forward a copy of each comment to the Dockets Management Branch (address above). Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 20, 1997.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–7836 Filed 3–27–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95P–0110]

Prescription Drug Advertising and Promotional Labeling; Development and Use of FDA Guidance Documents; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: As part of ongoing efforts initiated by the Food and Drug Administration (FDA) in March 1996 to ensure meaningful public participation in the guidance document development process, FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) is requesting public comment on guidance documents relating to prescription drug advertising and labeling. DDMAC has identified three general types of guidance documents on which it is seeking public comment. Specifically, DDMAC is requesting public comment on the rescission of guidances identified by DDMAC as obsolete, the revision and reissuance of DDMAC guidances that address current issues, and currently proposed guidance documents and suggestions of topics for new guidances that DDMAC may develop.

DATES: Written comments by June 26, 1997.

ADDRESSES: Submit written requests for copies of the guidances under review by DDMAC to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the guidances or related issues to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one. Comments should be identified with the docket number found in brackets in the heading of this document. Copies of the guidances under review by DDMAC are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Melissa M. Moncavage, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828, e–mail: ''moncavage@cder.fda.gov.''

SUPPLEMENTARY INFORMATION: Issues relating to FDA's development and issuance of guidance documents were raised in a citizen petition submitted by the Indiana Medical Devices Manufacturers Council, Inc. (IMDMC) (see Docket No. 95P–0110). The IMDMC petition requested that FDA control the initiation, development, and issuance of guidance documents by written procedures that ensure the appropriate level of meaningful public participation. In response to the petition, FDA agreed to take steps to improve the agency's guidance document procedures.

In the **Federal Register** of March 7, 1996 (61 FR 9181), FDA published a notice that set forth its proposal on how best to improve its guidance document procedures and solicited comment on these and additional ideas for improvement (March 1996 notice). On April 26, 1996, the agency held a public meeting to discuss these issues further. The comment period for the March 7 notice closed on June 5, 1996. In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice explaining how the agency will proceed in the future with guidance document development, issuance, and use. The notice included the agency document entitled ''Good Guidance Practices'' (the GGP's document), which sets forth the agency's policies and procedures for developing, issuing, and using guidance documents.

In the GGP's document, the agency defines ''guidance documents'' to include documents prepared for FDA staff, applicants and sponsors, and the public that: (1) Relate to the processing, content, and evaluation and approval of submissions; (2) relate to the design, production, manufacturing, and testing of regulated products; (3) describe the agency's policy and regulatory approach to an issue; or (4) establish inspection and enforcement policies and procedures. ''Guidance documents'' do not include documents relating to internal FDA procedures, agency reports, general information documents provided to consumers, speeches, journal articles and editorials, media interviews, press materials, warning letters, or other communications directed to individual persons or firms.

Guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. Rather, they explain the agency's current thinking on a certain subject. However, a company affected by a guidance may use an alternative approach if the alternative approach satisfies the requirements of the applicable statute, regulations, or both. A guidance document cannot itself be the basis for an enforcement action.

FDA has adopted a two-level approach to the development of guidance documents. The procedures for developing a guidance document will depend on whether that guidance document is a ''level 1'' guidance or a ''level 2'' guidance. Level 1 guidance documents generally include guidance that sets forth first interpretations of statutory or regulatory requirements, changes in interpretation or policy that are of more than a minor nature, unusually complex scientific issues, or highly controversial issues. Level 1 guidance documents are directed primarily to applicants or sponsors or other members of the regulated industry. Level 2 guidance documents include all other guidance documents. In general, the agency will solicit public comment during the development of level 1 guidance documents. For level 2 guidance documents, the agency may choose to solicit comment before implementing a guidance, but in general an opportunity for public comment will be provided upon issuance of the guidance document. (See FDA GGP's.)

The agency also is making efforts to keep the public up to date on the status of agency guidance development and to provide the public an opportunity to suggest possible topics for document development or revision.

