upon the request of the Government if at any time it should appear to the Government that the association is able to refinance its bonds by obtaining a loan for such purposes from responsible cooperative or private sources at reasonable rates and terms.

(10) To provide for, execute, and comply with Form FmHA 400-4, "Nondiscrimination Agreement," and Form FmHA 400-1, "Equal Opportunity Agreement," including an "Equal Opportunity Clause," which clause is to be incorporated in or attached as a rider to each construction contract and subcontract involving an amount in excess of $10,000.

(11) To place the proceeds of the loan on deposit in an account in a bank and in a manner approved by the Government.

(12) Not to sell, transfer, lease, or otherwise encumber the facility or any portion thereof or interest therein; not to permit others to do so, without the prior written consent of the Government.

(13) Not to borrow any money from any source, enter into any contract or agreement, or incur any other liabilities in connection with making enlargements, improvements, or extensions to, or for any other purpose in connection with the facility (exclusive of normal maintenance) without prior written consent of the Government, if such undertaking would involve the source of funds pledged to pay the debt to FmHA.

(14) That upon default in the payments of any principal and accrued interest on the bonds or in the performance of any covenant or agreement contained herein or in the instruments incident to making or insuring the loan, the Government, at its option, may:

(i) Declare the entire principal amount then outstanding and accrued interest, due and payable;

(ii) For the account of the association (payable from the source of funds pledged to pay the bonds or notes or any other legally permissible source), incur and pay reasonable expenses for repair, maintenance, and operation of the facility and such other reasonable expenses as may be necessary to cure the cause of default; and/or

(iii) Take possession of the facility, repair, maintain and operate, rent or otherwise dispose of the facility. Default under the provisions of the resolution or any instrument incident to the making or insuring of the loan may be construed by the Government to constitute default under any other instrument held by the Government and executed or assumed by the association, and default under any such instrument may be construed by the Government to constitute default hereunder.

(b) *Interim financing.* In all loans, exceeding $50,000, where it is possible for funds to be borrowed at reasonable interest rates on an interim basis from commercial sources for the construction period, such interim financing will be obtained so as to preclude the necessity for multiple advances of FmHA funds. When interim commercial financing is used, the application will be processed, including obtaining construction bids, to the stage where the FmHA loan would normally be closed, that is immediately prior to the start of construction. When the interim financing funds have been expended, the FmHA loan will be closed. Multiple advances may be used in conjunction with interim commercial financing when the applicant is unable to obtain sufficient funds through interim commercial financing in an amount equal to the loan. The FmHA loan proceeds (including advances) will be used to retire the interim commercial indebtedness. Before the FmHA loan is closed, the applicant will be required to provide FmHA with statements from the contractor, engineer, architect, and attorney that they have been paid to date in accordance with their contracts or other agreements and, in the case of the contractor, that he has paid his suppliers and subcontractors. If such statements cannot be obtained, the loan may be closed provided:

(1) Statements to the extent possible are obtained;

(2) The interests of FmHA can be adequately protected and its security position is not impaired;

(3) Adequate provisions are made for handling the unpaid accounts by withholding or escrowing sufficient funds to pay such claims.

(c) *Multiple advances.* * * *

* * * * *

(2) Advances will be requested in sufficient amounts to insure that ample funds will be on hand to pay costs of construction, rights-of-way and land, legal, engineering, interest, and other expenses as needed. The applicant will prepare Form FmHA 440-11, "Estimate of Funds Needed," to show the amount of funds needed during the 30-day period. Form AD-627, "Report of Federal Cash Transactions," will be prepared and submitted with each Form FmHA 440-11 after the initial advance of funds is made.

(d) *Applicant contribution.* Applicants contributing funds toward the project cost shall deposit these funds in its construction account on or before loan closing or start of construction, whichever occurs first. Project costs, paid prior to the required deposit time, with applicant funds shall be appropriately accounted for.

(e) *Supervised bank account.* Loan funds and any funds furnished by the applicant may be deposited in a supervised bank account in a bank having Federal Deposit Insurance Corporation (FDIC) coverage. Funds placed in a supervised bank account are public monies under Title 12 U.S.C. 265, and therefore any amount which exceeds the FDIC coverage will require a collateral pledge pursuant to Treasury Circular No. 176. If a supervised bank account is not used, arrangements will be agreed upon for the prior approval by FmHA of the bills, or vouchers upon which warrants will be drawn, so that the necessary control of payments from loan funds can be maintained and FmHA records can be kept current. Periodic audits of nonsupervised accounts shall be made by FmHA at such times and in such manner as the FmHA State Director prescribes in the conditions of loan approval. Mandatory State Laws regulating the depositories to be used shall be complied with.

(f) *Payment for construction.* Payment for construction will be made in accordance with the construction contract in amounts approved on Form FmHA 424-18, "Partial Payment Estimate." Advances for contract retainage will not be made until such retainage is due and payable under the terms of contract. Form AD-629, "Outlay Report and Request for Reimbursement for Construction Programs," will be used to account for funds expended in the last 30-day period. Each payment estimate must be approved by the governing body of the borrower. The review and acceptance of partial payment estimates by FmHA does not attest to the correctness of the quantities shown or that the work has been performed in accordance with the plans and specifications. A final Form AD-627 will be submitted to FmHA to include the final advance and all other advances not later than 90 days after the final advance has been made.

(g) *Funds remaining after construction is completed.* Should loan funds remain available, including obligated funds not advanced, after all costs incident to the basic project have been paid or provided for, such funds may be used for needed extensions, enlargements and improvements of the project with the prior permission of the FmHA State Director. If the additional work is to be undertaken by the contractor(s) already engaged in the construction of the project, the additional work may be authorized by a change order. Remaining project funds not needed for authorized extensions, enlargements, or improvements shall be returned to FmHA as a repayment on the loan in a proportionate amount of the FmHA loan to the total planned project cost, unless other disposition is required by the bond ordinance or resolution or by State statutes.

(h) *Obtaining insurance and fidelity bonds.* * * *

(i) *Distribution of recorded documents.* * * *

* * * * *

(7 U.S.C. 1989, delegation of authority by the Secretary of Agriculture, 7 CFR 2.23, delegation of authority by the Assistant Secretary for Rural Development, 7 CFR 2.70.)

Effective date: This amendment shall become effective on February 4, 1977.

Dated: January 26, 1977.

JOSEPH R. HANSON,
Acting Administrator,
Farmers Home Administration.

[FR Doc.77-3696 Filed 2-3-77;8:45 am]

proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Rural Electrification Administration

[7 CFR Part 1701]

RURAL TELEPHONE PROGRAM

Proposed Issuance of Memorandum on Use of Larger Pair Sizes of Filled Cables

Notice is hereby given that, pursuant to the Rural Electrification Act, as amended (7 U.S.C. 901 et seq.), REA proposes to issue a memorandum (File with REA Bulletin 383-1) which outlines restrictions on the use of loan funds for the purchase of nonfilled buried or underground cables and places increased emphasis on the use of filled cables in all sizes for application in buried or underground systems. On issuance of the proposed memorandum, Appendix A to Part 1701 will be modified accordingly.

Persons interested in the memorandum may submit written data, views or comments to the Director, Telephone Operations and Standards Division, Rural Electrification Administration, Room 1355, South Building, U.S. Department of Agriculture, Washington, D.C. 20250, on or before March 7, 1977. All written submissions made pursuant to this notice will be made available for public inspection at the Office of the Director, Telephone Operations and Standards Division during regular business hours.

The text of the proposed memorandum is as follows:

[File With REA Bulletin 383-1]

Subject: Use of Larger Pair Sizes of Filled Cables

To: All REA Telephone Borrowers, Consulting Engineers and Contractors

In a letter dated October 15, 1974, we informed all REA telephone borrowers, consulting engineers and contractors that the use of filled buried wires and cables would be mandatory up through 200 pairs. This action was taken in order to take advantage of improved maintenance experience and transmission stability over air core types.

We now feel there is sufficient justification for requiring all sizes of buried or underground cable to be of the filled type or to be pressurized. Accordingly, this is to inform all borrowers that effective on all projects bid after July 1, 1977, or on all orders placed by REA borrowers after this date, REA loan funds will not be authorized to be used for the purchase of nonfilled buried or underground cables unless such cables are to be utilized as part of a pressurized cable plant. For direct buried filled cables the BJF assembly units shall be specified in lieu of BJ units. For underground filled cables specify the "UF" unit in lieu of the "U" unit.

Dated: January 27, 1977.

C. R. BALLARD,
Assistant Administrator,
Telephone.

[FR Doc.77-3269 Filed 2-3-77;8:45 am]

Animal and Plant Health Inspection Service

[9 CFR Part 92]

FOREIGN EMBARKATION QUARANTINE STATION FOR LIVESTOCK

Proposed Criteria and Standards for Establishment

Correction

In FR Doc. 77-1966 appearing on page 3859 in the issue for Friday, January 21, 1977, on page 3860, middle column, the 14th line of § 92.4a(a)(7) should read "of such action; but such withdrawal or refusal shall con-".

SECURITIES AND EXCHANGE COMMISSION

[17 CFR Part 200]

[Release No. 33-5802, 34-13232, 35-19867, 39-453, IC-9628, IA-567; FOIA-48; File No. S7-674; Comment deadline: March 7, 1977]

GOVERNMENT IN THE SUNSHINE

Public Observation of Commission Meetings, Information and Requests, and Related Matters

The Securities and Exchange Commission today announced rulemaking proposals to implement the Government in the Sunshine Act, 5 U.S.C. 552b, ("Sunshine Act") which has, as its principal provision, the requirement that, unless exempt, "every portion of every meeting of an agency shall be open to public observation." 5 U.S.C. 552b(b). The Commission is soliciting comment on these proposed rules pursuant to the provision in the Sunshine Act which requires every agency subject to the open meetings requirements to publish notice in the FEDERAL REGISTER of its proposed implementing rules and to provide at least 30 days opportunity for public comment thereon.[1] The Act takes effect on March 12, 1977.

The Sunshine Act also establishes certain standards regarding ex parte communications in on-the-record agency proceedings and contains amendments to the Freedom of Information Act, 5 U.S.C. 552 ("FOIA"). Accordingly, the Commission has today also proposed amendments to its regulations concerning public requests for information (17 CFR Part 200, Subpart D), and, in the near future, will amend its existing Code of Behavior Governing Ex Parte Communications Between Persons Outside the Commission and Decisional Employees (17 CFR Part 200, Subpart F) to conform to 5 U.S.C. 557(d), enacted by the Sunshine Act.[2]

In announcing these rule proposals, the Commission emphasizes that the sole purpose of proposed new Subparts B and I of the Commission's rules—"Disposition of Commission Business" and "Regulations Pertaining to Public Observation of Commission meetings," respectively—is the implementation of the Sunshine Act. These rules are not intended to confer new rights, apart from those expressly conferred by the Act, nor to open to those who disagree with particular Commission decisions new avenues of attack—not available under existing law—upon Commission action for the protection of investors. See 5 U.S.C. 552b(h). Accordingly, the proposals herein should be interpreted in light of the purposes and terms of the Sunshine Act.

The proposals today announced would amend Subpart A (entitled "Organization and Program Management") and Subpart D (entitled "Information and Requests") of the Commission's existing rules in Part 200 of 17 CFR. In addition, these proposals would create a new Subpart B (entitled "Disposition of Commission Business") and a new Subpart I (entitled "Regulations Pertaining to Public Observation of Commission Meetings"). A brief synopsis of these rules appears below, and the full text is appended hereto.

