(c) *Related controls.* The Department of State, Office of Defense Trade Controls, maintains related controls on arms and military equipment under the International Traffic in Arms Regulations (22 CFR parts 120 through 130). You should also contact the Department of the Treasury's Office of Foreign Assets Control concerning any restrictions which might apply to U.S. persons involving financial transactions or dealings with the Federal Republic of Yugoslavia (Serbia and Montenegro).

Dated: February 26, 2001.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 01–5007 Filed 2–28–01; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 14, and 16

[Docket No. 98N–1042]

Revision of Administrative Practices and Procedures; Meetings and Correspondence; Public Calendars; Partial Stay, Amendments, and Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial stay, amendments, and correction.

SUMMARY: In accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan,'' published in the **Federal Register** of January 24, 2001 (66 FR 7702), this action temporarily stays until April 23, 2001, the effectiveness of the rule entitled ''Revision of Administrative Practices and Procedures; Meetings and Correspondence, Public Calendars'' published in the **Federal Register** of January 22, 2001 (66 FR 6465). The Food and Drug Administration (FDA) is also correcting an error in the docket number that appeared in the **Federal Register** of January 22, 2001, final rule.

DATES: This final rule is effective from January 22, 2001, to April 22, 2001. The correction to the docket number is effective January 22, 2001.

FURTHER INFORMATION CONTACT: Carol A. Kimbrough, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION: The final rule made the regulations relating to meetings, correspondence, and the agency's public calendar more concise and understandable to the public, minimized confusion about publicly available information concerning agency meetings, provided more effective disclosure of such information, and allowed FDA to reallocate resources to areas of more urgent public health need. To the extent that 5 U.S.C. 553 applies to this partial stay of effective date, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary and contrary to the public interest. The partial stay of effective date is necessary to give Department of Health and Human Services officials the opportunity for further review and consideration of new regulations, consistent with the Assistant to the President's memorandum of January 20, 2001. Seeking prior public comment on this partial stay and amendments would have been impractical, as well as contrary to the public interest in the orderly promulgation and implementation of regulations.

In FR Doc. 01–1566 appearing on page 6465 in the **Federal Register** of Monday, January 22, 2001, the following correction is made: On page 6465, in the third column, in the fifth line, ''[Docket No. 98–1042]'' is corrected to read ''[Docket No. 98N–1042]''.

As stated in the summary, the rule is stayed until April 23, 2001, in accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan,'' published in the **Federal Register** of January 24, 2001. Because the January 22, 2001, rule entitled ''Revision of Administrative Practices and Procedures; Meetings and Correspondence, Public Calendars'' inadvertently published with an immediate effective date, the mechanism for delaying the effective date is in some instances shown below to temporarily amend the rule to return to the provisions it contained before January 22, 2001.

For the reasons set forth in this document, FDA amends 21 CFR chapter I as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149; 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 10.30 [Amended]

2. Section 10.30(i)(6) is amended by removing ''§ 10.65(f)'' and by adding in its place ''§ 10.65(h)'' from January 22, 2001, to April 22, 2001.

§ 10.33 [Amended]

3. Section 10.33(k)(6) is amended by removing ''§ 10.65(f)'' and by adding in its place ''§ 10.65(h)'' from January 22, 2001, to April 22, 2001.

§ 10.35 [Amended]

4. Section § 10.35(h)(6) is amended by removing ''§ 10.65(f)'' and by adding in its place ''§ 10.65(h)'' from January 22, 2001, to April 22, 2001.

§ 10.40 [Amended]

5. Section 10.40(g)(7) is amended by removing ''§ 10.65(f)'' and by adding in its place ''§ 10.65(h)'' from January 22, 2001, to April 22, 2001.

§ 10.65 [Stayed]

6. Section 10.65 is stayed from January 22, 2001, to April 22, 2001.

7. Section 10.65a is added to subpart B from January 22, 2001, to April 22, 2001, to read as follows:

§ 10.65a Meetings and correspondence.

(a) In addition to public hearings and proceedings established under this part and other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner. Action on meetings and correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(b) The Commissioner may conclude that it would be in the public interest to hold an open public meeting to discuss a matter (or class of matters) pending before FDA, at which any interested person may participate.