DDMAC guidances on achieving compliance with the prescription drug advertising and labeling statutes and regulations have been issued to the pharmaceutical industry since 1970 in various forms, often as letters or guidance papers. As a result of FDA's GGP effort, DDMAC has decided to reissue its guidance documents in a standardized format and grouped by common topic, such as content, format, class of drugs, or how to interact with DDMAC. To that end, DDMAC is undertaking a review of all such guidances to determine the following: (1) Which guidances are obsolete; (2) which guidances address current issues, but may need revision; and (3) whether there are new topics on which DDMAC should develop guidance documents. Once the guidance review process is completed, new and reissued DDMAC guidances will be made available, in

paper and electronic format, as they are completed.

DDMAC also has examined systematically its guidance development process and is implementing changes to ensure meaningful public participation in its guidance development process. DDMAC is seeking public comment on the following three types of guidance documents: List 1 contains DDMAC guidance documents that have been, or will be, rescinded because they are obsolete; List 2 contains DDMAC guidance documents (level 1 and level 2) that address current issues, but that may need some revision before they are reissued; and List 3 contains suggestions for guidance documents DDMAC may develop to address current prescription drug advertising and labeling issues.

Interested persons may, on or before June 26, 1997, submit to the Dockets Management Branch (address above) written comments regarding this document. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Anyone with general comments, concerns, or questions about DDMAC guidance documents may submit their comments at any time to the Dockets Management Branch.

I. List 1—DDMAC Guidance Documents Considered Obsolete

List 1 contains the titles and dates of all guidance documents on prescription drug advertising and labeling that have been reviewed by DDMAC and that have been rescinded or will be rescinded by this document because they are obsolete; some may have been superseded by subsequent policies, and some are being revised and will be reissued as described in List 2 of this notice. The guidances are listed in chronological order, and a description of the original guidance is included with a statement explaining its status. Guidances in this list that were superseded by subsequent guidances or are being revised are cross-referenced to the proposed revised guidances in Lists 2 and 3. For example, the letter dated June 27, 1970, in List 1 is cross-referenced to the proposed revised guidance in List 2.D.4 ''Oral Contraceptive Products—Differentiation Claims.'' Guidances in List 1 that are being revised in new guidances will remain in effect until the revised guidance is published in final form.

Although it may be rescinding a guidance on a specific issue at this time, the agency may consider the need to reissue a guidance on that issue. Therefore, DDMAC welcomes comments on the rescission, or future rescission, of the guidances in List 1 and encourages parties to submit their comments to the Dockets Management Branch (address above).

1. Letter dated June 27, 1970—This letter to oral contraceptive manufacturers objected to attempts to differentiate products based on alleged thromboembolic risk with higher estrogen levels. This risk theory was based on information described as ''British data.'' This guidance was superseded by guidances dated June 19, 1991, and January 31, 1992, in this list. These latter guidances will be incorporated into 2.D.4, ''Oral Contraceptive Products—Differentiation Claims.''

2. Statement dated March 18, 1971—This statement to all manufacturers of antibiotic drugs addressed the use of in vitro data to support claims that an antibiotic is bactericidal. This guidance was superseded by the guidance dated September 1994 in this list. The latter guidance will be incorporated into guidance 2.D.2, ''Anti-infective Drug Products.''

3. Guidance dated 1971—This guidance to all manufacturers of psychotropic drugs requested firms to stop the use of claims suggesting the use of these products for everyday anxieties. This guidance was revised in the July 25, 1985, guidance in this list, which was later rescinded.

4. Guidance dated October 8, 1974—This guidance from Commissioner Schmidt to Synapse Communication Services stated that educational material and programs could be considered labeling. This guidance will be combined with the ''Sabshin criteria'' guidance, May 22, 1975, in this list, to create 2.A.6, ''Scientific and Educational Materials—Criteria for Independence.''

5. Guidance dated May 22, 1975—This guidance detailed criteria to be considered when judging the independence of a publication for determination of labeling status. These criteria are commonly called the ''Sabshin criteria.'' This guidance will be combined with the guidance dated October 8, 1974, of this list, to create 2.A.6, ''Scientific and Educational Materials—Criteria for Independence.''

