

necessary for a particular transdermal product.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Mary M. Fanning, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5845.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled "Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products." Transdermal products have properties that may lead to skin irritation and/or sensitization. The delivery system, or the system in conjunction with the drug substance, may cause these reactions. Skin irritation and skin sensitization studies are designed to detect irritation and sensitization under conditions of maximal stress and may be used during the assessment of transdermal drug product for ANDA's.

A draft guidance entitled "Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products" was published in the **Federal Register** of February 26, 1999 (64 FR 9516). Eight comments were received between February and April of 1999, and this guidance has been revised after careful consideration of those comments.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on skin irritation and sensitization testing of generic transdermal drug products. It does not 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 statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management

Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 24, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-1500]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Health Insurance Common Claims Forms and Supporting Regulations in 42 CFR 414.40, 424.32, and 424.44; *Form No.:* HCFA-1500, 1490U, and 1490S (OMB # 0938-0008); *Use:* This form is a standardized form for use in the Medicare/Medicaid programs to apply for reimbursement for covered services; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-

for-profit institutions; *Number of Respondents:* 1, 321, 417; *Total Annual Responses:* 717,876,097; *Total Annual Hours:* 44,460,460.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 24, 2000.

John P. Burke,

Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00-2425 Filed 2-2-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-1957]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of

automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection

Request: Extension of a currently approved collection;

Title of Information Collection: SSO Report of State Buy In Problems and Supporting Regulations in 42 CFR 407.40;

Form No.: HCFA-1957 (0938-0035);

Use: The HCFA-1957 is issued to assist with communications between the Social Security District Offices, Medicaid State Agencies and HCFA Central Offices in the resolution of beneficiary complaints, regarding entitlement under state buy-ins. It is used when a problem arises which cannot be resolved thru normal data exchange.

Frequency: On occasion;

Affected Public: State, Local or Tribal Government, and Individuals or Households;

Number of Respondents: 2,000;

Total Annual Responses: 2,000;

Total Annual Hours: 716.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-

14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 24, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00-2427 Filed 2-2-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Loan Repayment and Scholarship, Submission for OMB Review; Comment Request; National Institutes of Health Undergraduate Scholarship Program for Individuals From Disadvantaged Backgrounds

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of Loan Repayment and Scholarship, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 26, 1999, and allowed 60 days for public comment. One request for a copy of the data collection instrument was received and fulfilled. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: National Institutes of Health Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds (UGSP). *Type of Information Collection Request:* Revision of a previously approved collection (OMB No. 0925-0438, expiration date February 29, 2000). *Form Numbers:* NIH 2762-1, NIH 2762-2, NIH 2762-3, and NIH 2762-4. *Need and Use of Information Collection:* The NIH makes available scholarship awards to students from disadvantaged backgrounds who are committed to careers in biomedical research. The scholarships pay for tuition and reasonable educational and living expenses up to \$20,000 per academic year at an accredited undergraduate institution. In return, for each year of scholarship support, the recipient is obligated to serve as a full-time paid employee in an NIH research laboratory for 10 consecutive weeks during the months of June through August and for 1 year after graduation. If the recipient pursues a post-graduate degree (graduate, medical, dental, or veterinarian school), the post-graduation service obligation may be deferred with the approval of the Secretary, Department of Health and Human Services. The information proposed for collection will be used by the Office of Loan Repayment and Scholarship to determine an applicant's eligibility for participation in the UGSP. The UGSP is authorized by Section 487D of the Public Health Service (PHS) Act (42 USC 288-2), as amended by the NIH Revitalization Act of 1993 (Publ. L. 103-43). *Frequency of Response:* Initial application and annual renewal application. *Affected Public:* Applicants (high school or undergraduate students), recommenders, undergraduate institution financial aid staff. The annual reporting burden estimates are as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Applicant	250	1.0	3.167	791.75
Recommender	750	1.0	1.0	750.00
Financial Aid Staff	250	1.0	.5	125.00
Totals	1,250			1,666.75

The annualized cost to respondents is estimated at \$29,263.81. There are no capital costs, operating costs, or maintenance costs to report.

Request for comments: Written comments and/or suggestions from the

public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including

whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3)