AMENDMENTS TO SUBPART A—ORGANIZATION AND PROGRAM MANAGEMENT

The Commission proposes to amend 17 CFR 200.21, which describes the duties of the Commission's General Counsel, to add a reference to the General Counsel's responsibility for certifying that particular Commission meetings may properly be closed to the public. Such a certification is required by 5 U.S.C. 552b(f)(1), as implemented by the Commission's proposed § 200.406. In the case of the absence of the General Counsel, the most senior Associate General Counsel or Assistant General Counsel available would be deemed to be the Acting General Counsel for purposes of executing the certification in question. In the absence of both the General Counsel and every Associate and Assistant General Counsel, such attorney as the General Counsel designates would perform this

[1] Section 552b(g) requires that each agency consult with the Administrative Conference of the United States in formulating rules to implement the Sunshine Act. The Commission has engaged in such consultation, by furnishing copies of the preliminary drafts of these rules to the Conference, by discussions with Conference personnel, and by attendance at the Conference's seminar on this subject.

[2] In this release, the Commission also solicits comments on proposed clarifying Freedom of Information Act ("FOIA") amendments. The Sunshine Act expressly requires the opportunity for public comment only as to rules implementing the new open meetings requirements.

task. While the Commission believes it important to provide for the performance of the certification function in the absence of the General Counsel, the Commission does not intend that this responsibility will routinely be discharged except by the General Counsel.

NEW SUBPART B—DISPOSITION OF COMMISSION BUSINESS

Proposed new Subpart B of Part 200, which reflects existing Commission procedures, is intended to describe generally the manner in which the Commission conducts business requiring a vote of the members of the Commission. Section 200.40 pertains to the joint disposition of business, at Commission meetings or otherwise, and embodies the provision in 5 U.S.C. 552b(b) which will prohibit joint deliberations among Commission members except in accordance with the Sunshine Act.

Sections 200.41 and 200.42 reflect the existing practice by which the Commission occassionally conducts business without joint deliberations among its members. Section 200.41 provides for sequential consideration of matters not requiring joint deliberation. Section 200.42 delegates to an individual Commissioner, to be designated as "duty officer," certain of the Commission's functions pursuant to the terms of 15 U.S.C. 78d–1. Although not expressly required by the delegation statute, § 200.42 (c) provides that every action taken by the duty officer shall be submitted to the full Commission for affirmation as soon as practicable. While the procedures in § 200.41 or § 200.42 will not be utilized where joint deliberation would be preferable, the Commission believes that it must retain the flexibility to employ such procedures when agency business so demands.

AMENDMENTS TO SUBPART D—INFORMATION AND REQUESTS

Section 5(b) of the Sunshine Act amends exemption 3 under the Freedom of Information Act, 5 U.S.C. 552(b)(3) and, accordingly, the Commission proposes to amend its corresponding FOIA exemption to reflect the statutory change. In addition, the Commission is proposing technical amendments to its rules implementing exemptions 2, 4, 7, and 8 in order to describe more clearly the scope of these exemptions in the context of the Commission's operations and the manner in which the Commission is currently applying these exemptions. Since FOIA exemptions 1, 2, 3, 4, 7, and 8 parallel Sunshine exemptions appearing in 5 U.S.C. 552b(c) (1), (2), (3), (4), (7), and (8), the Commission is proposing to conform the wording of its rules to implement these identical FOIA and Sunshine exemptions.

The Commission is also proposing to amend § 200.80(a), which describes information published in the FEDERAL REGISTER, to include those notices required to be so published by the Sunshine Act. Similarly, the proposed amendment to the listing of documentary material available to the public which appears in § 200.80a, Appendix A, would add thereto certain documents required to be prepared pursuant to the Sunshine Act.

NEW SUBPART I—REGULATIONS PERTAINING TO PUBLIC OBSERVATION OF COMMISSION MEETINGS

The Commission is proposing 11 rules, to be codified in proposed new Subpart I of Part 200, to implement the open meetings requirements of the Sunshine Act. Below is a brief description of each of these proposed rules.

Section 200.400—This rule would state that Commission meetings are to be open to the public, except as otherwise provided pursuant to Subpart I. See 5 U.S.C. 552b(b).

Section 200.401—Proposed Rule 401 would define various terms utilized elsewhere in new Subpart I. The definition of "meeting" is drawn from 5 U.S.C. 552b(a)(2). Similarly, the definition of the term "financial institution" has been taken from the legislative history of the Sunshine Act. See S. Rep. No. 94–354, p. 24.

Section 200.402—Rule 402 would authorize the Commission to close meetings which fall within one of the 10 specified exemptions in 5 U.S.C. 552b(c). To the extent feasible, in setting forth these exemptions the Commission, for the guidance of the public, has provided a description of the various types of Commission action which would appear to be encompassed by each exemption. The proposed rule makes clear, however, that these descriptions are merely illustrative and not exhaustive. As stated above, where these statutory exemptions under the Sunshine Act parallel statutory exemptions under the FOIA, identical language has been employed in both the Commission's FOIA and Sunshine rules. Subsection (c) provides that the Commission may, in its discretion, open any meeting even if closable pursuant to one or more exemptions. Subsection (d) of Rule 402 authorizes the Commission to delete from the announcement of a meeting any information which falls within one of the 10 specified exemptions.

Section 200.403—Proposed Rule 403 would implement the provisions of 5 U.S.C. 552b(e) requiring announcement and publication of a notice of Commission meetings. Subsection 403(c) authorizes expedited procedures for urgent matters, and Subsection 403(d) authorizes an abbreviated notice for certain closed Commission meetings. See 5 U.S.C. 552b(d)(4). A note to this proposed rule describes the general plan which the Commission presently foresees following in scheduling its meetings. As stated therein, the note is provided for the guidance of the public but is not, in any event, binding on the Commission.

Section 200.404—Proposed Rule 404 would provide the general procedure by which the Commission may take action to close a Commission meeting; the steps described are those required by 5 U.S.C. 552b(d) (1) and (3).

Section 200.405—On the basis of a review of the matters actually considered by the Commission during the past several months, and on the basis of the legislative history of the Sunshine Act, the Commission has determined that it is entitled to utilize the simplified procedure for closing Commission meetings which fall within exemptions 4, 8, 9(A), or 10 of 5 U.S.C. 552b(c). The steps described are those permitted by 5 U.S.C. 552(d)(4). That paragraph provides, in pertinent part:

"Any agency, a majority of whose meetings may properly be closed to the public pursuant to paragraph (4), (8), (9)(A), or (10) of subsection (c) [of 5 U.S.C. 552b]; or any combination thereof, may provide by regulation for the closing of such meetings or portions thereof in the event that [specified steps are taken]."

Section 200.406—Proposed Rule 406 would require that, for every closed Commission meeting, the General Counsel shall publicly certify that, in his or her opinion, the meeting may properly be closed to the public. This rule would implement the first sentence of 5 U.S.C. 552b(f)(1).

Section 200.407—Proposed Rule 407 would require the Secretary to maintain a verbatim transcript or recording of all closed meetings, except that the Secretary may maintain detailed minutes in lieu of a verabtim record for meetings closed pursuant to paragraphs (8), (9)(A), or (10) of 5 U.S.C. 552b(c). This rule would also require the Secretary to retain both the General Counsel's certification and a statement of the presiding officer setting forth the time, place, and persons present, for each closed meeting. See 5 U.S.C. 552b(f)(1).

Section 200.408—Proposed Rule 408 would provide for public access to any nonexempt portion of the transcript or recording of a closed meeting within 20 days of the receipt, by the FOIA Officer, of any request for such transcript or recording. See 5 U.S.C. 552b(f)(2). In addition, the Commission proposes an administrative appeal procedure comparable to that now in place under the FOIA, for review of the denial of access to a transcript or recording (or portion thereof). The Sunshine Act does not expressly mandate such an appeal procedure.

Section 200.409—Proposed Rule 409 would create a discretionary administrative review procedure whereby interested persons may seek reconsideration of the decision to open or close a meeting. While 5 U.S.C. 552b(d)(2) requires this procedure as to certain open meetings, the Commission proposes, for the benefit of the public, also to establish a comparable procedure as to closed meetings in order, where possible, to resolve in advance claims regarding closed meetings.

Section 200.410—This proposed rule would cover three miscellaneous matters: Subsection (a) prohibits unauthorized recording or photography of open meetings and insures maintenance of decorum generally; Subsection (b) authorizes the Commission to clear its meeting room in the event that discussion at an open meeting begins to touch on matters properly the subject of closed deliberations; and Subsection (c) provides that access to documents discussed at meetings may only be obtained pursuant to the FOIA.

CONCLUSION AND REQUEST FOR COMMENT

The Commission believes that the proposals herein will fully implement both the letter and spirit of the Sunshine Act while at the same time protecting the Commission's need, in order properly and fairly to discharge its responsibilities under the federal securities laws, to prevent public disclosure of certain information. The Commission recognizes, however, that the implementation of the Sunshine Act will entail many changes in its existing procedures, and intends to afford careful consideration to the views of all interested persons.

Comments concerning these proposals should be submitted, in triplicate, to George A. Fitzsimmons, Secretary, Securities and Exchange Commission, Washington, D.C. 20549 before the close of business on March 11, 1977. All such communications should refer to File S7–674 and will be available for public inspection and copying at the Commission's

Public Reference Room, 1100 L Street, N.W., Washington, D.C. The text of the proposals discussed herein is set forth below.

TEXT OF PROPOSED RULES

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

1. Section 200.21 of Subpart A of Title 17 CFR is amended by adding the following to § 200.21 to read as follows:

Subpart A—Organization and Program Management

§ 200.21 The General Counsel.

* * * * *

The General Counsel is also responsible for publicly certifying, pursuant to § 200.406, that, in his or her opinion, particular Commission meetings may properly be closed to the public. In the absence of the General Counsel, the most senior Associate General Counsel available shall be deemed the General Counsel for purposes of § 200.406. In the absence of the General Counsel and every Associate General Counsel, the most senior Assistant General Counsel available shall be deemed the General Counsel for purposes of § 200.406. In the absence of every Associate General Counsel and every Assistant General Counsel, such attorneys as the General Counsel may designate (in such order of succession as the General Counsel directs) shall exercise the responsibilities imposed by § 200.406.

2. New Subpart B is added to Part 200 to read as follows:

Subpart B—Disposition of Commission Business

Sec.

Subpart B—Disposition of Commission Business

§ 200.40 Joint disposition of business by Commission meeting.

Any disposition of Commission business which entails joint deliberation among the members of the Commission shall occur at Commission meetings in accordance with the definitions and procedures set forth in Subpart I of this part. The Commission's Secretary shall prepare and maintain a Minute Record reflecting the official action taken at such meetings.

§ 200.41 Disposition of business by seriatim Commission consideration.

(a) Whenever the Commission's Chairman, or the Commission member designated as duty officer pursuant to § 200.42, is of the opinion that joint deliberation among the members of the Commission upon any matter is unnecessary in light of the nature of the matter, impracticable, or contrary to the requirements of agency business, but is of the view that such matter should be the subject of a vote of the Commission, such matter may be disposed of by circulation of any relevant materials concerning the matter to at least that number of Commission members necessary to take action thereon. Each participating Commission member shall report his or her vote to the Secretary, who shall record it in the Minute Record of the Commission.

(b) Whenever any member of the Commission so requests, any matter circulated for disposition pursuant to § 200.41(a) shall be withdrawn from circulation and scheduled instead for joint Commission deliberation.

§ 200.42 Disposition of business by exercise of authority delegated to individual Commissioner.

