

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A draft guidance entitled "Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products" was published in the **Federal Register** of February 26, 1999 (64 FR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.

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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