and the significant use of medications by this age group.

This draft guidance discusses which application holders are responsible for submitting revised labeling and summarizes the implementation schedule for submitting geriatric labeling. The geriatric labeling regulation includes six paragraphs (§ 201.57(f)(10)(i) through (f)(10)(vi)) that outline various options for statements in the ''Geriatric use'' subsection, based on the type of information available and the interpretation of that information. The draft guidance summarizes the requirements of § 201.57(f)(10)(i) through (f)(10)(vi), and it provides detailed guidance on the submission of this information. In addition, the content and format for geriatric labeling, as well as the applicability of user fees to geriatric labeling supplements, are discussed in detail in the draft guidance document.

This draft guidance is a level 1 draft guidance document consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the content and format of geriatric labeling. 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 statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above).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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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: January 13, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1363 Filed 1–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1267]

Draft Guidance for Industry on NDA's: Impurities in Drug Substances; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''NDA's: Impurities in Drug Substances.'' This draft document recommends that applicants submitting new drug applications (NDA's) and holders of supporting Type II drug master files (DMF's) for drug substances not considered new drug substances refer to the guidance for industry on reporting drug substance impurities in the International Conference on Harmonisation (ICH) guidance document entitled ''Q3A Impurities in New Drug Substances.''

DATES: Written comments on the draft guidance document may be submitted by April 21, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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: Eric P. Duffy, Office of New Drug Chemistry, Office of Pharmaceutical Science, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7310.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''NDA's: Impurities in Drug Substances.'' Although ICH guidance document entitled ''Q3A Impurities in New Drug Substances,'' which was published in the **Federal Register** on January 4, 1996 (61 FR 371), provided guidance to industry on the reporting, identification, and qualification of impurities in new drug substances produced by chemical syntheses, FDA believes that the guidance provided in ICH Q3A also applies to drug substances produced by chemical syntheses that are not considered new drug substances. FDA recommends that applicants preparing NDA's and holders preparing Type II DMF's refer to the reporting information contained in that document.

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 reporting impurities in drug substances for certain NDA's and DMF's. 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 requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft 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 draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1364 Filed 1–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–263]

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: On Site Inspection for Durable Medical Equipment (DME) Supplier Location & Supporting Regulations in 42 CFR, Section 424.57.

Form Nos.: HCFA–R–263 (OMB# 0938–0749).

Use: To identify and implement measures to prevent fraud and abuse in the Medicare program. Controlling the entry of suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) to Medicare has been identified as one of the most effective ways to prevent fraud and abuse. To meet this challenge, HCFA is moving forward with a plan to improve the quality of the process for enrolling and reenrolling DMEPOS suppliers into the Medicare program by enhancing procedures for verifying supplier information collected on the Form HCFA 855S (DMEPOS Supplier Enrollment Application, OMB Approval No. 0938–0685). This form will be used to complete information on DMEPOS suppliers' compliance with regulations found in 42 CFR 424.57.

Frequency: On occasion.

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

Number of Respondents: 40,000.

Total Annual Responses: 40,000.

Total Annual Hours: 20,000.

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 Willinghan, Room: N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 11, 1999.

John P. Burke III,

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

[FR Doc. 99–1328 Filed 1–20–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–180]

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: Reinstatement, with change, of a previously approved collection for which approval has expired.

Title of Information Collection: Field Testing of the Uniform Needs Assessment Instrument (UNAI): Small-Scale Trial—Phase 2.

Form No.: HCFA–R–180 (OMB# 0938–0680).

Use: In testing, the Uniform Needs Assessment Instrument (UNAI) will be used to assess the needs of all patients being discharged from Medicare-certified hospitals who are identified, through use of a screener, as needing extensive hospital discharge planning and post-care. Dual assessments will be performed to assess inter-rater reliability. The UNAI is intended to help ensure appropriate post acute care and continuity of care between acute, post-acute and long-term care by transmitting key information to patients, families, and post acute care providers on the status and care needs of patients at the time of acute care discharge. The debriefing of discharge planners will examine the feasibility, burden, and utility of UNAI items and their view of the likely impact on the quality of discharge planning and continuity of care. The goal is to help HCFA determine whether such a system would improve quality of care for Medicare beneficiaries.

Frequency: On occasion.

Affected Public: Business or other for-profit, Individuals or Households, and Not-for-profit institutions.

Number of Respondents: 500.

Total Annual Responses: 720.

Total Annual Hours: 847.

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 Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 11, 1999.

John P. Burke III,

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

[FR Doc. 99–1329 Filed 1–20–99; 8:45 am]

BILLING CODE 4120–03–P