(a) *Delegation to duty officer.* (1) Pursuant to the provisions of Pub. L. No. 87-592, 76 Stat. 394, as amended by Section 25 of Pub. L. 94-29, 89 Stat. 163, the Commission hereby delegates to an individual Commissioner, to be designated as the Commission's "duty officer" by the Chairman of the Commission (or by the Chairman's designee) from time to time, all of the functions of the Commission: *Provided, however,* That no such delegation shall authorize the duty officer (i) to exercise the function of rulemaking, as defined in the Administrative Procedure Act of 1946, as codified, 5 U.S.C. 551, et seq., with reference to general rules as distinguished from rules of particular applicability; (ii) to make any rule, pursuant to section 19(c) of the Securities Exchange Act of 1934; or (iii) to preside at the taking of evidence as described in section 7(a) of the Administrative Procedure Act, 5 U.S.C. 556(b).

(2) To the extent feasible, the designation of a duty officer shall rotate, under the administration of the Secretary, on a regular weekly basis among the members of the Commission other than the Chairman.

(b) *Exercise of duty officer authority.* (1) The authority delegated by this rule shall be exercised when, in the opinion of the duty officer, action is required to be taken which, by reason of its urgency, cannot be scheduled for consideration at a Commission meeting. After consideration of a staff recommendation involving such a matter, the duty officer shall report his or her action thereon to the Secretary.

(2) In any consideration of Commission business by a duty officer, the provisions of Subpart I herein, § 200.400 et seq., shall not apply, whether or not the duty officer, in exercising his or her authority, consults with, or seeks the advice of, other members of the Commission.

(c) *Commission affirmation of duty officer action.* (1) Any action authorized by a duty officer pursuant to § 200.42(a) shall be either (i) circulated to the members of the Commission for affirmation pursuant to § 200.41; or (ii) scheduled for affirmation at a Commission meeting at the earliest practicable date consistent with the procedures in Subpart I.

(2)(i) The Commission may, in its discretion, at any time review any unaffirmed action taken by a duty officer, either upon its own initiative or upon the petition of any person affected thereby. The vote of any one member of the Commission, including the duty officer, shall be sufficient to bring any such unaffirmed action taken by a duty officer before the Commission for review.

(ii) A person or party adversely affected by any unaffirmed action taken by a duty officer shall be entitled to seek review by the Commission of the duty officer's unaffirmed actions, but only in the event that the unaffirmed action by the duty officer (A) denies any request for action pursuant to sections 8(a) or 8(c) of the Securities Act of 1933, or the first sentence of section 12(d) of the Securities Exchange Act of 1934; (B) suspends trading in a security pursuant to section 12(k) of the Securities Exchange Act of 1934; or (C) is pursuant to any provision of the Securities Exchange Act of 1934 in a case of adjudication, as defined in section 551 of Title 5, United States Code, not required by that Act to be determined on the record after notice and opportunity for hearing (except to the extent there is involved a matter described in section 554(a) (1) through (6) of Title 5, United States Code).

(3) Affirmed or unaffirmed action taken by the duty officer shall be deemed to be, for all purposes, the action of the Commission unless and until the Commission directs otherwise. Rule 26 of the Commission's rules of practice, 17 CFR 201.26, shall not apply to duty officer action.

Subpart D—Information and Requests

3. Section 200.80 of Subpart D of Part 200 is amended as follows: Paragraph (a)(1)(v) is amended; paragraph (a)(1)(vi) is added; and paragraphs (b)(2), (3), (4), and (8) are amended to read as follows:

§ 200.80 Commission records and information.

(a)(1) *Information published in the* FEDERAL REGISTER. * * *

(v) Each amendment, revision, or repeal of the foregoing; and

(vi) The notice of Commission meetings described in § 200.403, but only to the extent, and under the conditions, specified in § 200.403.

* * * * *

(b) *Nonpublic matters.* * * *

(2) Related solely to the internal personnel rules and practices of the Commission or any other federal, state, local, or foreign governmental authority or agency, including, but not limited to:

(i) Operation rules, guidelines, and manuals of procedure for investigators, attorneys, accountants, and other employees other than those which establish legal requirements to which members of the public are expected to conform; or

(ii) Hiring, termination, promotion, discipline, compensation, or reward of any Commission employee or member, the existence, investigation, or disposition of a complaint against any Commission employee or member, the physical or mental condition of any Commission

employee or member, the handling of strictly internal matters, matters which would tend to infringe on the privacy of the staff or members of the Commission, or similar subjects.

(3) Specifically exempted from disclosure by statute (other than 5 U.S.C. 552): *Provided*, That such statute (i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld.

(4) Disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential, including, but not limited to:

* * * * *

(7) (i) Investigatory records compiled for law enforcement purposes to the extent that the production of such records would: (A) Interfere with enforcement activities undertaken or likely to be undertaken by the Commission or the Department of Justice, or any United States Attorney, or any federal, state, local, or foreign governmental authority, any professional association, or any securities industry self-regulatory organization; (B) deprive a person of a right to a fair trial or an impartial adjudication; (C) constitute an unwarranted invasion of personal privacy; (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source; or (E) disclose investigative techniques and procedures; or (F) endanger the life or physical safety of law enforcement personnel.

(ii) The term "investigatory records" includes, but is not limited to, all documents, records, transcripts, evidentiary materials of any nature, correspondence, related memoranda, or work product concerning any examination, any investigation (whether formal or informal), or any related litigation, which pertains to, or may disclose, the possible violation by any person of any provision of any statute, rule, or regulation administered by the Commission, by any other federal, state, local, or foreign governmental authority, by any professional association, or by any securities industry self-regulatory organization. The term "investigatory records" also includes all written communications from, or to, any person complaining or otherwise furnishing information respecting such possible violations, as well as all correspondence or memoranda in connection with such complaints or information.

(8) Contained in, or related to, any examination operating, or condition report prepared by, on behalf of, or for the use of, the Commission, any other federal, state, local, or foreign governmental authority, or any securities industry self-regulatory organization, responsible for the regulation or supervision of financial institutions.

* * * * *

4. Add the following sentence to § 200.80a.

§ 200.80a Appendix A Documentary material available to the public.

* * * * *

MISCELLANEOUS

* * * * *

Notices of Commission meetings announced to the public as described in § 200.403; announcements of Commission action to close a meeting, or any portion thereof, as described in § 200.404(b) and § 200.405(c); and certifications by the General Counsel, pursuant to § 200.406, that a Commission meeting, or any portion thereof, may be closed to the public.

5. New Subpart I is added to Part 200 to read as follows:

Subpart I—Regulations Pertaining to Public Observation of Commission Meetings

Sec.

Subpart I—Regulations Pertaining to Public Observation of Commission Meetings

§ 200.400 Open meetings.

Except as otherwise provided in this subpart, meetings of the Commission shall be open to public observation.

§ 200.401 Definitions.

As used in this subpart—

(a) "Meeting" means the joint deliberations of at least the number of individual members of the Securities and Exchange Commission required to take action on behalf of the Commission where such deliberations determine or result in the joint conduct or disposition of official Commission business, but does not include deliberations required or permitted by § 200.41 or § 200.42 (respecting seriatim and duty officer disposition of Commission business, respectively), or by §§ 200.403, 200.404, or 200.405 (respecting whether particular Commission deliberations shall be open or closed and related matters).

(b) "Portion of a meeting" means the consideration during a meeting of a particular topic or item separately identified in the notice of Commission meetings described in § 200.403.

(c) "Open," when used in the context of a Commission meeting or a portion thereof, means that the public may attend and observe the deliberations of the Commission during such meeting or portion of a meeting, consistent with the provisions of § 200.410 (respecting decorum at meetings and other related matters).

(d) "Closed," when used in the context of a Commission meeting or a portion thereof, means that the public may not attend or observe the deliberations of the Commission during such meeting or portion of a meeting.

(e) "Announce," and "make publicly available," when used in the context of the dissemination of information, mean, in addition to any specific method of publication described in this subpart, that a document containing the information in question will be posted for public inspection in, or adjacent to, the lobby of the Commission's headquarters offices, will be available to the public through the Commission's Public Reference Section, and will be available to the press through the Commission's Office of Public Affairs, all in Washington, D.C.

(f) The term "likely to," as used in § 200.402, illustrating the circumstances under which Commission meetings may be closed, and the circumstances in which information may be deleted from the notice of Commission meetings, means that the discussion of Commission business, or publication of information, reasonably could encompass matters which the Commission is authorized, by the Government in the Sunshine Act, Pub. L. 94-409, as implemented by this subpart, to consider or discuss at a closed meeting (or a closed portion of a meeting).

(g) The term "financial institution," as used in § 200.402(a), authorizing the closure of certain Commission meetings, includes, but is not limited to, banks, savings and loan associations, credit unions, brokers and dealers in securities or commodities, exchanges dealing in securities or commodities, national securities associations, investment companies, investment advisers, securities industry self-regulatory organizations subject to 15 U.S.C. 78s, and institutional managers as defined in 15 U.S.C. 78m(f).

(h) The term "person" includes, but is not limited to, any corporation, partnership, company, association, joint stock corporation, business trust, unincorporated organization, government, political subdivision, agency, or instrumentality of a government.

§ 200.402 Closed meetings.

(a) *Nonpublic matters.* Pursuant to the general or special procedures for closing Commission meetings, as set forth in § 200.404 or § 200.405, respectively, a meeting, or any portion thereof, shall be closed to public observation where the Commission determines that such meeting, or a portion thereof, is likely to—

(1) Disclose matters specifically authorized under criteria established by an executive order to be kept secret in the interests of national defense or foreign policy, and in fact properly classified pursuant to such executive order.

(2) Relate solely to the internal personnel rules and practices of the Commission or any other Federal, state, local, or foreign governmental authority or agency, including, but not limited to, discussion concerning

(i) Operation rules, guidelines, and manuals of procedure for investigators, attorneys, accountants, and other employees, other than those rules, guidelines, and manuals which establish legal requirements to which members of the public are expected to conform; or

(ii) Hiring, termination, promotion, discipline, compensation, or reward of any Commission employee or member, the existence, investigation, or disposition of a complaint against any Commission employee or member, the physical or mental condition of any Commission employee or member, the handling of strictly internal matters, which would tend to infringe on the privacy of the staff or members of the Commission, or similar subjects.

(3) Disclose matters specifically exempted from disclosure by statute (other than 5 U.S.C. 552): *Provided*, That such statute requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or establishes particular criteria for withholding or refers to particular types of matters to be withheld.

(4) Disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential, including, but not limited to:

(i) Information contained in letters of comment in connection with resignation statements, applications for registration or other material filed with the Commission, replies thereto, and related material which is deemed to have been submitted to the Commission in confidence or to be confidential at the instance of the registrant or person who has filed such material unless the contrary clearly appears; and

(ii) Information contained in any document submitted to or required to be filed with the Commission where the Commission has undertaken formally or informally to receive such submission or filing for its use or the use of specified persons only, such as preliminary proxy material filed pursuant to Rule 14a-6 under the Securities Exchange Act (17 CFR 240.14a-6), reports filed pursuant to Rule 316(a) under the Securities Act (17 CFR 230.316(a)), agreements filed pursuant to Rule 15c-3-1(c)(7(G) under the Securities Exchange Act 17 CFR 240.15c-1(c)(7)(vii)), schedules filed pursuant to Part I of Form X-17A-5 (17 CFR 249.617) in accordance with Rule 17a-5(b)(3) under the Securities Exchange Act (17 CFR 240.17a-5(b)(3), statements filed pursuant to Rule 17a-5(k)(1) under the Securities Exchange Act 17 CFR 240.17a-5(k)(1)), confidential reports filed pursuant to Rules 17a-9, 17a-10, 17a-12 and 17a-16 under the Securities Exchange Act (17 CFR 240. 17a-9, 240.17a-12, and 240.17a-16), and any information filed with the Commission and confidential pursuant to section 45 of the Investment Company Act of 1940, 15 U.S.C. 80a-44, or Rule 45a-1 thereunder (17 CFR 270.45a-1); and

(iii) Information contained in reports, summaries, analyses, letters, of memoranda arising out of, in anticipation of, or in connection with, an examination or inspection of the books and records of any person or any other investigation.