(1) The Commissioner shall give public notice through the public calendar described in § 10.100(a) of the time and place of the meeting and of the matters to be discussed, and may also publish notice of the meeting.

(2) The meeting will be informal, i.e., any interested person may attend and participate in the discussion without

prior notice to the agency unless the notice of the meeting specifies otherwise.

(3) No official transcript or recording of the meeting will be made unless it appears to the agency that it will be useful. A written memorandum summarizing the substance of the meeting will be prepared by an FDA representative in all cases.

(c) A meeting with a person outside the Department, including a person in the executive or legislative branch of the Federal Government, concerning a pending court case, administrative hearing, or other regulatory action or decision, which involves more than a brief description of the matter, is to be summarized in a written memorandum, which is filed in the administrative file on the matter.

(d) Every person outside the Federal Government may request and obtain a private meeting with a representative of FDA in agency offices to discuss a matter.

(1) The person requesting a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom there is a commercial arrangement within the meaning of § 20.81(a). Neither FDA nor any other person may require the attendance of a person who is not an employee of the executive branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and FDA.

(2) FDA will determine which representatives of the Agency will attend the meeting. The person requesting the meeting may request but not require or preclude the attendance of a specific FDA employee.

(3) Whenever appropriate (e.g., the meeting involves a matter covered by paragraph (c) of this section or other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be desirable), a written memorandum summarizing the substance of the meeting will be prepared by an FDA representative.

(4) A person who wishes to attend a private meeting, but who either is not permitted to attend by the person requesting the meeting or by FDA or who cannot attend because the meeting is conducted by telephone, may obtain a separate meeting with FDA to discuss the same matter or an additional matter.

(e) FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the Agency. In pursuing this responsibility the following general policy applies where agency employees are invited by persons outside the Federal Government to attend or participate in meetings outside agency offices as representatives of the Agency.

(1) A person outside the executive branch may invite an agency representative to attend or participate in a meeting outside agency offices. The agency representative is not obligated to attend or participate, but may do so where it is in the public interest and will promote the objectives of the act.

(2) The agency representative may request that the meeting be open if that would be in the public interest. The agency representative may decline to participate in a meeting held as a private meeting if that will best serve the public interest.

(3) An agency representative may not knowingly participate in a meeting which is closed on the basis of sex, race, or religion.

(4) A meeting, whether open or closed, is subject to paragraph (d)(3) of this section with respect to memoranda summarizing the substance of the meeting.

(f) Representatives of FDA may initiate a meeting or correspondence with any person outside the Federal Government on any matter concerning the laws administered by the Commissioner.

(1) A meeting initiated by FDA representatives which involves a small number of interested persons, for example, a meeting with a petitioner or with two manufacturers of a particular product which requires additional testing or with a trade association employee to discuss an industry labeling problem, may be a private meeting. A meeting initiated by FDA representatives which involves a large number of interested persons, for example, 10 manufacturers of an ingredient in a discussion of appropriate testing or labeling, must be held as an open conference or meeting under paragraph (b) of this section.

(2) Whenever appropriate (e.g., the meeting involves a matter covered by paragraph (c) of this section or another important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be desirable), a written memorandum summarizing the substance of the meeting will be prepared by an FDA representative.

(g) A person who participates in a meeting described in paragraphs (b) through (f) of this section may also prepare and submit to FDA for inclusion in the administrative file a written memorandum summarizing the substance of the meeting.

(h) Memoranda of meetings prepared by an FDA representative or by any other person and all correspondence which relate to a matter pending before the agency will promptly be filed in the administrative file of the proceeding.

(i) A meeting with a representative of Congress relating to a pending or potential investigation, inquiry, or hearing by a congressional committee or a Member of Congress will be summarized in a written memorandum which is to be forwarded to the Food and Drug Administration, Office of Legislative Affairs. This provision does not restrict the right of an agency employee to participate in the meeting.

(j) A meeting of an advisory committee is subject to the requirements of part 14.

(k) Under 42 U.S.C. 2631(a)(8), a log or summary is to be made of all meetings between representatives of FDA and industry and other interested parties to implement the Radiation Control for Health and Safety Act of 1968.