6. Letter dated October 6, 1975—This letter to all manufacturers of radiopharmaceutical products advised of the applicability of the advertising and labeling regulations to the promotion of radiopharmaceutical products. This guidance was issued at the time that these products first came under the prescription drug requirements. Because it is now generally understood that radiopharmaceuticals are prescription drugs, this guidance is rescinded.

7. Guidance dated February 11, 1977—This guidance on the acceptability of claims of quality control procedures in reminder promotion was primarily intended for generic drug manufacturers. Since the inception of the generic drug rating system, generic drug manufacturers have been able to use the ratings in FDA's *Approved Drug Products* publication to reflect the status of their products. Therefore, this guidance is rescinded.

8. Guidance dated February 14, 1977—This second guidance to radiopharmaceutical product manufacturers advised them of the prescription status of their products and the applicability of FDA regulations. Because it is now generally understood that radiopharmaceuticals are prescription drugs, this guidance is rescinded.

9. Guidance dated June 28, 1978—This guidance addressed boxed warnings in brief summaries for estrogen products. The warnings addressed the increased risks of endometrial carcinoma and use in pregnancy. When this guidance was issued, these products had new boxed warnings in their labeling. Because the warning information is now routinely included in all advertising, this guidance is rescinded.

10. Guidance dated early 1980's—This guidance presented conditions under which an industry press release will not be considered labeling. This guidance will be combined with the guidance in this list dated July 24, 1991, on video news releases to create 2.A.5, ''Print and Video News Releases.''

11. Guidance dated early 1980's—This guidance stated conditions under which the dissemination of sole-sponsored publications by or on behalf of the drug sponsor would not be regulated as labeling. The guidance will be revised to create 2.A.7, ''Single-Sponsored Publications—Criteria for Independence.''

12. Guidance dated April 6, 1981—This guidance to all manufacturers of estrogen products addressed claims for the use of estrogen products for vasomotor symptoms and other symptoms of menopause. Because the products have been approved for these uses, this guidance is rescinded.

13. Guidance dated June 16, 1981—This guidance to all manufacturers of

oral contraceptives addressed the use of the results of the ''Walnut Creek Study'' in claims of lowered side-effect risk. FDA's position was that the study did not support any changes in the risk information at that time. Because the study is no longer used in promotion, this guidance is rescinded.

14. Guidance dated April 22, 1982—This guidance addressed the agency's position regarding responses to solicited and unsolicited requests for drug product information. The guidance will be incorporated into guidance 2.A.8, ''Solicited and Unsolicited Requests for Information.''

15. Guidance dated July 6, 1982—This guidance to industry addressed the scientific support necessary for comparative advertising disseminated by or on behalf of the drug sponsor. This guidance will be combined with the guidances in this list dated October 27, 1988, and February 22, 1994, to create 2.A.1, ''Comparative Promotional Materials.''

16. Guidance dated July 21, 1982—This guidance to all manufacturers of purified insulin products addressed claims of superiority based on the purification of the product by removing, for example, pro-insulin and animal proteins. With the development of recombinant deoxyribonucleic acid (DNA) human insulins, the promotion issue is no longer relevant to these products. Therefore, this guidance is rescinded.

17. Guidance dated July 22, 1982—This guidance to industry addressed limitations on and formats for advertising not-yet-approved drug products. This document was superseded by guidances in this list dated August 1985, August 1986, and April 1994.

18. Guidance dated August 10, 1982—This guidance to all manufacturers of sustained-release theophylline products addressed the use of pharmacokinetic and biopharmaceutic data to support clinical claims. Because those claims are no longer used to differentiate products, this guidance is rescinded.

19. Guidance dated November 10, 1982—This guidance to all advertisers of benzodiazepine products addressed clinical claims supported by nonclinical or pharmacokinetic data. This guidance was superseded by a guidance in this list dated July 25, 1985.

20. Memorandum dated March 15, 1983—This memorandum from the Division of Drug Monographs to manufacturers described data and calculations needed to support claims of zero-order kinetics with clinical implications. Because issues of constant absorption and product differentiation are no longer used in promotion, this guidance is rescinded.