(5) Involve accusing any person of a crime, or formally censuring any person, including, but not limited to, consideration of whether to:

(i) Institute, continue, or conclude administrative proceedings or any formal or informal investigation or inquiry, whether public or nonpublic, against or involving any person; or

(ii) Commence, participate in, or terminate judicial proceedings alleging a violation of any provision of the federal securities laws, or the rules and regulations thereunder, or any other statute or rule a violation of which is punishable as a crime; or

(iii) Issue a report or statement discussing the conduct of any person and the relationship of that conduct to possible violations of any provision of the federal securities laws, or the rules and regulations thereunder, or any other statute or rule a violation of which is punishable as a crime; or

(iv) Transmit, with or without recommendation, any Commission memorandum, file, document, or record to the Department of Justice, a United States Attorney, any federal, state, local, or foreign governmental authority, any professional association, or any securities industry self-regulatory organization, in order that the recipient may consider the institution of proceedings against any person or the taking of any action that might involve accusing any person of a crime or formally censuring any person; or

(v) Seek from, act upon, or act jointly with respect to, any information, file, document, or record where such action could lead to accusing any person of a crime or formally censuring any person by any entity described in paragraph (a)(5)(iv) of this section.

(6) Disclose information of a personal nature, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

(7)(i) Disclose investigatory records compiled for law enforcement purposes, or information which, if written, would be contained in such records, to the extent that the production of such records would: (A) Interfere with enforcement activities undertaken, or likely to be undertaken, by the Commission or the Department of Justice, or any United States Attorney, or any federal, state, local, or foreign governmental authority, any professional association, or any securities industry self-regulatory organization; (B) deprive a person of a right to a fair trial or an impartial adjudication; (C) constitute an unwarranted invasion of personal privacy; (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source; (E) disclose investigative techniques and procedures; or (F) endanger the life or physical safety of law enforcement personnel.

(ii) The term "investigatory records" includes, but is not limited to, all documents, records, transcripts, evidentiary materials of any nature, correspondence, related memoranda, or work product concerning any examination, any investigation (whether formal or informal), or any related litigation, which pertains to, or may disclose, the possible violation by any person of any provision of any statute, rule, or regulation administered by the Commission, by any other federal, state, local, or foreign governmental authority, by any professional association, or by any securities industry self-regulatory organization. The term "investigatory records" also includes all written communications from, or to, any person complaining or otherwise furnishing information respecting such possible violations, as well as all correspondence or memoranda in connection with such complaints or information.

(8) Disclose information contained in, or related to, any examination, operating, or condition report prepared by, on behalf of, or for the use of, the Commission, any other federal, state, local, or foreign governmental authority, or any securities industry self-regulatory organization, responsible for the regulation or supervision of financial institutions.

(9) Disclose information the premature disclosure of which would be likely to

(i)(A) Lead to significant financial speculation in currencies, securities, or commodities, including, but not limited to, discussions concerning the proposed or continued suspension of trading in any security, or the possible investigation of, or institution of activity concerning, any person with respect to conduct involving or affecting publicly-traded securities, or (B) Significantly endanger the stability of any financial institution; or

(ii) Significantly frustrate the implementation, or the proposed implementation, of action by the Commission, any other federal or state governmental authority or agency, or any securities industry self regulatory agency: *Provided, however*, That this subdivision (ii) shall not apply in any instance where the Commission has already disclosed to the public the precise content or nature of itse proposed action, or where the Commission is expressly required by law to make such disclosure on its own initiative prior to taking final agency action on such proposal.

(10) Specifically concern the Commission's consideration of, or its actual: issuance of a subpoena (whether by the Commission directly or by any Commission employee or member); participation in a civil action or proceeding, an action in a foreign court or international tribunal, or an arbitration; or initiation, conduct, or dispostion of a particular case of formal adjudication pursuant to

the procedures in 5 U.S.C. 554, or otherwise involving a determination on the record after opportunity for a hearing; including, but not limited to, matters involving

(i) The institution, prosecution, adjudication, dismissal, settlement, or amendment of any administrative proceeding, whether public or nonpublic; or

(ii) The commencement, settlement, defense, or prosecution of any judicial proceeding to which the Commission, or any one or more of its members or employees, is or may become a party; or

(iii) The commencement, conduct, termination, status, or disposition of any inquiry, investigation, or proceedings to which the power to issue subpoenas is, or may become, attendant; or

(iv) The discharge of the Commission's responsibilities involving litigation under any statute concernng the subject of bankruptcy; or

(v) The participation by the Commission (or any employee or member thereof) in, or involvement with, any civil judicial proceeding or any administrative proceeding, whether as a party, as amicus curiae, or otherwise; or

(vi) The disposition of any application for a Commission order of any nature where the issuance of such an order would involve a determination on the record after opportuntiy for a hearing.

(b) *Interpretation of exemptions.* The examples set forth § 200.402(a)(1) through (10) of particular matters which may be the subject of closed Commission deliberations are to be construed as illustrative, but not as exhaustive, of the scope of those exemptions.

(c) *Public interest determination.* Notwithstanding the provisions of § 200.402(a) (concerning the closing of Commission meetings), but subject to the provisions of § 200.409(a) (respecting the right of certain persons to petition for the closing of a Commission meeting), the Commission may conduct any meeting or portion of a meeting in public where the Commission determines, in its discretion, that the public interest renders it appropriate to open such a meeting.

(d) *Nonpublic matter in announcements.* The Commission may delete from the notice of Commission meetings described in § 200.403, from the announcements concerning closed meetings described in §§ 200.404(b) and 200.405(c), and from the General Counsel's certification described in § 200.406, any information or description the publication of which would be likely to disclose matters of the nature described in § 200.402(a) (concerning the closing of Commission meetings).

§ 200.403 Notice of Commission meetings.

(a) *Content of notice.* (1) In the case of open meetings, or meetings closed pursuant to the procedures specified in § 200.404, the Commission shall announce the items to be considered. For each such item, the announcement shall include:

(i) A brief description of the generic or precise subject matter to be discussed;

(ii) The date, place, and aproximate time at which the Commission will consider the matter;

(iii) Whether the meeting, or the various portions thereof, shall be open or closed; and

(iv) The name and telephone number of the Commission official designated to respond to requests for information concerning the meeting at which the matter is to be considered.

(2) Every announcement of a Commission meeting described in this subsection, or any amended announcement described in § 200.403(c), shall be transmitted to the FEDERAL REGISTER for publication.

(b) *Time of notice.* The announcement of Commission meetings referred to in § 200.403(a) shall be made publicly available (and submitted immediately thereafter to the FEDERAL REGISTER for publication) at least one week prior to the consideration of any item listed therein, except where a majority of the members of the Commission determine, pursuant to § 200.403(c), that Commission business requires earlier consideration of the matter. In the event of such a determination, the announcement shall be made publicly available (and submitted to the FEDERAL REGISTER) at the earliest practicable time.

(c) *Amendments to notice.* (1) (i) The time or place of a meeting may be changed following any public announcement that may be required by § 200.403(a). In the event of such action, the Commission shall announce the change at the earliest practicable time.

(ii) The subject matter of a meeting, or the determination of the Commission to open or close a meeting (or a portion of a meeting), may be changed following any public announcement that may be required by § 200.403(a), if (A) a majority of the entire membership of the Commission determines, by a recorded vote, that Commission business so requires and that no earlier announcement of the change was possible; and (B) the Commission publicly announces such change and the vote of each member upon such change at the earliest practicable time.

(2) Notwithstanding the provisions of this paragraph (c), matters which have been announced for Commission consideration may be deleted, or continued in whole or in part to the next scheduled Commission meeting, without notice.

(d) *Notice of meetings closed pursuant to special procedure.* In the case of meetings closed pursuant to the special procedures set forth in § 200.405, the Commission shall make publicly available, in whole or in summary form,

(1) A brief description of the general subject matter considered or to be considered, and

(2) The date, place, and approximate time at which the Commission will, or did, consider the matter. The announcement described in this subsection shall be made publicly available at the earliest practicable time, and may be combined, in whole or in part, with the announcement described in § 200.403(a).

NOTE.—The Commission intends, to the extent convenient, to adhere to the following schedule in organizing its weekly agenda: Closed meetings to consider matters concerning the enforcement of the federal securities laws and the conduct of related investigations will generally be held on Tuesdays and on Thursday afternoons. An open meeting will generally be held each Thursday morning to consider matters of any appropriate nature. On Wednesdays, either open or closed meetings, or both, will generally be held according to the requirements of the Commission's agenda for the week in question. Normally, no meetings will be scheduled on Mondays, Fridays, Saturdays, Sundays, or legal holidays.

The foregoing tentative general schedule is set forth for the guidance of the public, but is not, in any event, binding upon the Commission. In every case, the scheduling of Commission meetings shall be determined by the demands of Commission business, consistent with the requirements of this Subpart I. When feasible, the Commission will endeavor to announce the subject matter of all then-contemplated open meetings during a particular month at least one week prior to the commencement of that month.

When and if convenient after the conclusion of a closed Commission meeting, the Commission will endeavor to make publicly available a notice describing (subject to the provision in § 200.402(d) regarding nonpublic matter in announcements) the items considered at that meeting and any action taken thereon.

§ 200.404 General procedure for determination to close meeting.

(a) *Action to close meeting.* Action to close a meeting pursuant to § 200.402(a) or (c) shall be taken only upon a vote of a majority of the entire membership of the Commission. A separate vote of the Commission members shall be taken with respect to each Commission meeting a portion or portions of which are proposed to be closed to the public pursuant to § 200.402(a), or with respect to any information which is proposed to be withheld under § 200.402(d); *Provided, however,* That a single vote may be taken with respect to a series of meetings, a portion or portions of which are proposed to be closed, or with respect to any information concerning such series of meetings, so long as each meeting in such series relates to the same matters and is scheduled to be held no more than thirty days after the initial meeting in such series. The vote of each Commission member participating in such vote shall be recorded and no proxies shall be allowed.

(b) *Announcement of action to close meeting.* Within one day of any vote pursuant to paragraph (a) of this section or § 200.409(a) (relating to review of Commission determinations to open a meeting), the Commission shall make publicly available:

(1) A written record reflecting the vote of each participating member of the Commission on the question; and

(2) In the case of a meeting or portion thereof to be closed to the public, a writ-

ten explanation of the Commission's action closing the meeting or a portion thereof, together with a list describing generically or specifically the persons expected to attend the meeting and their affiliation; and

(3) For every closed meeting, the certification executed by the Commission's General Counsel as described in § 200.406.

§ 200.405 Special procedure for determination to close meeting.

(a) *Finding.* Based, in part, on a review of several months of its meetings, as well as the legislative history of the Sunshine Act, the Commission finds that a majority of its meetings may properly be closed to the public pursuant to § 200.402(a) (4), (8), (9)(i), or (10), or any combination thereof.

