Pharmaceutical equivalents and pharmaceutical alternatives are defined similarly in the Orange Book. Under these definitions, a tablet and a capsule cannot be rated as therapeutic equivalents in the Orange Book even if they have been demonstrated to be bioequivalent.

FDA has received two citizen petitions asking the agency to revise the current policy that does not permit tablets and capsules to be rated as therapeutically equivalent. Kleinfeld, Kaplan and Becker (Kaplan) submitted a petition dated August 11, 1995, that asks FDA to take the following actions: (1) Revise the Orange Book to specify therapeutic equivalence evaluations for products that contain the same active ingredient, but are in a different solid oral dosage form (i.e., tablets and capsules); (2) change the Orange Book designations ''Tablet, Oral'' and ''Capsule, Oral,'' to ''Solid, Oral''; and (3) change the definitions of ''Pharmaceutical equivalents'' and ''Pharmaceutical alternatives'' in FDA's regulations in 21 CFR 320.1(c) and (d) and in the Orange Book to accommodate the requested changes. The petition suggests, as an alternative, that FDA could rule that tablets and capsules are the same dosage form (i.e., solid oral) and are thus pharmaceutical equivalents. Under the latter approach, grant of a suitability petition (under section 505(j)(2)(C) of the act (21 U.S.C. 355(j)(2)(C)) and 21 CFR 314.93) would not be a prerequisite for FDA to approve a tablet form of a capsule product, or vice versa.

The National Association of Pharmaceutical Manufacturers (NAPM) submitted a citizen petition dated August 27, 1996, requesting that ''FDA deem all solid oral dosage form drug products (e.g., tablets and capsules) as the same dosage form, which, upon a showing of bioequivalence, will be considered in all respects to be 'pharmaceutical equivalents.''' NAPM argues that tablets and capsules are ''more properly regarded as a single dosage form, i.e., solid oral dosage forms.'' Both petitions assert that there is no scientific basis for distinguishing between tablets and capsules that have been demonstrated to be bioequivalent.

Recently, the issue of whether tablets and capsules can be listed in the Orange Book as therapeutically equivalent has taken on added significance. Some innovator firms, whose period of marketing protection (either through patent or exclusivity) is about to expire, have succeeded in delaying generic competition by, for example, voluntarily withdrawing the new drug application (NDA) for the tablet formulation of a product and submitting a second NDA for the drug product in capsule form. In such a case, if there are already filed abbreviated new drug applications (ANDA's) for the tablet product, these ANDA's cannot be approved immediately upon expiration of the innovator's period of market protection. Before these ANDA's can be approved, an interested party must file a petition asking the agency to determine whether the innovator product was withdrawn for reasons of safety or effectiveness. The agency must then determine that the product was not withdrawn for these reasons, publish that determination, and relist the product in the Orange Book. Even after a withdrawn product has been relisted in this way, generic competition may still be affected. For example, if physicians continue to write prescriptions by brand name rather than by generic name, substitution of the generic *tablet* for the brand name *capsule* may not be permitted under the applicable State drug product selection statute.

FDA is soliciting public comment on the two citizen petitions discussed above. Among the questions the agency would particularly like to see addressed are the following:

1. Should any potential change in current FDA policy be limited to permitting bioequivalent tablets and capsules to be listed as therapeutic equivalents in the Orange Book, or should FDA regard tablets and capsules as the same (i.e., solid oral) dosage form?

2. What would be the implications of regarding all tablets and capsules as the same dosage form?

3. Is there a sound scientific basis for the current distinction between tablets and capsules?

4. What would be the impact on patients of rating bioequivalent tablets and capsules as therapeutically equivalent, or of adopting the term ''solid oral'' as a dosage form? Are there reasons for some patients or health care practitioners to prefer either tablets or capsules?

5. How would listing tablets and capsules as therapeutic equivalents in the Orange Book affect current substitution practices under State drug product selection statutes? What would be the impact on drug selection by formularies?