21. Letter dated September 19, 1983—This letter to manufacturers of nitroglycerin patches provided summary wording regarding the less-than-effective status of those products. The summary was to be used in place of the Drug Efficacy Study Investigation statement wording required in the regulations. This guidance will be revised to create 2.D.6, ''Transdermal Nitroglycerin Products.''

22. Guidance dated December 30, 1983—This guidance to manufacturers of once-daily theophylline products addressed submission of promotional material. This guidance was effective for only 6 months and, therefore, is rescinded.

23. Letter dated February 16, 1984—This letter to all manufacturers of oral contraceptives concerned a study by Pike et al. (published in *Lancet*) and discussed relative potencies of progestins; it could not be used as the basis for promotional claims. Because this study is no longer used in promotion, this guidance is rescinded.

24. Guidance dated December 20, 1984—This guidance to all manufacturers of antimicrobial and antimycotic agents detailed how the terms: ''Clinical cure, bacteriological cure, and improvement'' were to be used and defined in promotion. This guidance was later clarified in the February 27, 1986, document in this list. Both of these documents will be revised and combined with the March 18, 1971, guidance document in this list on antimicrobial and antimycotic promotion to create 2.D.2, ''Anti-infective Drug Products.''

25. Letter dated July 25, 1985—This letter to all manufacturers of benzodiazepine products concerned certain promotional statements. This guidance revised the 1971 guidance in this list on psychotropic drugs. Because these products are no longer promoted using such statements, this guidance is rescinded.

26. Guidance dated August 1985—This guidance was addressed to the industry on preapproval promotion. This guidance was superseded by a guidance dated August 1986 and two guidances dated April 1994 in this list.

27. Guidance dated September 1985—This guidance to the industry described what FDA would view as institutional, corporate, or health messages. This guidance was revised in a guidance in this list dated June 6, 1988. The concepts in these guidances will be revised to create 2.A.4, ''Institutional and Help-Seeking Advertisements,'' and 2.C.3, ''Preapproval Promotion.''

28. Guidance dated September 1985—This guidance to the industry addressed the use of overprinting of images or promotional phrases over the brief summary wording. This guidance will be slightly revised to create 2.B.2, ''Overprinting of Images or Promotional Phrases.''

29. Guidance dated February 27, 1986—This guidance to industry clarified the December 20, 1984, guidance on antimicrobial drug promotion. This guidance will be revised and combined with the March 18, 1971, guidance in this list concerning antibiotic and antimycotic promotion to create 2.D.2, ''Anti-infective Drug Products.''

30. Letter dated May 2, 1986—This letter to manufacturers of oral contraceptive products specified that patient booklets should contain the approved patient package insert as a permanent part of the booklet. Because the principles regarding labeling requirements are well established with this product class, this guidance is rescinded.

31. Guidance dated August 1986—This guidance to industry consolidated and added provisions to the July 22, 1982, and September 1985 guidances in this list regarding preapproval promotion disseminated by or on behalf of the drug sponsor. The August 1986 guidance specified formats for preapproval drug promotion. The guidance was later superseded by two documents, both dated April 1994, and described later in List 1.

32. Guidance dated December 1987—This guidance to the industry noted that proposed revisions to the investigational new drug regulations could affect the preapproval promotion guidance documents previously issued. Because the content of the guidance went through notice-and-comment rulemaking and was codified in the Code of Federal Regulations (21 CFR 312.7), this guidance is rescinded.

33. Guidance dated March 1988—This guidance described the process for the review of proposed material to be relied on by industry as official agency action. This guidance was superseded by the document dated July 1993, in List 1.

34. Guidance dated June 6, 1988—This guidance to industry revised the September 1985 guidance concerning institutional and disease-oriented promotional messages. The concepts in this guidance will be revised and incorporated into 2.A.4, ''Institutional and Help-Seeking Advertisements,'' and 2.C.3, ''Preapproval Promotion.''