(b) *Action to close meeting.* The Commission may, by recorded vote of a majority of its members at the commencement of any meeting or portion thereof, determine to close any meeting or a portion thereof properly subject to being closed pursuant to § 200.402(a) (4), (8), (9)(i), or (10), or any combination thereof. The procedure described in this rule may be utilized notwithstanding the fact that a meeting or portion thereof properly subject to being closed pursuant to § 200.402(a) (4), (8), (9)(i), or (10), or any combination thereof, could also be closed pursuant to § 200.402(a) (1), (2), (3), (5), (6), (7), or (9)(ii), or any combination thereof.

(c) *Announcement of action to close meeting.* In the case of a meeting or a portion of a meeting closed pursuant to this rule, as soon as practicable the Commission shall make publicly available:

(1) A written record reflecting the vote of each participating member of the Commission to close the meeting; and

(2) The certification described in § 200.406, executed by the Commission's General Counsel.

§ 200.406 Certification by the General Counsel.

For every Commission meeting closed pursuant to § 200.402(a) (1) through (10), the General Counsel of the Commission (or, in his or her absence, the attorney designated by General Counsel pursuant to § 200.21) shall publicly certify that, in his or her opinion, the meeting may be closed to the public and shall state each relevant exemptive provision.

§ 200.407 Transcripts, minutes, and other documents concerning closed Commission meetings.

(a) *Record of closed meetings.* Except as provided in § 200.407(b), the Commission's Secretary shall prepare a complete transcript or electronic recording adequate to record fully the proceedings of each closed meeting, or closed portion of a meeting.

(b) *Minutes of closed meetings.* In the case of a meeting, or portion of a meeting, closed to the public pursuant to § 200.402(a) (8), (9)(i), or (10), the Secretary may, in his or her discretion or at the direction of the Commission, prepare either the transcript or recording described in § 200.407(a), or a set of minutes. Such minutes shall fully and clearly describe all matters discussed and shall provide a full and accurate summary of any actions taken, and the reasons therefor, including a description of each of the views expressed on any item and the record of any rollcall vote (reflecting the vote of each participating Commission member on the question). All documents specifically considered by the Commission in connection with any action shall be identified if such minutes are maintained.

(c) *Retention of certificate and statement.* The Secretary shall retain a copy of every certification executed by the General Counsel pursuant to § 200.406, together with a statement from the presiding officer of the meeting, or portion of a meeting to which the certification applies, setting forth the time and place of the meeting, and the persons present.

(d) *Minute Record.* Nothing herein shall affect the provisions of §§ 200.13a and 200.40 requiring the Secretary to prepare and maintain a Minute Record reflecting the official actions of the Commission.

§ 200.408 Public access to transcripts and minutes of closed Commission meetings; record retention.

(a) *Public access to record.* Within twenty days (excluding Saturdays, Sundays, and legal holidays) of the receipt by the Commission's Freedom of Information Act Officer of a written request, or within such extended period as may be agreeable to the person making the request, the Secretary shall make available for inspection by any person in the Commission's Public Reference Room, the transcript, electronic recording, or minutes (as required by § 200.407 (a) or (b)) of the discussion of any item on the agenda, except for such item or items as the Freedom of Information Act Officer determines to involve matters which may be withheld under § 200.402 or otherwise. Copies of such transcript, or minutes, or a transcription of such recording disclosing the identity of each speaker, shall be furnished to any person at the actual cost of duplication, as set forth in § 200.80e, and, if a transcript is prepared, the actual cost of such transcription.

(b) *Review of deletion from record.* Any person who has been notified that the Freedom of Information Act Officer has determined to withhold any transcript, recording, or minute, or portion thereof, which was the subject of a request for access pursuant to § 200.402 (a), or any person who has not received a response to his or her own request within the 20 days specified in § 200.408 (a), may appeal the adverse determination or failure to respond by applying for an order of the Commission determining and directing that the transcript, recording or minute, or deleted portion thereof, be made available. Such application shall be in writing and should be directed to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549. The applicant shall state such facts and cite such legal or other authorities as the applicant may consider appropriate. The Commission shall make a determination with respect to any appeal pursuant to this subsection within 20 days (excepting Saturdays, Sundays and legal public holidays) after the receipt of such appeal, or within such extended period as may be agreeable to the person making the request. The Commission may determine to withhold any record that is exempt from disclosure pursuant to § 200.402(a), although it may disclose a record, even if exempt, if, in its discretion, it determines it to be appropriate to do so.

(c) *Retention of record.* The Commission, by its Secretary, shall retain a complete verbatim copy of the transcript, or a complete copy of the minutes, or a complete electronic recording of each meeting, or portion of a meeting, closed to the public, for a period of at least two years after such meeting, or until one year after the conclusion of any Commission proceeding with respect to which the meeting or portion was held, whichever occurs later.

§ 200.409 Administrative appeals.

(a) *Review of determination to open meeting.* Following any announcement stating that the Commission intends to open a meeting or a portion thereof, any person whose interests may be directly and substantially affected by the disposition of the matter to be discussed at such meeting may make a request, directed to the Commission's Secretary, that the meeting, or relevant portion thereof, be closed pursuant to § 200.402(a) (5), (6), or (7). The Secretary shall circulate such a request to the members of the Commission, along with a supporting statement provided by the requestor setting forth the requestor's interest in the matter and the reasons why the requestor believes that the meeting (or portion thereof) should be closed, and the Commission, upon the request of any one of its members, shall vote by recorded vote on whether to close such meeting or portion.

(b) *Review of determination to close meeting.* Following any announcement that the Commission intends to close a meeting or a portion thereof, any person may make written or telegraphic request, directed to the Commission's Secretary, that the meeting or a portion thereof be open. Such a request shall set forth the requestor's interest in the matter and the reasons why the requestor believes that the meeting (or a portion thereof) should be open to the public. The Secretary shall circulate such a request and supporting statement to the members of the Commission, and the Commission, upon the request of any one of its members, shall vote whether to open such a meeting or a portion thereof.

§ 200.410 Miscellaneous.

(a) *Unauthorized recordings; maintenance of decorum.* Nothing in this subpart shall authorize any member of the public to be heard at, or otherwise participate in, any Commission meeting, or

to record any Commission meeting or portion thereof by electronic or photographic devices. The Commission may exclude any person from attendance at any meeting whenever necessary to preserve decorum, or where appropriate or necessary for health or safety reasons, or where necessary to terminate behavior unauthorized by this subsection. Any person desiring to record or photograph an open Commission meeting may apply to the Commission's Secretary for permission to do so, setting forth the requestor's interest in the matter and the reasons why the requestor desires to record or photograph the Commission's proceedings. The Commission's determination whether or not to permit such conduct shall be confided to its exclusive discretion; *Provided, however,* That nothing herein shall preclude any person from taking notes at, or publicly or privately reporting on, the Commission's open meetings.

(b) *Suspension of open meeting.* Subject to the satisfaction of any procedural requirements which may be required by this subpart, nothing in this subpart shall preclude the Commission from directing that the room be cleared of spectators, temporarily or permanently, whenever it appears that the discussion during an open Commission meeting is likely to involve any matter described in § 200.402(a) (respecting closed meetings).

(c) *Access to Commission documents.* Except as expressly provided, nothing in this subpart shall authorize any person to obtain access to any document not otherwise available to the public or not required to be disclosed pursuant to Subpart D. Access to documents considered or mentioned at Commission meetings may only be obtained subject to the procedures set forth in, and the provisions of, Subpart D.

By the Commission.

GEORGE A. FITZSIMMONS,
Secretary.

FEBRUARY 2, 1977.

[FR Doc.77-3807 Filed 2-3-77;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 1]

[Docket No. 76P-0470]

NUTRITION LABELING

Exemption for Certain Dairy Products

The Food and Drug Administration (FDA) is proposing to allow declaration of the fat content in the labeling of certain dairy products without requiring full nutrition labeling; comments by April 4, 1977.

The Commissioner of Food and Drugs, pursuant to a petition submitted by the Milk Industry Foundation (MIF), Washington, D.C., is proposing an exemption from the nutrition labeling requirements of § 1.17 (21 CFR 1.17). The exemption would permit certain dairy products listed in § 1.1c(a)(7)(i) (21 CFR 1.1c(a)(7)(i)) to include a declaration of the fat content in the ingredient statement without requiring full nutrition labeling. Section 1.17(a) currently requires that when any nutrition information, other than sodium content, is included on the label or in the labeling or advertising of a food, the food's label must bear full nutrition labeling; this has the effect, in the absence of the proposed exemption, of requiring nutrition labeling when the fat content is included on the labels of dairy products, which is required by some States. Those foods listed in § 1.1c(a)(7)(i) and required by Federal regulations, other than § 1.17, to bear a declaration of the milkfat content and/or nutrition labeling are not affected by this proposal. The Commissioner proposes to make the exemption effective upon publication of a final regulation in the FEDERAL REGISTER, and, pending publication of a final regulation, he is staying application of § 1.17 to declarations of fat content that comply with all provisions of the proposal. Comments concerning this proposal may be filed with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

The petitioner's requested revision of § 1.17 would add a new paragraph as follows:

> The fat content of any food listed in § 1.1c(a)(7)(i) may be declared in the ingredient statement for that food without compliance with this section, if the fat content is otherwise not referred to on the label or in labeling or in advertising.

As grounds in support of the proposal, the petitioner states that an inequitable situation exists regarding a least two States' labeling requirements for dairy products. The petitioner points out that laws in these States, established prior to the Federal requirement for nutrition labeling, require a declaration of milkfat content on virtually all dairy foods and that therefore, in order to comply with the provisions of § 1.17, full nutrition labeling is required.

The petitioner asserts that a statement of milkfat content has been used historically to identify and differentiate many dairy products and that such a decelaration is more a statement of identity than a statement of nutrition information. The petitioner concludes that "conveying product identification information in an ingredient statement was never intended to be a nutrient claim" and cites the exemptions afforded by § 1.17(h)(6) and (h)(7) in support of this proposition: Section 1.17(h)(6) applies to a nutrient(s) included in a food solely for technological purposes; § 1.17(h)(7) applies to a standardized food containing an added nutrient(s) and included in another food as a component. Both exemptions allow declaration in the ingredient statement without providing full nutrition labeling so long as neither the nutrient(s) nor the component is otherwise referred to on the label or in labeling or in advertising.

The full petition and a subsequent supplement are available for inspection from 9 a.m. to 4 p.m., Monday through Friday, at the office of the Hearing Clerk, Food and Drug Administration.

The Commissioner has considered the petition and concludes that a proposed exemption should be published for comment. However, the text of the exemption proposed by MIF might be construed as having the effect of exempting all foods listed in §1.1c(a)(7)(i) from the nutrition labeling requirements of § 1.17 when the milkfat content is declared in the ingredient statement, even though other reasons may exist for requiring nutrition labeling. The Commissioner is of the opinion that full nutrition labeling should be a consistent requirement for all vitamin and protein-fortified foods listed in § 1.1c(a)(7)(i), such as vitamin D milk and protein-fortified skim milk, that are required by Part 18 (21 CFR Part 18) to contain nutrition information in the name of the food.

In addition, the language employed in the petitioner's proposed regulation does not limit the exemption to a "percentage declaration" of the fat content as discussed in the petition.

The Commissioner, therefore, proposes a modification of the petitioner's proposal so as to allow a percentage declaration of the fat content, appearing solely in the ingredient statement, without "triggering" nutrition labeling. The Commissioner's proposal explicitly limits the exemption to those foods listed in § 1.1c(a)(7)(i) that are not required by other Federal regulations to bear full nutrition labeling. The Commissioner's proposal would permit the percentage declaration to refer to "fat," "milkfat," or "butterfat" content.