§ 10.100 [Stayed]

8. Section 10.100 is stayed from January 22, 2001, to April 22, 2001.

9. Section 10.100a is added to subpart B from January 22, 2001, to April 22, 2001, to read as follows:

§ 10.100a Public calendars.

(a) *Prospective public calendar of public proceedings.* (1) A public calendar will be prepared and made publicly available each week showing, to the extent feasible, for the following 4 weeks, the public meetings, conferences, hearings, advisory committee meetings, seminars, and other public proceedings of FDA, and other significant public events involving FDA, e.g., congressional hearings.

(2) A copy of this public calendar will be placed on public display in the following places:

(i) Dockets Management Branch.

(ii) Office of the Associate Commissioner for Public Affairs.

(iii) A central place in each center.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

(b) *Retrospective public calendar of meetings.* (1) A public calendar will be prepared and made publicly available each week showing for the previous week meetings with persons outside the executive branch and other significant events involving the representatives of FDA designated under paragraph (b)(3) of this section, but telephone

conversations will be included on an optional basis and meetings with the working press, except for ''house organs'' (i.e., publications of firms that manufacture or distribute regulated products, or industry associations), and with on-site contractors will not be included. Meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees will be included when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision and involves more than a brief description of the matter.

(2) The calendar will include all meetings, conferences, seminars, social events sponsored by the regulated industry, and speeches. The calendar will specify the date and the person and subject matter involved. When more than one FDA representative is in attendance, only the presiding or head representative will report the meeting on the public calendar. If a large number of persons is involved, the name of each need not be specified. Meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment in FDA) will not be reported.

(3) The following FDA representatives and their deputies are subject to the requirements of paragraphs (b)(1) and (2) of this section:

(i) Commissioner of Food and Drugs.

(ii) Deputy Commissioner.

(iii) Associate Commissioners.

(iv) Executive and Special Assistants to the Commissioner.

(v) [Reserved]

(vi) Director, National Center for Toxicological Research.

(vii) Center Directors.

(viii) Chief Counsel for the Food and Drug Administration, or any representative of that office attending on behalf of the Chief Counsel.

(4) A copy of the public calendar will be placed on public display in the following places:

(i) Dockets Management Branch.

(ii) Office of the Associate Commissioner for Public Affairs.

(iii) A central place in each center.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

10. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

11. Section 14.20 is amended by adding paragraph (e) from January 22, 2001, to April 22, 2001, to read as follows:

§ 14.20 Notice of hearing before an advisory committee.

* * * * *

(e) All advisory committee meetings are to be included on the public calendar described in § 10.100(a).

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

12. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

13. Section 16.60 is amended by adding paragraph (a)(3) from January 22, 2001, to April 22, 2001, to read as follows:

§ 16.60 Hearing procedure.

(a) * * *

(3) If the hearing is a public hearing, it will be announced on the public calendar described in § 10.100(a) whenever feasible, and any interested person who attends the hearing may participate to the extent of presenting relevant information.

* * * * *

Dated: February 23, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–4962 Filed 2–28–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 203 and 205

[Docket No. 92N–0297]

RIN 0905–AC81

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying, until April 1, 2002, the effective date regarding certain requirements of the final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA is further delaying the effective date for certain requirements in the PDMA final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a ''health care entity'' in the final rule. In the **Federal Register** of May 3, 2000 (65 FR 25639), the agency previously delayed until October 1, 2001, the effective date of these requirements. The other provisions of the final rule became effective on December 4, 2000. The agency is taking this action to address concerns about the requirements raised by affected parties.

FDA believes that this further delay of the effective date of certain requirements in the PDMA final rule satisfies the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan,'' published in the **Federal Register** on January 24, 2001 (66 FR 7702). That memorandum requested Federal agencies to delay by 60 days the effective date of any regulation that was not effective as of January 20, 2001. The action taken in this document to further delay the effective date of certain requirements of PDMA exceeds 60 days. To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. As explained in the **SUPPLEMENTARY INFORMATION** section entitled ''Need to Further Delay the Effective Date,'' the delay will give distributors additional time to exhaust inventories of drugs that do not have acceptable pedigrees to avoid economic harm. Additionally, the delay will allow more time for FDA to make recommendations to Congress, for Congress to evaluate those recommendations and, if necessary,