35. Letter dated October 27, 1988—This letter was addressed to industry with attached excerpts from a speech

describing the criteria for comparative promotional claims. This guidance has been revised and will be combined with documents dated July 7, 1982, and February 22, 1994, in this list to create 2.A.1, ''Comparative Promotional Materials.''

36. Letter dated January 19, 1990—This letter to all manufacturers of transdermal nitroglycerin products concerned the inclusion of a double-boxed warning from the approved labeling in the brief summaries. This guidance was applicable for 6 months and, therefore, is rescinded.

37. Letter dated June 19, 1991—This letter to all manufacturers of oral contraceptives discussed the use of claims of hormonal activity to differentiate products. The guidance also recommended against consumer advertising. A guidance dated January 31, 1992, rescinded the recommendation against consumer advertising. The remaining guidance topics will be revised to create 2.D.4, ''Oral Contraceptive Products—Differentiation Claims.''

38. Guidance dated July 24, 1991—This guidance to all manufacturers stated that video news releases would be considered labeling and should be submitted under the provisions of 21 CFR 314.81. This guidance will be revised to create 2.A.5, ''Print and Video News Releases.''

39. Letter dated January 31, 1992—This letter to all manufacturers of oral contraceptives clarified the June 19, 1991, letter in this list and removed the recommendation against consumer promotion. This document will be revised and combined with other guidance documents concerning oral contraceptive promotion to create 2.D.4, ''Oral Contraceptive Products—Differentiation Claims.''

40. Letter dated February 13, 1992—This letter to nicotine transdermal system manufacturers addressed promotional concepts and information and considerations for reminder messages to consumers. This guidance was revised and will be combined with the September 11, 1992, guidance in this list to create 2.D.5, ''Transdermal Nicotine Products.''

41. Guidance dated June 5, 1992—This guidance to all manufacturers of aerosol inhalation steroid products stated that a caution statement should be included in all promotion. The guidance will be slightly revised to create 2.D.1, ''Aerosol Steroid Safety Information.''

42. Letter dated June 22, 1992—This letter to all manufacturers of ionic and nonionic contrast media discussed the need to use data to substantiate certain claims that were used to differentiate products. This guidance will be slightly revised to create 2.D.3, ''Ionic and Nonionic Contrast Media.''

43. Letter dated September 11, 1992—This letter to all nicotine transdermal system manufacturers outlined critical points regarding advertisements and promotional material. This guidance will be revised and combined with the February 13, 1992, guidance in this list to create 2.D.5, ''Transdermal Nicotine Products.''

44. Letter dated May 20, 1993—This letter to industry listed product exhibits and programs naming products in program books for professional meetings. In light of the current format in program books, this guidance is rescinded.

45. Guidance dated July 1993, ''Current Issues and Procedures''—This guidance addressed six topics. The topics in this document will be separated, and new single-topic guidances will be created or will be combined with other guidances with similar topics into new guidances. The new documents that will be created from these six topics follow:

a. Issues relating to filing submissions with DDMAC will be addressed in 2.C.2, ''Filing Requirements and Other Communication for Advertising and Labeling.''

b. Issues relating to communicating with DDMAC by facsimile and letter will be addressed in 2.C.2, ''Filing Requirements and Other Communication for Advertising and Labeling.''

c. Issues relating to submitting foreign language material will be addressed in 2.C.1, ''Data on File and Foreign Language Publications References.''

d. Issues regarding submitting proposed direct-to-consumer advertising will be addressed in 3.2, ''Direct-to-Consumer Promotion.''

e. Issues regarding electronic material will be addressed in 2.C.2, ''Filing Requirements and Other Communication for Advertising and Labeling.''

f. Issues dealing with launch campaigns will be addressed in 2.C.4, ''Prepublication Review of Promotional Materials.''

46. Guidance dated July 1993—This guidance to industry revised and reissued the March 1988 guidance on submission of material for prepublication review and comment. This guidance will be combined with the launch campaign topic in the preceding July 1993 guidance and the March 1994 guidance in List 1 to create 2.C.4, ''Prepublication Review of Promotional Materials.''

