as mentioned previously, the counterfeit task force expects to issue a report with draft recommendations for public comment in September of this year. In addition, the agency expects to hold a public meeting on these issues later this year as well. Comments on the draft report and the issues discussed at the public meeting will sought in future issues of the **Federal Register**.

Dated: August 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21751 Filed 8–25–03; 8:45 am]

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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 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: The Health Education Assistance Loan (HEAL) Program: Forms—0915–0108—Extension

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 and electronic submissions 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 Contract Application and Borrower Deferment Forms, and Borrower Loan Status and Loan Transfers/Purchases and Consolidation Tape Specification and Submission

Reporting

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)(1), Lender due-diligence activities

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)(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. 0915–0043, Promissory Note, Repayment Schedule, Call Report

Notification 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

42 CFR 60.42(b), Lender Quarterly Report on HEAL Loans Outstanding (Call Report)

OMB Approval No. 0915–0204, Physicians Certification of Permanent and Total Disability

Reporting

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

OMB Approval No. 0915–0227, Federal Health Education Assistance Loan Refinancing Application/Promissory Note

Reporting

42 CFR 60.7, Application for loan

42 CFR 60.18 Consolidation of a HEAL loan

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—28 Participating Lenders			
60.32(b) & (c) Application for lender contract		0.00	0
60.40(c)(1)(iv) Bankruptcy Report to the Secretary	78	12 min	15
60.42(d) Audit	8	240 min. (4 hrs.)	32
60.42(e) Evidence of Fraud	0	120 min. (2 hrs.)	0
60.43(b) Evidence of Cause for Administrative Hearing	0	180 min. (3 hrs.)	0
Subtotal	86		47
Subpart E: School—190 Participating Schools			
60.56(c) Biennial Audit	0	0.00	0
60.60(b) Evidence of Cause for Administrative Hearing	0	0.00	0
60.61(b) Evidence of Fraud	0	0.00	0
60.61(d) Bankruptcy Documentation	78	10 min	13
Subtotal	78		13
Total Reporting			60
NOTIFICATION			
Subpart B: Borrower—7,930 Borrowers			
60.0(a)(5) Sale or Transfer of Loan		Burden included in 60.38a	
60.8(b)(3) Status Change	7,852	10 min	1,309

TABLE OF REGULATORY SECTIONS AND RESPONDENT BURDEN—Continued

Type of burden	Transactions per year	Estimated time per transaction	Annual response burden (hours)
60.61(d)* Bankruptcy	78	10 min	13
Subtotal	7,930		1,322
Subpart D: Lender—28 Participating Lenders			
60.33(g) Denial of Loan	0	14 min	0
60.33(h) Borrower Indebtedness	3,000	1 min	50
60.34(c) Biannual Debt Status	133,178	10 min	22,196
60.35(a)(1) Delinquent Payment Notice to Borrower	34,648	10 min	5,775
60.35(c)(2) Delinquent Notice to Credit Reporting Agency	8,662	10 min	1,443
60.35(e) Final Demand Letter	695	10 min	116
60.37(a) Right to Forbearance	3,000	5 min	250
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	78	25 min	32
Subtotal	191,961		30,687
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	0	25 min	0
60.57 Borrower Identifying Information	73	8 min	10
60.61(a)(1) Entrance Interview	0	35 min	0
60.61(a)(2) Exit Interview	73	50 min	61
60.61(a)(2) Student Departure Notification to Lender	190	35 min	111
60.61(a)(3) Unresolved Discrepancies to Lender	0	12 min	0
60.61(a)(7) Change in Student Address to Lender	73	10 min	12
Subtotal	409		194
Total Notification			32,203
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—28 Participating Lenders			
60.31(c) Procedures for Servicing & Collecting Loans	28	240 min (4 hrs.)	112
60.33(e) Promissory Note	Burden included in 60.42(a)(2)		
60.34(b)(2) Terms of Repayment Schedules	8,130	5 min	667
60.35(a)(1) Attempts to Collect Delinquent Payment	8,662	5 min	722
60.35(a)(2) Documentation of Skip-tracing	131	10 min	22
60.37(a)(1) Documentation of Borrower's Inability to Pay	2,065	15 min	516
60.37(c) Renewals of Forbearance	2,065	10 min	344
60.37(c)(1) Basis for Belief of Borrower Intent to Default	800	10 min	133
60.40(a) Documentation of Insurance Claims	695	70 min	811
60.42(a)(1) Loan Records	Burden included in 60.42(a)(2)		
60.42(a)(2) Borrower's Payment History	66,589	15 min	16,647
Subtotal	89,165		19,974
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			
60.57 Retention of Reports to the Secretary	190	45 min	143
60.61(a)(1) Entrance Interview			
60.61(a)(2) Exit Interview	73	5 min	6
60.61(a)(4) HEAL Check Receipt	0	300 min	0
60.61(a)(5) Complete Records of HEAL Borrowers	90,000	15 min	22,500
60.61(a)(6) Criteria for Student Budgets	190	10 min	32

TABLE OF REGULATORY SECTIONS AND RESPONDENT BURDEN—Continued

Type of burden	Transactions per year	Estimated time per transaction	Annual response burden (hours)
Subtotal	90,453		22,681
Total Recordkeeping			42,655
Total Annual Burden			74,918

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 16C–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 19, 2003.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–21752 Filed 8–26–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

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Proposed Project: Evaluation of the Implementation and Outcomes of the Maternal and Child Health Bureau's National Healthy Start Program—NEW

HRSA's Maternal and Child Health Bureau is planning to conduct a survey to collect information concerning Healthy Start, a community-based initiative, to understand how Healthy Start services are expected to change local health care systems and service delivery and ultimately affect maternal and child health outcomes. The purpose of the survey is to collect consistent and comprehensive information across current grantees about their Healthy Start program, its organizational configuration, community context, and the extent to which the program components address service needs and contribute to grantees meeting their Healthy Start goals. A two-part survey consisting of a mail component followed by a telephone follow-up is proposed. The mail survey will focus on obtaining descriptive and quantitative data that is currently not available. The phone survey will be used to obtain grantee assessments of program achievements, factors that facilitated their achievements, and challenges that they faced.

Data collection will cover information on the five service components (case management, health education, outreach, perinatal depression screening, and interconceptional care), and the four systems-building components (consortium, collaboration with Title V, local health systems action plan, and sustainability plan) that comprise the Healthy Start program. Data gathered from the survey will be used to provide HRSA the information necessary to assess the grantees' achievements of three core Healthy Start program goals: (1) Reduced racial and ethnic disparities in access to and utilization of health services; (2) improved local health care system; and (3) increased consumer or community voice in health care decisions. The survey will provide information that is currently unavailable from the service delivery and performance measure data. Based on the data collected in this survey, the National Evaluator will conduct cross-site analyses.

The estimated burden on respondents is as follows:

Respondents	Number of respondents	Hours per respondent	Total burden hour
Grantees	96	4 (assume mail and phone)	384