to differentiate products, but that will no longer be acceptable without data substantiating the claim.

4. ''Oral Contraceptive Products—Differentiation Claims''—This guidance to industry will combine and revise 1.1, 1.37, and 1.39 regarding promotional claims that attempt to differentiate oral contraceptive products.

5. ''Transdermal Nicotine Products''—This guidance to industry will combine and revise 1.40 and 1.43 regarding the appropriate characterization of nicotine products and their use for smoking cessation.

6. ''Transdermal Nitroglycerin Products''—This guidance to industry will be based on 1.21 regarding the wording to be used in the boxed warnings for these products.

III. List 3—Currently Proposed Guidance Documents and Suggestions for New Guidances That DDMAC Should Develop

List 3 of this document contains proposed topics that are, or may be, the subject of future DDMAC guidance documents. An important component of public comment consists of the public's suggestions for when guidance is needed and what the agency's priorities should be. DDMAC therefore welcomes: (1) Comments on the topics listed below, (2) requests for additional topics for guidance related to prescription drug advertising and promotional labeling, and (3) comments on the order in which the topics should be addressed. Once comments have been received, guidance documents will be developed as agency resources permit. When guidance documents become available for public review and comment, the agency will announce their availability in the **Federal Register**. The following proposed topics are listed in alphabetical order:

1. ''Accelerated Approval''—FDA intends to develop a guidance on the submission of promotional materials for products approved under subpart H of 21 CFR part 314. (See § 314.550, *Promotional Materials*.)

2. ''Direct-to-Consumer Promotion''—FDA is developing a guidance to industry on direct-to-consumer promotion of regulated products. FDA held a public hearing and sought written public comment on this topic in 1995. In the **Federal Register** of May 14, 1996 (61 FR 24314), FDA published a document on one issue pertaining to direct-to-consumer promotion and requested comments to clarify certain other issues. The comment period closed August 12, 1996.

3. ''Drug Product Promotion at International Meetings Held in the United States''—FDA is developing a guidance to industry to address issues regarding drug product promotion at international meetings held in the United States.

4. ''Infomercial''—FDA is considering the development of a guidance to industry concerning television infomercials.

5. ''Information About Investigational Drugs''—FDA is developing guidance on 21 CFR 312.7 regarding the dissemination of press releases by sponsors, or on their behalf, containing information concerning investigational drugs.

6. ''Promotion on the Internet''—FDA is identifying issues to be addressed in a guidance document about this new promotional medium. FDA held a public meeting on this issue on October 16 and 17, 1996, and also sought written comments. This meeting was announced in the **Federal Register** of September 16, 1996 (61 FR 48707).

7. ''Promotion to Managed Care Organizations''—FDA is developing a guidance to industry regarding marketing, pharmacoeconomic claims, and information exchange in managed care environments. FDA held a public hearing and sought written public comment on this in 1995.

Dated: March 21, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–7911 Filed 3–27–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket Nos. 95P–0262 and 96P–0317]

Citizen Petitions Concerning Therapeutic Equivalency Ratings Between Tablets and Capsules; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on two citizen petitions that ask the agency to revise its current policy concerning therapeutic equivalency ratings between tablets and capsules. The petitions propose that a tablet and a capsule containing the same active ingredient in the same dosage strength that have been demonstrated to be bioequivalent be listed as therapeutic equivalents in the publication ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' FDA is seeking public comment in order to assist the agency in deciding whether to revise its current policy.

DATES: Submit written comments by June 26, 1997.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5644.

SUPPLEMENTARY INFORMATION: The publication ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book) identifies drug products approved on the basis of safety and effectiveness by FDA under the Federal Food, Drug, and Cosmetic Act. The Orange Book also contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations are prepared to serve as public information and advice to State health agencies, prescribers, and pharmacists, to promote public education in the area of drug product selection, and to foster containment of health costs.

For two drug products to be listed as therapeutically equivalent in the Orange Book, the products, among other criteria, must be pharmaceutical equivalents. FDA regulations define pharmaceutical equivalents as follows:

Pharmaceutical equivalents means drug products that contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, in identical dosage forms, but not necessarily containing the same inactive ingredients, and that meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times and/or dissolution rates.

(see 21 CFR 320.1(c))

Tablets and capsules containing the same active ingredient in the same dosage strength are defined as pharmaceutical alternatives rather than pharmaceutical equivalents. Pharmaceutical alternatives are defined as follows:

Pharmaceutical alternatives means drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form or as the same salt or ester. Each such drug product individually meets either the identical or its own respective compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times and/or dissolution rates.

(see 21 CFR 320.1(d))

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.

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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