C. Intergovernmental Review of Federal Programs

This program is not covered by Executive Order 12372.

D. Application Process

(1) Application Submission by Mail:

Each application should include one signed original and two (2) copies of the grant application, including all attachments. Assurances and certifications must be completed. Submission of the application constitutes certification by the applicant that it is in compliance with Drug-Free Workplace and Debarment and these forms do not have to be submitted. The application must be hand delivered or mailed by the closing date to: U.S. Department of Health and Human Services, Administration for Children and Families, ACYF/Office of Grants Management 370 L'Enfant Promenade, S.W., Mail Stop HHH 326–F, Washington, DC 20447–0002, Attention: Lois B. Hodge—ANA No. 93612–002.

(2) Application Submission by Courier:

Hand delivered applications are accepted during the normal working hours of 8 a.m. to 4:30 p.m., Monday through Friday, on or prior to the established closing date at: Administration for Children and Families, ACYF/Office of Grants Management, ACF Mail Room, Second Floor Loading Dock, Aerospace Center 901 D Street, S.W., Washington, DC 20024, Attention: Lois B. Hodge, ANA No. 93612–002.

The application must be signed by an individual authorized: (1) To act for the applicant tribe, village or organization, and (2) to assume the applicant's obligations under the terms and conditions of the grant award.

(3) Application Consideration:

The Commissioner of the Administration for Native Americans determines the final action to be taken with respect to each grant application received under this announcement.

The following points should be taken into consideration by all applicants:

- Incomplete applications and applications that do not otherwise conform to this announcement will not be accepted for review. (Incomplete applications include a missing Form SF 424 or no signed Form 424 or does not include proof of non-profit status, if applicable.) Applicants will be notified in writing of any such determination by ANA.
- Complete applications that conform to all the requirements of this program announcement are subjected to a competitive review and evaluation process. An independent review panel consisting of reviewers familiar with environmental problems of Indian tribes and Alaska Native villages will evaluate each application against the published criteria in this announcement. The results of this review will assist the Commissioner in making final funding decisions.
- The Commissioner's decision will also take into account the comments of ANA staff, state and Federal agencies having performance-related information, and other interested parties.
- As a matter of policy the Commissioner will make grant awards consistent with the stated purpose of the announcement and all relevant statutory and regulatory requirements under 45 CFR parts 74 and 92 applicable to grants under this announcement.
- After the Commissioner has made decisions on all applications, unsuccessful applicants will be notified in writing within approximately 120 days of the closing date. Successful applicants are notified through an official Financial Assistance Award (FAA) document. The Administration for Native Americans staff cannot respond to requests for funding decisions prior to the official notification to the applicants. The FAA will state the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the grant award, the effective date of the award, the project period, the budget period, and the amount of the non-Federal matching share requirement.

(Catalog of Federal Domestic Assistance Program Number 93.612 Native American Programs)

Dated: January 4, 2000.

Gary N. Kimble,

Commissioner, Administration for Native Americans.

[FR Doc. 00–432 Filed 1–7–00; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5435]

Draft Guidance for Industry on Photosafety Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Photosafety Testing.'' The draft guidance is intended to help applicants decide whether they should test for photosensitivity and assess potential human risk for photochemical carcinogenesis (cancer) and enhancement of UV-induced skin carcinogenesis during the development of topically and systemically administered drug products. The draft guidance describes a consistent, science-based approach for considering testing. FDA is soliciting comments and seeking information from interested persons concerning photosafety testing.

DATES: Submit written comments on the draft guidance document by April 10, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft 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 draft 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 draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD–024), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5476.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Photosafety Testing.'' This draft guidance is intended to help applicants decide whether to test for photosensivity and potential human risk for photochemical carcinogenesis and enhancement of UV-induced skin carcinogenesis by topically and systemically administered drug products.

In the absence of data from photosensitivity tests conducted in animals or humans, warnings about the potential for photosensitization generally have been added to labels after adverse reactions resulted during widespread clinical use of products. Identification of photosensitivity effects before widespread human exposure is preferable to learning via adverse event reports.

This draft guidance considers: (1) Photosensitivity and photococarcinogenicity, (2) testing of drug product or testing of drug

substance, (3) testing for photosensitivity (photoirritation and photoallergy), (4) testing for the enhancement of UV-associated skin carcinogenesis (direct photochemical carcinogenicity or indirect effects in skin), (5) reasons for a separate approach to testing nonphotosensitizing drugs for long-term photosafety, and (6) current needs for assay development.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on testing for photosafety. 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, on or before April 10, 2000, submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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 draft 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: December 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–429 Filed 1–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–0209 and HCFA–R–0245]

Agency Information Collection Activities: Submission for OMB Review; 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection.

Title of Information Collection: Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies (HCFA–3006–IFC) and Supporting Regulations in 42 CFR 484.11 and 484.20.

Form No.: HCFA–R–0209 (OMB# 0938–0761).

Use: The information collection requirements contained in the HCFA–3006 regulation state that HHAs must report data from the OASIS data set as a condition of participation for HHAs. Specifically, the above named rule provides guidelines for HHAs for the electronic transmission of the OASIS data set as well as responsibilities of the State agency or OASIS contractor in collecting and transmitting this information to HCFA. These requirements are necessary to establish a prospective payment system for HHAs and to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs.

Frequency: As determined by HHA and monthly.

Affected Public: Business or other for profit, Not for profit institutions, Federal Government, and State, Local, or Tribal Government.

Number of Respondents: 8,200.

Total Annual Responses: 8,200.

Total Annual Hours: 996,368.

2. *Type of Information Collection Request:* Revision of a currently approved collection.

Title of Information Collection: Medicare and Medicaid Programs: Use of Outcome and Assessment Information Set (OASIS) as Part of the Conditions of Participation for Home Health Agencies (HCFA–3007–F) and Supporting Regulations in 42 CFR 484.55.

Form No.: HCFA–R–0245 (OMB# 0938–0760).

Use: These information collection requirements revise the existing conditions of participation that home health agencies (HHAs) must meet to participate in the Medicare program. Specifically, this final rule requires that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, this final rule requires that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, when evaluating adult, non-maternity patients. These changes are an integral part of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care.

Frequency: Upon patient assessment.

Affected Public: Business or other for profit, Not for profit institutions, Federal Government, and State, Local, or Tribal Government.

Number of Respondents: 8,200.

Total Annual Responses: 8,200.

Total Annual Hours: 967,600.

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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 29, 1999.

John Parmigiani,

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

[FR Doc. 00–518 Filed 1–7–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–9005–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Second Quarter, 1999

AGENCY: Health Care Financing Administration (HCFA), HHS.