The Commissioner points out that fat is a naturally occurring component, not an added substance, in those products listed in § 1.1c(a)(7)(i). Therefore, it is not an "ingredient" within the meaning of sections 403(g)(2) and (i)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(g)(2) and (i)(2)). Hence, a declaration of the milkfat content in the ingredient statement would not mean that milkfat is an "ingredient" as this term is used in section 403 of the act. The Commissioner, though not considering milkfat to be an ingredient pursuant to the act, does propose that a declaration of the milkfat content be permitted to appear in the ingredient statement because the ingredient statement is considered to be the most appropriate place on the label for conveying this type of product information.

The Commissioner proposes that the declaration in the ingredient statement not be given undue prominence and that it appear on the information panel in a type size not larger than the minimum required by § 1.8b(i) (21 CFR 1.8b(i)) for declaration of net quantity of contents. Use of larger type size, or location of the percentage declaration elsewhere on the label, e.g., in the statement of identity, would be deemed a "nutrition claim" and require full nutrition labeling.

The Commissioner proposes to make the exemption effective upon publication of a final order in the FEDERAL REGISTER, and he advises that, pending issuance of a final regulation in this matter, he is staying application of § 1.17 to declarations of fat content that comply with all requirements of this proposal.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403(a), 701(a), 52 Stat. 1041 as amended, 1047 as amended, 1055 (21 U.S.C. 321(n), 343(a), 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), it is proposed that § 1.17 be amended by adding new paragraph (h)(14) to read as follows:

§ 1.17 Food; nutrition labeling.

* * * * *

(h) * * *

(14) A percentage declaration of the fat (milkfat, butterfat) content appearing in the ingredient statement on the label of a food listed in § 1.1c(a)(7)(i) does not constitute a "nutrition claim or information" within the meaning of paragraph (a) of this section *Provided*, That:

(i) The declaration appears on the information panel (for requirements for information panels, see § 1.8d) with no greater prominence than any other printed matter appearing on the panel, and in a type size no larger than the minimum type size required by § 1.8b(i) for the declaration of net quantity of contents, and

(ii) The declaration is not required by other regulations in this chapter.

Interested persons may, on or before April 5, 1977, submit to the Hearing Clerk, Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments (preferably in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107. A copy of the inflation impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: January 27, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-3222 Filed 2-3-77;8:45 am]

[21 CFR Parts 1, 8, 200, 201]

[Docket No. 77N-0009]

FD&C YELLOW NO. 5

Labeling in Food and Drugs for Human Use and Restriction on Use in Certain Human Drugs

The Food and Drug Administration (FDA) is proposing to require the label declaration of FD&C Yellow No. 5 when used to color foods and ingested drugs and to prohibit its use in certain drugs for human use. These restrictions are considered necessary because of mounting evidence of allergic-type reactions to FD&C Yellow No. 5. Interested persons have until April 5, 1977 to submit comments.

In the FEDERAL REGISTER of May 8, 1969 (34 FR 7447), the Commissioner of Food and Drugs issued an order listing FD&C Yellow No. 5 (also known as tartrazine when not certified by FDA for use in food, drugs, and cosmetics) for use in food under § 8.275 (21 CFR 8.275) and for use in ingested drugs under § 8.4175 (21 CFR 8.4175). This action was supported by safety data in a color additive petition (CAP 23) and other relevant data. The petition was submitted by the Certified Color Industry Committee, c/o Hazleton Laboratories, Falls Church, VA (now the Certified Color Manufacturers Association, 900 17th St. NW., Washington, D.C. 20006); notice of filing was published in the FEDERAL REGISTER of March 27, 1965 (30 FR 4083).

No specific restrictions were placed on the use of FD&C Yellow No. 5 other than the requirements of batch certification by FDA. The color is provisionally listed for use in externally applied drugs and in cosmetics under § 8.501(a). The closing date for this provisional listing is January 31, 1977. A proposal was published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41860) to postpone this closing date to December 31, 1980, conditioned upon the timely submission of reports from new chronic toxicity studies. Regulations finalizing this proposal are expected to be published in the near future.

An order listing FD&C Yellow No. 5 for use in externally applied cosmetics under § 8.7255 (21 CFR 8.7255) was published in the FEDERAL REGISTER of January 21, 1974 (39 FR 2358). However, the effective date of that order was stayed by the submission of objections to, among other things, certain restrictions that were to be placed on use of the color. Published elsewhere in this issue of the FEDERAL REGISTER is a notice announcing the stay of the effective date of that order.

DISCUSSION OF PROBLEM

Since FD&C Yellow No. 5 was listed for use in food and ingested drugs, evidence of allergic-type responses caused by ingestion of substances containing the color has accumulated. These responses to FD&C Yellow No. 5 occur primarily in patients who also have aspirin intolerance, although an absolute association has not been established. The phenomenon of aspirin intolerance in certain persons with underlying allergic disorders, including bronchial asthma, nasal polyposis, vasomotor rhinitis, and skin allergies to various substances, has been known for over 50 years. The aspirin reaction is manifested by asthmatic symptoms, urticaria, angioedema, or nasal symptoms. The overall incidence of aspirin intolerance in the United States is unknown. Samter and Beers (Ref. 1) cited a report by Pearson on a large asthmatic population in which 2.3 percent were said to be aspirin intolerant. Chafee and Settipane (Ref. 2), on the other hand, reported an incidence of 4.3 percent in their large population of asthmatics. These figures were obtained solely on the basis of clinical history. Chafee and Settipane found that among their patients with rhinitis, 0.7 percent were aspirin intolerant.

It has also long been known that some persons are sensitive to organic chemicals. However, the first person to report an association between FD&C Yellow No. 5 and allergic-type reactions was Lockey (Ref. 3. In 1959, Lockey reported generalized urticaria in three patients after ingestion of one or more tablets of a corticosteroid containing FD&C Yellow No. 5. The patients were an asthmatic, a patient known to be very sensitive to drugs of coal tar origin who was taking a steroid for a skin rash due to a topical mercurial, and a patient with a collagen disease who was known to be aspirin intolerant.

Since the 1960's, there has been increasing numbers of reports establishing that there is a strong association between aspirin intolerance and FD&C Yellow No. 5 intolerance. Chafee and Settipane (Ref. 4) described an asthmatic patient with aspirin sensitivity (angioedema) whose chronic asthma and acute attacks were exacerbated after taking certain antiasthmatic drugs, vitamins, premarin, and certain foods. In double-blind studies, she was reported to be allergic to FD&C Yellow No. 5 and, mildly, to FD&C Red No. 4. Drugs containing FD&C Yellow No. 5 could provoke symptoms with a single dose. On the basis of these findings, the authors recommended that FD&C dyes be required to be listed on food and drug packages.

The precise incidence of intolerance of FD&C Yellow No. 5 in the total population or even in aspirin-intolerant patients is not known. Over an 11-year period, Samter and Beers (Ref. 1) followed over 1,000 aspirin-intolerant patients diagnosed on the basis of history. They hospitalized for study 182 of these aspirin-intolerant patients. All were asthmatic, but they had had vasomotor rhinitis and nasal polyps for years before developing asthma. Of the 182 aspirin-intolerant patients, nine (5 percent) were intolerant of tartrazine, FD&C Yellow No. 5. In a double-blind study using some of these patients, 3 of 40 aspirin-intolerant patients (7.5 percent) receiving 25 milligrams of tartrazine developed symptoms.

Juhlin et al. (Ref. 5) found that seven of seven aspirin-intolerant patients developed asthma or urticaria to only 1 to 2 milligrams of tartrazine. One of the seven reacted only slightly to 1 milli-

gram but reacted strongly to 5 milligrams of tartrazine. Thus, these authors found a 100-percent incidence of tartrazine intolerance in their limited studies. Although the test was single blind, there were no reactors to a placebo. One of the patients had been taking an antihistamine containing only 30 micrograms of tartrazine per tablet for a month in an attempt to relieve urticaria which began after taking an aspirin tablet. There was no improvement in the urticaria until 3 days after the patient stopped taking the antihistamine.

Michaelsson and Juhlin (Ref. 6), in a study involving provocation tests with aspirin, azo dyes, and two commonly used food preservatives in patients with recurrent urticaria or angioedema, found that 39 of 52 patients developed a reaction to something—e.g., 35 of these had urticaria to aspirin; 19 to tartrazine (12 cases after 1 to 3 milligrams, the rest after 5 to 18 milligrams); and 22 to sodium benzoate (42 percent). There were also 10 cases of urticaria due to Sunset Yellow (FD&C Yellow No. 6) and some of these were not sensitive to tartrazine. It is not possible from this paper to ascertain the precise percentage of aspirin-intolerant patients who were also intolerant of FD&C Yellow No. 5, but it would appear to be about 50 percent

Settipane and Pudupakkam (Ref. 7) recently performed a tartrazine-placebo-controlled double-blind crossover study in 40 patients who had a history of aspirin intolerance and in 40 normal controls. Most of the aspirin-intolerant patients had asthma, the remainder had rhinitis and rhinorrhea. Many of these also had urticaria. The patients were challenged with 0.44 milligram of tartrazine or placebo (except for two who received 0.22 milligram). Six (15 percent) of the 40 aspirin-intolerant patients given tartrazine developed urticaria or bronchospasm, together with at least a 20-percent reduction in three pulmonary function tests. There were no reactions to the placebo, and none of the normal controls developed any reactions.

It is not possible to state precisely the incidence of intolerance to FD&C Yellow No. 5 in the United States. Further, there is a broad range of degree of intolerance, some patients reacting to a fraction of a milligram and others requiring 5 milligrams or more (the dosages found in foods). Using the incidence of 4.3 percent aspirin intolerance in a population of asthmatics and 0.7 percent in a population with rhinitis, as reported by Chafee and Settipane (Ref. 4) in their large practice involving over 3,781 patients with these diseases, calculations of the incidence can be estimated. In Chafee and Settipane's report, about half the patients had allergic rhinitis, only. The other patients had asthma alone or asthma plus rhinitis. The incidence of asthma in the United States is estimated to be 1 to 2 percent. Thus, if there are 2 to 4 million asthmatics in the United States and about a 4-percent incidence of aspirin intolerance in asthmatics, there could be 80,000 to 160,000 cases of aspirin intolerance among asthmatics. If Chafee and Settipane's practice is indicative of the relative incidence of asthma vs. allergic rhinitis, there are 2 to 4 million patients with allergic rhinitis, of whom 14,000 to 28,000 could be aspirin intolerant. Thus, a total of 94000 to 188,000 know aspirin-intolerant patients could be assumed. If it is further assumed that 50 percent of aspirin-intolerant patients are intolerant to FD&C Yellow No. 5, using Michaelsson and Juhlin's urticara and angioedema population (Ref. 6), then there would be 47,000 to 94,000 FD&C Yellow No. 5 intolerant patients.

The amount of FD&C Yellow No. 5 ingested is undoubtedly important in the potential provocation of a reaction. In many cases, however, it is not possible to ascertain the amount of FD&C Yellow No. 5 ingested by the people who reported the allergic-type symptoms to their physicians and, accordingly, the threshold value for provocation of a reaction to FD&C Yellow No. 5 has not been defined in the literature. The determination of the threshold amount may be particularly difficult in those persons who show allergic-type reactions to FD&C Yellow No. 5 only after having ingested the color additive in foods or drugs over a prolonged period. Samter and Beers (Ref. 1) tested one dose of 25 milligrams of FD&C Yellow No. 5 in 40 aspirin-intolerant patients, three of whom reacted positively. Juhlin et al. (Ref. 5), on the other hand, reported that some patients promptly showed allergic-type reactions after a single ingestion of as little as 1 milligram of tartrazine (FD&C Yellow No. 5).