6. What would be the economic impact of various proposed changes?

7. How would FDA action in this area relate to United States Pharmacopoeia (USP) monographs?

Interested persons may, on or before June 26, 1996, submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments are to be identified with the docket numbers found in brackets in the heading of this document. The NAPM and Kaplan petitions and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Copies of the citizen petitions may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Dated: March 21, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–7912 Filed 3–27–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

(1965, 2649, 5011A–U6, 5011B–U6)

Agency Information Collection Activities: Proposed Collection; Comment Request

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 the 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:* Extension of a currently approved collection; *Title of Information Collection:* Request for Hearing—Part B Medicare Claim, 42 CFR 405.821; *Form No.:* HCFA–1965; *Use:* Section 1869 of the Social Security Act authorizes a hearing for any individual who is dissatisfied with any determination and amount of benefit paid. This form is used so that a party may request a hearing by a Hearing Officer because the review

determination failed to satisfy the appellant. *Frequency:* Annually, Quarterly and Monthly; *Affected Public:* Individual or Households, and Not for profit institutions; *Number of Respondents:* 55,000; *Total Annual Hours:* 9,167.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Reconsideration of Part A Insurance Benefits, 42 CFR 405.711; *Form No.:* HCFA–2649; *Use:* Section 1869 of the Social Security Act authorizes a hearing for any individual who is dissatisfied with the intermediary's Part A determination or the amount paid. This form is used by a party to request a reconsideration of the initial determination. *Frequency:* Annually, Quarterly and Monthly; *Affected Public:* Individuals or Households, and Not for profit institutions; *Number of Respondents:* 62,000; *Total Annual Hours:* 15,500.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Part A Medicare Hearing by an Administrative Law Judge, 42 CFR 498.40; *Form No.:* HCFA–5011A–U6; *Use:* Section 1869 of the Social Security Act authorizes a hearing for any individual who is dissatisfied with the intermediary's Part A determination or the amount paid. This form is used by the beneficiary or other qualified appellant to request a hearing by an Administrative Law Judge if the reconsideration determination fails to satisfy the appellant. *Frequency:* Annually, Quarterly and Monthly; *Affected Public:* Individuals or Households, and Not for profit institutions; *Number of Respondents:* 10,000; *Total Annual Hours:* 2,500.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Part B Medicare Hearing by an Administrative Law Judge; *Form No.:* HCFA–5011B–U6; *Use:* Section 1869 of the Social Security Act authorizes a hearing for any individual who is dissatisfied with the carrier's Part B determination or the amount paid. This form is used by the beneficiary or other qualified appellant to request a hearing by an Administrative Law Judge if the hearing officer's decision fails to satisfy the appellant. *Frequency:* Annually, Quarterly and Monthly; *Affected Public:* Individuals or Households, and Not for profit institutions; *Number of Respondents:* 10,000; *Total Annual Hours:* 2,500.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, 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 Financial and Human Resources, Management Analysis and Planning Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 19, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 97–7892 Filed 3–27–97; 8:45 am]

BILLING CODE 4120–03–P

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 35, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish 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, 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: AIDS Drug Assistance Program [ADAP]: Monthly Client Utilization and Program Expenditure Assessment Project—NEW

State AIDS Drug Assistance Programs [ADAP], funded under Title II of the Ryan White Comprehensive AIDS Resources Emergency [CARE] Act Amendments of 1996 [Pub. L. 104–146], are designed to provide low income, uninsured, and underinsured individuals with access to HIV/AIDS medications that prevent serious deterioration of health arising from HIV disease, including prevention and treatment of opportunistic diseases.

Due to the increasing need for pharmaceuticals among uninsured and underinsured low-income individuals who are HIV+ or diagnosed with AIDS, and recognizing the importance of program planning and budget forecasting to maximize resources, the Division of HIV Services [DHS], Health Resources and Services Administration [HRSA], proposes to collect relevant client utilization data and program expenditure information on a voluntary monthly reporting basis from State ADAPs. This effort is designed to assist Title II grantees, State ADAPs, the DHS/HRSA funding agency staff, and policy makers at both the federal and State level to better understand the level of client need for medications that the programs are functioning under and the resources used to meet the needs, and to provide indicators of where future action may be required and the most appropriate response(s).

A report is proposed that will collect time-specific data for the number of enrolled clients, the number of clients served, the level of funding expended, and the prices of five to seven specified pharmaceuticals dispensed by each program. In addition, the report will provide a forum for tracking the most current changes in each State ADAP with respect to available funding, eligibility criteria, clinical guidelines, and formulary changes. The individual State reports will be compiled into summary reports and distributed back to grantees and State ADAPs on a monthly basis, as well as available for use by HRSA and the Office of Management and Budget. These results will be used to guide program planning, to formulate budget recommendations, and to monitor the balance between available resources and State needs. The burden estimates are as follows: