§ 240.3a12–6 Definition of "common trust fund" as used in section 3(a)(12) of the act.

The term "common trust fund" as used in section 3(a)(12) of the Act (15 U.S.C. 78c(a)(12)) shall include a common trust fund which is maintained by a bank which is a member of an affiliated group, as defined in section 1504(a) of the Internal Revenue Code of 1954 (26 U.S.C. 1504(a)), and which is maintained exclusively for the collective investment and reinvestment of monies contributed thereto by one or more bank members of such affiliated group in the capacity of trustee, executor, administrator, or guardian, *Provided,* That:

(a) The common trust fund is operated in compliance with the same State and Federal regulatory requirements as would apply if the bank maintaining such fund and any other contributing banks were the same entity; and

(b) The rights of persons for whose benefit a contributing bank acts as trustee, executor, administrator, or guardian would not be diminished by reason of the maintenance of such common trust fund by another bank member of the affiliated group.

(15 U.S.C. 78c(b))

IV. It is proposed to amend Part 270 of Chapter II of Title 17 of the Code of Federal Regulations, Rules and Regulations, Investment Company Act of 1940, by adding a new § 270.3c–4 to read as follows:

§ 270.3c–4 Definition of "common trust fund" as used in section 3(c)(3) of the Act.

The term "common trust fund" as used in section 3(c)(3) of the Act (15 U.S.C. 80a–3(c)(3)) shall include a common trust fund which is maintained by a bank which is a member of an affiliated group, as defined in section 1504(a) of the Internal Revenue Code of 1954 (26 U.S.C. 1504(a)), and which is maintained exclusively for the collective investment and reinvestment of monies contributed thereto by one or more bank members of such affiliated group in the capacity of trustee, executor, administrator, or guardian, *Provided,* That:

(a) The common trust fund is operated in compliance with the same State and Federal regulatory requirements as would apply if the bank maintaining such fund and any other contributing banks were the same entity; and

(b) The rights of persons for whose benefit a contributing bank acts as trustee, executor, administrator, or guardian would not be diminished by reason of the maintenance of such common trust fund by another bank member of the affiliated group.

(15 U.S.C. 80a–6(c), 80a–37(a))

By the Commission.

GEORGE A. FITZSIMMONS,
Secretary.

OCTOBER 21, 1977.

[FR Doc.77–31330 Filed 10–27–77;8:45 am]

[6740–02]

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[18 CFR Part 141]

[Docket No. RM77–2]

DATA ON COST AND QUALITY OF FUELS FOR ELECTRIC PLANTS

Change in Public Availability of Form No. 423; Extension of Comment Period

AGENCY: Federal Energy Regulatory Commission.

ACTION: Further Extension of Time.

SUMMARY: The Commission is granting a further extension of time to and including October 28, 1977, within which to file comments in the proposed rulemaking proceeding docketed as RM77–2. This extension is granted to ensure that all parties have adequate time in which to comment on the Commission's proposed change in public availability of Form No. 423.

DATE: Comments must be received on or before October 28, 1977.

ADDRESS: Send comments to: Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE,. Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT:

Kenneth F. Plumb, Secretary, 202–275–4166.

SUPPLEMENTARY INFORMATION: On October 13, 1977, the Office of Consumer Affairs, U.S. Department of Health, Education, and Welfare, filed a request to further extend the time for filing comments on the Notice of Proposed Rulemaking, issued August 15, 1977 and published September 29, 1977 (42 FR 51609). A previous extension of time to October 14, 1977, was granted by Commission Notice issued September 26, 1977.

KENNETH F. PLUMB,
Secretary.

[FR Doc.77–31470 Filed 10–27–77;8:45 am]

[4110–03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 341]

[Docket No. 76N–0052]

OVER-THE-COUNTER DRUGS

Proposed Monograph for OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products; Amendment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration is issuing a clarification of the dosage statements for phenylpropanolamine and eliminating an inconsistency regarding combination products containing an oral bronchodilator and an antitussive. This action is taken at the recommendation of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products.

DATE: Comments by December 27, 1977.

ADDRESS: Written comments (preferably in quadruplicate and identified with the Docket Number found in the heading of this document) may be sent to the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (HFD–510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of September 9, 1976 (41 FR 38312), the Commissioner of Food and Drugs issued the recommendations and proposed monograph of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products. On the basis of comments received, members of the Panel have requested that the Panel's published recommendations and proposed monograph be amended to clarify the dosage statement for phenylpropanolamine administered orally as a nasal decongestant.

During the Panel's deliberations, the basic adult dosage recommendation for orally administered phenylpropanolamine was 25 mg every 4 hours, not to exceed 150 mg in 24 hours. This was extended to also include a 50-mg dosage recommendation every 8 hours to provide for timed-release dosage forms. However, the Panel was informed that all timed-release formulations are subject to the new drug procedures because such dosage formulations are so complex that the state of the art does not permit standardization to the point of inclusion in an OTC drug monograph as a Category I condition. Therefore, dosage recommendations in the proposed monograph should apply only to conventional formulations, and reference to "50 mg every 8 hours" and equivalent children's dosages should be deleted from the Panel's published recommendations and proposed monograph.

The corrected statement in the proposed monograph for orally administered phenylpropanolamine preparations consistent with the Panel's basic recommendation for adults, is "25 mg every 4 hours not to exceed 150 mg in 24 hours." For children 6 to 12, it is "12.5 mg every 4 hours not to exceed 75 mg in 24 hours." For children 2 to 6, it is "6.25 mg every 4 hours not to exceed 37.5 mg in 24 hours."

In addition, the Commissioner is aware of an inconsistency in the Panel's recommendations and proposed monograph regarding the combination of an oral bron-

chodilator and an antitussive. In paragraph II.C.9.e.(6) of the September 9, 1976 preamble (41 FR 38326), the Panel identified such combinations as irrational and classified them as Category II when labeled for cough associated with asthma. The provision for such a combination was inadvertently included in the proposed monograph and should be deleted because the proposed monograph contains only Category I conditions. Accordingly, for clarification and to resolve the inconsistency, the Commissioner is amending both the preamble and the proposed monograph of September 9, 1976.

In the preamble to the proposal, the Commissioner stated that he has reviewed the potential environmental impact and also considered the inflation impact of the Panel's recommendations and proposed monograph and that copies of the environmental and inflation impact assessments are on file with the Hearing Clerk. He concludes that this amendment would in no way alter those assessments. Accordingly the preamble is amended on page 38401 by revising paragraph VIII.B.1.e.(3) to read as follows:

(3) *Dosage.* Dosages are based on the phenylpropanolamine hydrochloride equivalent. Adult oral dosage is 25 mg every 4 hours not to exceed 150 mg in 24 hours. Children 6 to under 12 years oral dosage is 12.5 mg every 4 hours not to exceed 75 mg in 24 hours. Children 2 to under 6 years oral dosage is 6.25 mg every 4 hours not to exceed 37.5 mg in 24 hours. For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701(a), 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055 (21 U.S.C. 321, 352, 355, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner is amending the proposed monograph published in the FEDERAL REGISTER of September 9, 1976, as follows:

1. In proposed § 341.20, by revising paragraph (e) to read as follows:

§ 341.20 Nasal decongestants.

* * * * *

(e) *Phenylpropanolamine preparations (phenylpropanolamine bitartrate, phenylpropanolamine hydrochloride, phenylpropanolamine maleate) (oral).* Dosages are based on the phenylpropanolamine hydrochloride equivalent. Adult oral dosage is 25 mg every 4 hours not to exceed 150 mg in 24 hours. Children 6 to under 12 years oral dosage is 12.5 mg every 4 hours not to exceed 75 mg in 24 hours. Children 2 to under 6 years oral dosage is 6.25 mg every 4 hours not to exceed 37.5 mg in 24 hours. For children under 2 years, there is no recommended dosage except under the advice and supervision of a physician.