47. Guidance dated August 1993—This guidance to industry clarified the requirements for telephone advertisements. This guidance will be revised in 2.A.9, ''Telephone Advertisements.''

48. Guidance dated February 22, 1994—This guidance to industry addressed comparative efficacy claims for nonsteroidal anti-inflammatory drugs and equally prominent information on adverse effects. This guidance will be revised and combined with the July 6, 1982, and October 27, 1988, guidances and the pertinent topic in the April 1994 ''Current Issues and Procedures'' guidance in this list to create 2.A.1, ''Comparative Promotional Materials.''

49. Guidance dated March 1994—This guidance to industry addressed the submission of proposed launch promotional material for review. This guidance will be combined with topics in the July 1993 ''Current Issues and Procedures'' and the other July 1993 guidance in this list to create 2.C.4, ''Prepublication Review of Promotional Materials.''

50. Guidance dated April 1994—This guidance to industry addressed promotion of products prior to approval, which superseded the August 1986 document. This guidance will be combined with the following April 1994 guidance, part a., to create 2.C.3, ''Preapproval Promotion.''

51. ''Current Issues and Procedures'' guidance dated April 1994—This guidance to industry covered 10 topics. The topics in this guidance will be separated, and new single-topic guidances will be created or will be combined with other guidances with similar topics into revised guidances. The revised guidances that will be created from these 10 topics follow:

a. Preapproval promotion issues will be addressed in 2.C.3, ''Preapproval Promotion.''

b. Issues related to brand and generic name presentation will be addressed in 2.B.3, ''Placement of Brand and Established Names in Promotional Materials.''

c. Broadcast advertisement issues will be addressed in 2.B.4, ''Prominence of Risk Information in Broadcast Advertisements.''

d. Issues related to comparative claims will be addressed in 2.A.1, ''Comparative Promotional Materials.''

e. Direct-to-consumer promotion issues will be be reconsidered in 3.2, ''Direct-to-Consumer Promotion.''

f. Fair balance issues will be addressed in 2.B.1, ''Fair Balance.''

g. Issues related to formulary kits will be addressed in 2.A.2, ''Formulary Kits as Promotional Labeling.''

h. Issues related to generic drug advertisements will be addressed in 2.A.3, ''Generic Drug Promotional Labeling and Advertising.''

i. Issues related to unsolicited information will be addressed in 2.A.8, ''Solicited and Unsolicited Requests for Information.''

j. Wrap-around advertisement issues will be addressed in 2.B.5, ''Wrap-Around Advertisements.''

k. Issues related to ''Data on file'' references will be addressed in 2.C.1, ''Data on File and Foreign Language Publications References.''

52. Letter dated September 1994—This letter for anti-infective drug product manufacturers addressed several advertising claims including the use of in vitro data, comparative claims, cost-effectiveness claims, presentation of indications, and use of pharmacokinetic data. This guidance will be revised and combined with the March 18, 1971, December 20, 1984, and February 27, 1986, guidances in this list concerning antibiotic promotion to create 2.D.2, ''Anti-infective Drug Products.''

II. List 2—Guidances That Address Current Issues, But Require Revision

List 2 contains guidance documents that will be revised and reissued as part of DDMAC's review of its prescription drug advertising and labeling guidances. Documents mentioned in List 1 are referenced. For example, 1.51, refers to List 1, document 51, the April 1994 guidance entitled ''Current Issues and Procedures.'' To simplify their presentation, guidances in List 2 have been grouped into the following general topics: A—Content of Promotional Materials; B—Format of Promotional Materials; C—Procedures for Interacting with DDMAC; and D—Issues Related to Product or Class. In some cases, a guidance may address issues under more than one topic. Guidances are listed in alphabetical order under each topic.

A. Content of Promotional Materials

1. ''Comparative Promotional Materials''—This guidance to industry will combine and revise 1.15, 1.35, 1.48, and 1.51.d. These guidances discussed comparative promotional claims for a variety of drug products.