The Food and Drug Administration has long been concerned about allergies involving food, drugs, and cosmetics. The Commissioner recognizes that many substances to which man is exposed, including those occurring in nature, may elicit allergic-type reactions in some unusually susceptible or idiosyncratic individuals. A great variety of materials has been implicated in allergic-type reactions, e.g., dusts of various kinds, pollens, feathers, insect fragments, bee stings, seeds, dandruff, and a number of foods. In general, hypersensitive persons may react by exhibiting a number of responses, which may include angioedema, urticaria, bronchial asthma, pruritis, and vascular purpura.

In evaluating the reports described above, the Commissioner concludes that there is no evidence in the available information on FD&C Yellow No. 5 that demonstrates a significant hazard to the general population when the color is used at current levels and in the manner now practiced. However, because of the evidence of a causal relationship between FD&C Yellow No. 5 and serious allegic-type responses in certain susceptible individuals, the Commissioner concludes that action must be taken to limit the potential for exposure of such persons to the color through ingestion of food or drugs.

There are no reports of reactions to FD&C Yellow No. 5 from external application and, accordingly, the use of the color additive in externally applied drugs and cosmetics is not considered to present a likelihood of allergic-type responses. Cosmetic articles such as mouthwashes, dentifrices, and lipsticks are also unlikely to induce allergic-type responses because of the very small amount of the cosmetic that may actually be ingested. Furthermore, as of May 31, 1976, all newly ordered labels for cosmetics have been required to declare the specific colors present. Under these circumstances, persons who are hypersensitive to FD&C Yellow No. 5 will, by careful review of the product labeling, be able to avoid cosmetic products containing the color. The Commissioner concludes, therefore, that no further action is required as to cosmetics in general or for externally applied drugs.

Proposal for Foods

Persons who know they are intolerant of FD&C Yellow No. 5 are likely to be selective in the types of foods that they use and, with appropriate label declaration would be able to avoid the potential hazard from allergic-type reactions to the color in food by reading the label. Accordingly, a label declaration of the presence of FD&C Yellow No. 5 in food for humans, whether added as the straight color, a mixture, or a lake, would enable persons intolerant to FD&C Yellow No. 5 to minimize exposure to the color.

The basis for the proposed action is the provision of section 706(b)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376(b)(3)), which provides that regulations for the listing of a color additive shall "prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to * * * and directions or other labeling or packaging requirements for such additive)." FD&C Yellow No. 5 has clearly been shown to produce allergic-type responses in humans and thus a requirement for label declaration of the color is justified. The evidence that other color additives may elicit similar responses is limited and, accordingly, the Commissioner concludes that similar labeling requirements should not be extended to other color additives at this time. Under the proposed amendment, foods containing colors other than FD&C Yellow No. 5 can continue to be labeled in accordance with the requirements concerning the label declaration of color additives prescribed by section 403 (i) and (k) of the act (21 U.S.C. 343 (i) and (k)), which permits declaration collectively as artificial color.

There is no evidence that any color, including FD&C Yellow No. 5, elicits allergic-type reactions in animals. Accordingly, label declaration of FD&C Yellow No. 5 in animal feeds and pet food would not be required.

The Commissioner concludes that labeling for food products should be revised as soon as possible to include the declaration of FD&C Yellow No. 5 among the list of ingredients. Therefore, he proposes that the effective date for this portion of the final regulation be 1 year after its date of publication in the Federal Register. The Commissioner believes this

will provide sufficient time to permit use of current stocks of labeling and revision of labeling to include a declaration of the presence of FD&C Yellow No. 5. Manufacturers could, of course, revise their labeling before the effective date of the regulation, and the Commissioner encourages them to do so.

PROPOSAL FOR DRUGS FOR HUMAN USE

The use of color additives in ingested drugs for human use is an old, accepted practice in the pharmaceutical industry. The use of color additives in drugs serves a necessary public health function because it permits drugs of identical size and shape to be distinguished. The distinction provided by the use of colors provides an important quality control tool in the dispensing of drugs to prevent mixups between otherwise similarly appearing drugs. The ability to distinguish among different products is also very important to persons taking many drugs, especially to the patient who may think in terms of taking a drug of a particular color rather than by the name of the drug. Color additives in drugs also assist in the identification of a drug in cases of accidental overdose.

Because yellow is a primary color, it is widely used as a color additive in drugs. Of the three yellow color additives available for use in ingested drugs, FD&C Yellow No. 5 is the most widely used. It is used to produce not only typically yellow shades but also variations of green, brown, orange, and other related colors. It is estimated that approximately 60 percent of all colored drug tablets for human use sold in the United States contains FD&C Yellow No. 5.

Thus, in view of the extent of use of FD&C Yellow No. 5, a substantial number of drugs would have to be reformulated if the color additive were prohibited in drugs for human use. Further, while reformulating their products to eliminate FD&C Yellow No. 5, some firms might decide to eliminate all color additives. The considerable time and effort necessary to reformulate drug products and the loss of product identification would be unimportant if considered necessary for the protection of public health and if there were no suitable alternative course of action. However, on the basis of the current information available concerning the nature and extent of the problem of intolerance of FD&C Yellow No. 5, the Commissioner believes that prohibiting all drug uses of FD&C Yellow No. 5 is not necessary for the protection of patients who are intolerant of FD&C Yellow No. 5, and that a labeling requirement similar to that for foods will be satisfactory.

The Commissioner concludes, however, that for drugs a simple listing of the color as FD&C Yellow No. 5 among the list of ingredients would not provide a sufficient safeguard for the person intolerant of FD&C Yellow No. 5. Generally, there is no uniform procedure for the declaration of ingredients on drug labeling; therefore, susceptible individuals might overlook such a listing. The listing of ingredients for ingested drug products has traditionally been used to designate active ingredients; consequently, listing of FD&C Yellow No. 5 may give an incorrect impression that it is an active ingredient. Finally, there may be physicians who are unaware that FD&C Yellow No. 5 may elicit allergic-type responses in certain susceptible individuals and for whom a simple listing would be inadequate.

For these reasons, the Commissioner concludes that the use of FD&C Yellow No. 5 in drugs should be declared in the form of a precautionary statement, i.e., "This product contains FD&C Yellow No. 5 which may cause allergic-type reactions in certain susceptible individuals".

This above decision would, of course, be subject to modification if new information becomes available indicating that the only way to protect sensitive persons would be to prohibit the use of FD&C Yellow No. 5.

Although a total prohibition against the use of FD&C Yellow No. 5 is not warranted, the Commissioner concludes that some action must be taken to limit the potential for exposure of these sensitive individuals to drugs containing FD&C Yellow No. 5. To achieve this objective, the Commissioner is proposing two alternative approaches for both over-the-counter (OTC) and prescription human drugs. In addition to comments on the proposals themselves, the Commissioner requests views concerning the advantages and disadvantages of the two alternative approaches.

OTC DRUG PROPOSAL I

The first proposal applicable to OTC drugs would amend the color additive regulations (21 CFR Part 8) to require that the presence of FD&C Yelow No. 5 be declared on the labels of all OTC drugs that are ingested as well as those that may be administered rectally or vaginally. A declaration of the presence of FD&C Yellow No. 5 on the label of these OTC drugs would enable persons who know they are intolerant of FD&C Yellow No. 5 to avoid drugs containing this color additive. Further, by having the presence declared on the label, physicians would more easily be able to identify persons intolerant of FD&C Yellow No. 5.

Under this proposal, the principal display panel of OTC drugs containing FD&C Yellow No. 5 that are ingested, as well as those that may be administered rectally or vaginally, would be required to contain the statement "This product contains FD&C Yellow No. 5 which is capable of producing allergic-type reactions in certain susceptible persons". The quantity of FD&C Yellow No. 5 would not have to be given.

OTC DRUG PROPOSAL II

Persons intolerant of FD&C Yellow No. 5, like many other persons, may take a variety of OTC drugs at one time or another to relieve or treat conditions or symptoms of a disease. Some of the drugs that may be taken are used to treat allergic or allergic-type conditions, including those allergic-type conditions that may arise as a result of ingestion of FD&C Yellow No. 5. As previously discussed, most persons reacting to FD&C Yellow No. 5 have other basic allergic problems including, in many cases, a sensitivity to aspirin. Thus, drugs used to treat allergic problems may be used widely by persons intolerant of FD&C Yellow No. 5. However, if a person intolerant of FD&C Yellow No. 5 is administered a drug containing FD&C Yellow No. 5 to treat an existing allergic problem, severe aggravation of the basic allergic condition may result. Further, in the haste of treating a serious allergic problem, a drug containing FD&C Yellow No. 5 could be taken by a person who knows he is intolerant even though the drug is labeled as containing the color additive. Likewise, a drug containing FD&C Yellow No. 5 could also be taken by a sensitive person to treat a serious allergic problem before the person's intolerance of FD&C Yellow No. 5 had been ascertained.

Another possibility which would not be resolved by the OTC Drug Proposal I is that all available drugs of a particular class that are used to treat a sensitive person's allergic condition might contain FD&C Yellow No. 5. Alternatively, the only drugs in a class which are effective for a person might all contain FD&C Yellow No. 5; thus, it could be impossible to select a drug free of FD&C Yellow No. 5.

In view of these considerations, the Commissioner is offering, as an alternative to OTC Drug Proposal I, a second proposal applicable to OTC drug products. This second proposal would include the labeling requirements of the first proposal plus a requirement that would prohibit the use of FD&C Yellow No. 5 in certain classes of drugs that are ingested, as well as those that may be administered rectally or vaginally. The classes of OTC drugs that would not be permitted under this proposal to contain FD&C Yellow No. 5 are analgesic, antihistaminic, cough and cold, oral nasal decongestant, and antiasthmatic drugs. These are the classes of OTC drugs that are most likely to be taken by persons intolerant of FD&C Yellow No. 5 to treat an allergic problem or as a substitute for aspirin.

PRESCRIPTION DRUG PROPOSAL I

The first proposal applicable to prescription drugs is a labeling requirement similar to that proposed for OTC drugs. In addition to a declaration of the presence of FD&C Yellow No. 5 on the label of all ingested prescription drugs (as well as those that may be administered rectally or vaginally) containing this color additive, the labeling required by § 201.100(d) (21 CFR 201.100(d)) would be required by proposed § 8.4175 (21 CFR 8.4175) to contain the statement "This product contains FD&C Yellow No. 5 which may cause allergic-type reactions in certain susceptible persons". This statement would be required to appear on the label and in the "How Supplied" section of the package insert, if present.

Although persons intolerant of FD&C Yellow No. 5 may not see the labeling on prescription drugs, they could remind their physicians of their intolerance. The physician could then avoid prescribing a drug containing FD&C Yellow No. 5 for

sensitive patients. In addition, as with OTC drugs, having the presence of FD&C Yellow No. 5 declared on the label would enable a physician to identify more easily persons intolerant of FD&C Yellow No. 5.

PRESCRIPTION DRUG PROPOSAL II

The second proposal applicable to prescription drugs would include the labeling requirements of the first prescription drug proposal and a prohibition against the use of FD&C Yellow No. 5 in seven classes of drugs. The following classes of ingested prescription drugs, as well as those that may be administered rectally or vaginally, would not be permitted to contain FD&C Yellow No. 5: analgesic drugs, antihistaminic drugs, cough and cold drugs, oral nasal decongestant drugs, antiathmatic drugs, nonsteroidal anti-inflammatory drugs, and glucocorticoid drugs.

The reasons for this proposal are the same as those set forth under OTC Drug Proposal II.