* * * * *

§ 341.40 [Amended]

2. In proposed § 341.40 *Permitted combinations of active ingredients,* by deleting and reserving paragraph (f).

§ 341.85 [Amended]

3. In proposed § 341.85 *Labeling of combinations of active ingredients,* by deleting and reserving paragraph (b).

Interested persons may, on or before December 27, 1977, submit to the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this amendment. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 20, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77–31235 Filed 10–27–77;8:45 am]

[4110–03]

[21 CFR Part 701]

COSMETIC INGREDIENT LABELING

Recognition of New Sources for Names of Ingredients Adopted for Ingredient Labeling

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This is a proposal to amend the cosmetic ingredient labeling regulation. This action is taken in response to a petition filed by the Cosmetic, Toiletry, and Fragrance Association, Inc. (CTFA) to recognize the second edition of its dictionary, and on the initiative of the Commissioner of Food and Drugs. If this proposal is adopted, recognition would be made of supplements and new editions of currently recognized compendia as sources of ingredient names adopted for used in cosmetic ingredient labeling.

DATE: Comments by December 27, 1977.

ADDRESS: Written comments to the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Heinz J. Eiermann, Bureau of Foods (HFF–440), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St., SW., Washington, D.C. 20204. 202–245–1530.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is proposing recognition of supplements and new editions of currently recognized compendia as sources of ingredient names adopted for use in cosmetic ingredient labeling. The new editions and supplements of these compendia offer greatly expanded compilations of cosmetic ingredient names. The proposal to recognize a new edition of the CTFA (Cosmetic, Toiletry and Fragrance Association, Inc.) Cosmetic Ingredient Dictionary is made in response to a petition by CTFA. Thirty-four names of ingredients listed in the dictionary copy for which recognition was petitioned are excluded from the proposal; some names are proposed to be adopted conditionally or for only a limited period of time; and for one ingredient, a different name is proposed. The adoption of new editions and supplements of other sources of cosmetic ingredient names is proposed by the Commissioner on his own initiative.

On June 24, 1976, the CTFA petitioned the Food and Drug Administration to recognize the second edition (1976) of the CTFA Cosmetic Ingredient Dictionary (CTFA Dictionary) as a new source of names of ingredients adopted for the purpose of ingredient labeling. It was requested that 21 CFR Part 701 be amended by revising § 701.3(c)(2)(i) and listing the dictionary's new edition. Recognition of the new ingredient dictionary was intended to effect the adoption of additional names of ingredients, particularly those listed in 10 bulletins issued by petitioner since recognition of the first edition of this dictionary. Copies of the CTFA petition of June 24, 1976 and the second edition (1976) of the CTFA Dictionary, received in the form of page proofs (Refs. 1 and 2), and all other references cited in this preamble are on file at the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

On September 17, 1976, the agency informed the CTFA that a review of the new dictionary had raised questions on important issues and that the approaches taken in the dictionary on these issues needed further support, or that alternative courses of action should be considered, before FDA acted on the petition (Ref. 3). On request by petitioner, FDA and CTFA representatives met on September 24 and October 15, 1976 for discussion of the dictionary-related issues (Refs. 4 and 5). On November 2, 1976, the CTFA responded in writing to the questions raised by FDA on the new dictionary edition (Ref. 6).

On January 13 and 19, 1977, the CTFA forwarded to FDA additional responses to the pending dictionary issues and submitted a second, revised set of page proofs of the second edition (1976) of the CTFA Dictionary (Refs. 7, 8, and 9). This set of page proofs contains some of the recommended changes adopted by the CTFA subsequent to FDA's letter of September 17 and the meetings of September 24 and October 15, 1976.

DISCUSSION OF CTFA DICTIONARY-RELATED ISSUES

The following review summarizes CTFA's accomplished and planned changes in the new cosmetic ingredient dictionary in response to the referenced discussions and exchanges of correspondence. Also discussed are the agency's proposed actions where CTFA's changes in the dictionary have not resolved pending questions in a satisfactory manner. Since the changes made by the CTFA in