2. ''Formulary Kits as Promotional Labeling''—This guidance to industry will revise 1.51.g, which discusses formulary kits as labeling. The revised guidance will also be considered in 3.7, a guidance being developed regarding promotion to managed care organizations.

3. ''Generic Drug Promotional Labeling and Advertising''—This guidance to industry will be based on the pertinent subject in 1.51.h. The guidance will explain the use of the terms ''AB rated'' and ''bioequivalent'' in promotional materials and price catalogs.

4. ''Institutional and Help-Seeking Advertisements''—This guidance to industry will be based on appropriate parts of 1.27 and 1.34. It will combine the concepts of institutional and disease-oriented advertising, especially as they pertain to consumers.

5. ''Print and Video News Releases''—This guidance to industry will combine and revise 1.10 and 1.38 to address under what circumstances press kits, new releases, and video news releases will be considered labeling.

6. ''Scientific and Educational Materials—Criteria For Independence''—This guidance to industry will combine 1.4 and 1.5. The guidance will discuss the criteria to be considered when judging the independence of scientific and educational publications, materials, and programs for determination of labeling status.

7. ''Single-Sponsored Publications—Criteria for Independence''—This guidance to industry will revise 1.11 to address when sole-sponsored publications will not be considered labeling.

8. ''Solicited and Unsolicited Requests for Information''—This guidance to industry will revise 1.14 and 1.51.i to address when distribution of product information by or on behalf of the drug sponsor will not be considered labeling.

9. ''Telephone Advertisements''—This guidance to industry will revise 1.47 concerning telephone advertisements. The guidance will address telephone advertisements and the regulations for broadcast advertising.

B. Format of Promotional Materials

1. ''Fair Balance''—This guidance to industry will revise the pertinent part of 1.51.f. The guidance will discuss the placement and relative prominence of fair balance information.

2. ''Overprinting of Images or Promotional Phrases''—This guidance to industry will be based on 1.28, which discusses the use of printing images or promotional phrases over the brief summary.

3. ''Placement of Brand and Established Names in Promotional Materials''—This guidance to industry will revise the part of 1.51.b that addresses issues related to type size and intervening matter between the brand and established names, as discussed in the regulations.

4. ''Prominence of Risk Information in Broadcast Advertisements''—This guidance to industry will revise the pertinent part of 1.51.c. The guidance will discuss graphics, sound effects, voice-overs, etc., that occur during the presentation of risk information in broadcast advertisements and that obscure or detract from risk information.

5. ''Wrap-Around Advertisements''—This guidance to industry will revise the pertinent part of 1.51.j regarding advertisements to be used on the front and back covers of a publication.

C. Procedures for Interacting with DDMAC

1. ''Data on File and Foreign Language Publications References''—This guidance to industry will revise the pertinent parts of 1.45.c and 1.51.k regarding how to submit these reference materials to the agency.

2. ''Filing Requirements and Other Communication for Advertising and Labeling''—This guidance to industry will revise the pertinent parts of 1.45.a, 1.45.b, and 1.45.e regarding how and where to file advertising and labeling pieces.

3. ''Preapproval Promotion''—This guidance to industry will combine and revise 1.34, 1.50, and 1.51.a. The guidance will address methods for regulated companies to provide certain information about their products prior to approval.

4. ''Prepublication Review of Promotional Materials''—This guidance to industry will combine and revise previous documents that addressed prepublication review of launch campaign materials and other promotional materials. The guidances that will be combined and revised include 1.45.f, 1.46, and 1.49.

D. Issues Related to Product or Class

1. ''Aerosol Steroid Safety Information''—This guidance to industry will revise 1.41, and will advise manufacturers of aerosol inhalation steroid products to use a caution statement in promotion.

2. ''Anti-infective Drug Products''—This guidance to industry will combine and revise 1.2, 1.24, 1.29, and 1.52 and include new issues in antibiotic promotion.

3. ''Ionic and Nonionic Contrast Media''—This guidance to industry will be based on 1.42, dated June 22, 1992, outlining certain claims for ionic and nonionic contrast media made by or on behalf of the drug sponsor that are used

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]

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[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))