PROPOSED DRUG REGULATIONS

In the proposed drug regulations set forth below, the Commissioner has decided to propose only the second approach for both OTC and prescription drugs for human use because it provides an optimal degree of safe conditions of use for the color. The second approach, while including the provisions of the first, would be more restrictive. Therefore, the Commissioner believes that the proposed changes to Parts 8 and 201 that would be made if the first proposed approach (i.e., a labeling requirement for all drugs containing FD&C Yellow No. 5) were finalized are readily apparent and do not require presentation. Even though only the second approaches are set forth in the proposed regulations, the Commissioner requests comments on both the OTC and prescription drug proposals. The Commissioner is also interested in receiving comments on the availability of drugs that do not contain FD&C Yellow No. 5 within the five OTC drug classes and the seven prescription drug classes included in the proposal set forth below.

EFFECTIVE DATES

As with the food labeling proposal, the Commissioner believes that the effective date of the final regulations as it pertains to labeling drugs for human use should also be 1 year after the date of their publication in the FEDERAL REGISTER. He believes this will provide sufficient time for manufacturers to obtain new labels. Each drug for human use containing FD&C Yellow No. 5 labeled after 1 year after the date of publication of the final regulations in the FEDERAL REGISTER, should bear a label indicating the presence of FD&C Yellow No. 5.

If the second proposal were adopted, the effective date of the labeling portion of the final regulation would be 1 year as stated above. With respect to the classes of drugs that would have to be reformulated to remove FD&C Yellow No. 5, the Commissioner proposes to make this portion of the final regulations effective 6 months after their date of publication in the FEDERAL REGISTER. After the effective date of this portion of the final regulations, the use of FD&C Yellow No. 5 in the manufacture of any drug among the classes of drugs prohibited from containing FD&C Yellow No. 5, would render the drug adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and subject to regulatory action. Further, the Commissioner proposes that the distribution by a manufacturer of any drug prohibited from containing FD&C Yellow No. 5 eighteen months after the date of publication of the final regulations will cause the product to be adulterated and subject to regulatory action. The prohibition of FD&C Yellow No. 5 would apply to its use as a straight color, a lake, or mixtures of straight colors. The Commissioner is not proposing to recall from the market any drugs containing FD&C Yellow No. 5 if they were manufactured or in process within 6 months of the date of publication of the final regulations or were distributed for sale within 18 months of the date of publication of the final regulations.

Manufacturers of new drugs containing FD&C Yellow No. 5 may revise their labeling to conform to this proposal at the earliest possible time after the effective date of the final regulations and should not wait until their supplemental application submitted under § 314.8 (21 CFR 314.8) has been approved. If the second proposal were adopted, a manufacturer of a new drug containing FD&C Yellow No. 5 in one of the classes of drugs that would be prohibited from containing the color additive would be allowed to either delete the use of any color additive or substitute other color additives in accordance with § 314.8(d)(3) and (e) pertaining to supplemental new drug applications.

To be in compliance with § 314.8, the holder of a new drug application would be required to submit data providing the new composition and showing that the change in composition does not interfere with any assay or control procedure used in manufacturing the drug, or that the assay and any other control procedure have been revised to make them adequate. The supplement would be required to include data available to establish the stability of the revised formulation. If the data are to limited to support a conclusion that the drug will retain its declared potency for a reasonable marketing period, a commitment to test the stability of marketed batches at reasonable intervals and to submit the data as they become available is required. Additionally, there must be a commitment to recall from the market any batch found to fall outside the approved specifications for the drugs.

The articles and publications cited in this preamble are listed below. In addition, other articles and publications used in support of this proposal are listed. Copies of the journal articles and other information forming the basis for the proposed actions are on public display in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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(1) Samter, M. and R. F. Beers, "Concerning the Nature of Intolerance to Aspirin," Journal of Allergy, 40:281–293, 1967.

(2) Chafee, F. H. and G. A. Settipane, "Aspirin Intolerance, I. Frequency in an Allergic Population," Journal of Allergy and Clinical Immunology, 53:193–199, 1974.

(3) Lockey, S. D., "Allergic Reactions due to FD&C Yellow No. 5, Tartrazine, an Aniline Dye Used as a Coloring and Identifying Agent in Various Steroids," Annals of Allergy, 17:719, 1959.

(4) Chafee, F. H. and G. A. Settipane, "Ashma Caused by FD&C Approved Dyes," Journal of Allergy, 40:65, 1967.

(5) Juhlin, L., G. Michaelsson, and O. Zetterstrom, "Urticaria and Asthma Induced by Food-and-Drug Additives in Patients with Aspirin Hypersensitivity," Journal of Allergy and Clinical Immunology, 50:92, 1972.

(6) Michaelsson, G. and L. Juhlin, "Urticaria Induced by Preservatives and Dye Additives in Foods and Drugs," British Journal of Dermatology, 88:525, 1973.

(7) Settipane, G. A. and R. K. Pudupakkam, "Aspirin Intolerance, III. Subtypes, Familial Occurrence of Cross Reactivity with Tartrazine," Journal of Allergy and Clinical Immunology, 56:215, 1975.

OTHER ARTICLES AND PUBLICATIONS

(1) Speer, S., Management of Childhood Asthma, Springfield: Charles C. Thomas, 1958.

(2) Criep, L. H., "Allergic Vascular Purpura," Journal of Allergy and Clinical Immunology, 48:7, 1971.

(3) Yurchak et al., "Immunologic Studies with Aspirin, Clinical Studies with Aspiryl-protein Conjugates," Journal of Allergy, 46:245, 1970.

(4) Johnson, H. M. et al., "Tartrazine: Solid-phrase Radioimmunoassay Studies of an Azo Dye Implicated in Allergic Reactions (Azo dyes and Allergy)," (unpublished paper).

(5) Samter, M. and R. F. Beers, "Intolerance to Aspirin, Clinical Studies and Consideration of Its Pathogenesis," Annals of Internal Medicine, 68:975–983, 1968.

(6) Cohon, M. S., "Tartrazine Revisited," Drug Intelligence and Clinical Pharmacy, 9:198, 1975.

(7) Smith, L. V. and R. J. Slavia, "Drugs Containing Tartrazine Dye," Journal of Allergy and Clinical Immunology, 58:456, 1976.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 502, 701, 706 (b), (c), and (d), 52 Stat. 1049–1051 as amended, 1055–1056 as amended, 74 Stat. 399–403 (21 U.S.C. 351, 352, 371, 376 (b), (c), and (d))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

1. In § 1.12 by revising paragraph (c) to read as follows:

§ 1.12 Food labeling; spices, flavorings, colorings, and chemical preservatives.

* * * * *

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all three of these, as may be necessary to render such statement likely to be read by the ordinary person under customary conditions of purchase and use of such food. The specific artificial color used in food shall be identified on the labeling when so required by its listing in Part 8 to assure safe conditions of use for the color additive.

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PART 8—COLOR ADDITIVES

2. In § 8.275(d) by redesignating the text that follows the *italicized* heading as paragraph (d)(1) and by adding new paragraph (d)(2) to read as follows:

§ 8.275 FD&C Yellow No. 5.

* * * * *

(d) *Labeling requirements.* (1) * * *

(2) Foods for human use that contain FD&C Yellow No. 5, including butter, cheese, and ice cream, shall specifically declare its presence by listing the color additive in the list of ingredients.

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3. In § 8.4175 by revising paragraphs (b) and (c) to read as follows:

§ 8.4175 FD&C Yellow No. 5.

* * * * *

(b) *Uses and restrictions.* (1) Except for the categories of drugs for human use in paragraph (b)(2) of this section, FD&C Yellow No. 5 may be used for coloring ingested drugs in amounts consistent with good manufacturing practice.

(i) FD&C Yellow No. 5 may not be used in the following categories of ingested prescription drugs for human use as well as those that may be administered rectally or vaginally:

Analgesic drugs
Antihistaminic drugs
Cough and cold preparations
Oral nasal decongestants
Antiasthmatics
Nonsteroidal anti-inflammatory drugs
Glucocorticoid drugs

(ii) FD&C Yellow No. 5 may not be used in the following categories of ingested OTC drugs for human use as well as those that may be administered rectally or vaginally:

Analgesic drugs
Antihistaminic drugs
Cough and cold preparations
Oral nasal decongestants
Antiasthmatics

(c) *Labeling requirements.* (1) The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 8.32.

(2) Ingested drugs for human use (as well as those that may be administered rectally or vaginally) containing FD&C Yellow No. 5 shall bear the statement "This product contains FD&C Yellow No. 5 which may cause allergic-type reactions in certain susceptible individuals" on their label and in the labeling on or within the package, if any. For prescription drugs containing FD&C Yellow No. 5, the labeling required by § 201.100(d) of this chapter shall bear the statement "This product contains FD&C Yellow No. 5 which may cause allergic-type reactions in certain susceptible individuals". This statement shall be set forth in the "How Supplied" section of the labeling.

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PART 200—GENERAL

4. In Subpart B by adding new § 200.55 to read as follows:

§ 200.55 Drugs for human use not permitted to contain FD&C Yellow No. 5.

Although § 8.4175 of this chapter provides for the use of FD&C Yellow No. 5 in most drugs, it prohibits FD&C Yellow No. 5 from being used in certain categories of systematically administered drugs for human use. If a drug within one of the categories of drugs for human use listed in § 8.4175 of this chapter contains any quantity of FD&C Yellow No. 5, the drug is deemed adulterated and subject to regulatory action.

PART 201—LABELING

5. In subpart C by adding new § 201.64 to read as follows:

§ 201.64 Declaration of presence of FD&C Yellow No. 5.

The labeling for each ingested over-the-counter drug for human use containing FD&C Yellow No. 5 (as well as those that may be administered rectally or vaginally) shall, as required by § 8.4175 of this chapter, bear the statement "This product contains FD&C Yellow No. 5 which may cause allergic-type reactions in certain susceptible individuals". The labeling statement shall appear on the principal display panel of the OTC drug product. A statement indicating the presence of FD&C Yellow No. 5 shall also appear on any labeling on or within the package.

6. In § 201.100 by revising paragraph (b)(6) and by adding new paragraph (b)(7) and (8) to read as follows:

§ 201.100 Prescription drugs for human use.

* * * * *

(b) * * *

(6) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug.

(7) For all ingested drugs containing FD&C Yellow No. 5, the statement "This product contains FD&C Yellow No. 5 which may cause allergic-type reactions in certain susceptible individuals" as required by § 8.4175 of this chapter.

(8) If a container is too small or otherwise unable to accommodate a label with sufficient space to bear all the required information but is packaged within an outer container from which it is removed for dispensing or use, the information required by paragraph (b)(2), (3), and (5) of this section may be contained in other labeling on or within the package from which it is to be dispensed, the information referred to in paragraph (b)(1) and (7) of this section may be placed on such outer container only, and the information required by paragraph (b)(6) of this section may be the crimp of the dispensing tube.

* * * * *

Interested persons may, on or before April 5, 1977, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments (preferably in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

NOTE.—The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107. A copy of the inflation impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: January 28, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.77-3338 Filed 2-3-77;8:45 am]

[21 CFR Part 128d]

[Docket No. 76N-0298]

PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

Proposed Amendments to Current Good Manufacturing Practice Regulations

Correction

In FR Doc. 77-124 appearing at page 807 in the issue for Tuesday, January 4, 1977, in the fifth line of the third paragraph, "radium-225", should read "radium-226".

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[23 CFR Part 922]

[FHWA Docket No. 76-22]

SAFER OFF-SYSTEM ROADS PROGRAM

Notice of Proposed Rulemaking

• *Purpose.* The purpose of this document is to publish proposed rules for the administration of the safer off-system roads program. •