Sunshine Act Meetings

Federal Register
Vol. 55, No. 179
Friday, September 14, 1990

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11:30 a.m., Friday, September 14, 1990.

PLACE: 2033 K St., NW., Washington, DC, 8th Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,
Secretary of the Commission.

[FR Doc. 90–21900 Filed 9–12–90; 12:34 pm]
BILLING CODE 6351-01-M

FEDERAL COMMUNICATIONS COMMISSION

September 12, 1990.

The Federal Communications Commission will hold an Open Meeting on the subject listed below on Wednesday, September 19, 1990, which is scheduled to commence at 9:00 a.m., in Room 856, at 1919 M Street, NW. Washington DC.

Item No., Bureau, and Subject

1—Common Carrier—Title: Policy and Rules Concerning Rates for Dominant Carriers (CC Docket No. 87–313), *Report and Order*. Summary: The Commission will consider the adoption of a *Report and Order* that provides a new incentive-based system of regulating local exchange carriers beginning January 1, 1991.

2—Common Carrier—Title: Represcribing the Authorized Rate of Return for Interstate Services of Local Exchange Carriers (CC Docket 89–624), *Order*. Summary: The Commission will consider the adoption of an *Order* represcribing the authorized unitary rate of return for the interstate services of local exchange carriers.

3—Chief Engineer—Title: An Inquiry Relating to Preparation for the International Telecommunication Union World Administrative Radio Conference for Dealing with Frequency Allocations in Certain Parts of the Spectrum. (Gen. Docket No. 89–554) Summary: The Commission will consider whether to adopt a Second Notice of Inquiry in this proceeding.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Steve Svab, Office of Public Affairs, telephone number (202) 632–5050.

Issued: September 12, 1990.
Federal Communications Commission.
Donna R. Searcy,
Secretary.
[FR Doc. 90–21937 Filed 9–12–90; 3:44 pm]
BILLING CODE 6712-01-M

FEDERAL COMMUNICATIONS COMMISSION

September 12, 1990.

The Federal Communications Commission will hold a Closed Meeting in Room 814 on the subjects listed below on Wednesday, September 19, 1990, following the Open Meeting, which is scheduled to commence at 9:00 a.m., in Room 856, at 1919 M Street, NW., Washington, DC.

Item No., Bureau, and Subject

1—General Counsel—Further action in the Chicago, Illinois, UHF television comparative renewal proceeding (MM Docket No. 83–575, 83–576).

2—General Counsel—Application for review in the Mount Vernon, Indiana FM proceeding (MM Docket No. 88–84).

3—General Counsel—Application for review in the Bradenton, Florida, comparative TV proceeding (Docket No. 87–532).

4—General Counsel—Eight Applications for Review in the Orlando, Florida television proceeding (MM Docket No. 85–216).

These items are closed to the public because they concern Adjudicatory Matters. (See 47 CFR 0.603(j).)

The following persons are expected to attend:

Commissioners and their Assistants
Managing Director and members of his staff
The Secretary
General Counsel and members of his staff
Director, Office of Public Affairs and members of his staff

Action by the Commission September 7, 1990, Chairman Sikes; Commissioners Quello, Marshall, Barrett, and Duggan voting to consider these matters in closed session.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Steve Svab, Office of Public Affairs, telephone number (202) 632–5050.

Issued: September 12, 1990.
Federal Communications Commission.
Donna R. Searcy,
Secretary.
[FR Doc. 90–21938 Filed 9–12–90; 3:44 pm]
BILLING CODE 6712-01-M

INTER-AMERICAN FOUNDATION BOARD

Meeting

TIME AND DATE: September 27, 1990, 5:30–9:00 p.m.

PLACE: 1515 Wilson Boulevard, Fifth Floor, Rosslyn, Virginia 22209.

STATUS: Open except for the portion specified as closed session as provided in 22 CFR 1004.4.

MATTERS TO BE CONSIDERED:

1. Approval of May 2, 1990, Board Meeting Minutes.
2. Approval of Revised By-Laws.
3. Designation of Board of Directors' Presidential Search Committee and Discussion of Search Procedures. Closed Session as provided in 22 CFR Part 1004.4.
4. Designation by Chairman of Interim President.
5. Review of Board Travel Policy and Procedures.
6. Recommendations and Discussion of SPTF Disbursements in Nicaragua.
7. Discussion of proposed FY 1992 Budget.
8. President's Report.

CONTACT PERSON FOR MORE INFORMATION: Charles M. Berk, Secretary to the Board of Directors, (703) 841–3812.

Dated: September 10, 1990.
Charles M. Berk,
Sunshine Act Officer.
[FR Doc. 90–21946 Filed 9–12–90; 3:44 pm]
BILLING CODE 7025-01-M

LEGAL SERVICES CORPORATION

Board of Directors Meeting; Notice

TIME AND DATE: A meeting of the Board of Directors will be held on September 23–24, 1990. The meeting will commence at 1:00 p.m.

PLACE: The Oxford Alexis Hotel, 1600 Seventeenth Street, The Sage Room, Denver, CO, 303–628–5400.

STATUS OF MEETING: Open [A portion of the meeting may be closed, subject to a vote by a majority of the Board of Directors, to discuss personnel, privileged or confidential, personal, investigatory and litigation matters under the Government in the Sunshine Act [54 U.S.C. 552b (c) (2), (4), (5), (7),

and (10) and 45 CFR 1622.5 (a), (c), (d), (e), (f), and (h)].

MATTERS TO BE CONSIDERED:

1. Approval of Agenda.
2. Approval of Minutes.
   —July 30, 1990
   —August 9, 1990
3. Welcoming Remarks by Frederic K. Conover, President, Colorado Bar Association.
4. Chairman's Remarks.
   (a) Status Report on Reauthorization, Appropriations and Confirmation Hearings.
   (b) Discussion of Future Board Meeting Schedule.
   (c) Report on Symposium of Twenty-Five Years of Federally Funded Legal Services.
   (d) Committee Selection.
5. President's Report.
   (a) Status Report on the Corporation.
   (b) Report on Reduction in Funding of California Rural Legal Assistance.
6. Discussion and Consideration of Reauthorization and Reform Proposals.
7. Report on Budgetary Matters.
   (a) Discusison of Corporation's Fiscal Year (FY) 1990. Consolidated Operating Budget.
   (b) Status of FY 1991 Appropriations.
   (c) Discussion of Proposed FY 1992 Budget Mark.

CONTACT PERSON FOR MORE INFORMATION: Maureen R. Bozell, Executive Office, (202) 863–1839.

Date Issued: September 12, 1990.

Maureen R. Bozell,

Corporation Secretary.

[FR Doc. 90–21952 Filed 9–12–90; 3:45 pm]

BILLING CODE 7050–01–M

RESOLUTION TRUST CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Board of Directors of the Resolution Trust Corporation will meet in open session on Tuesday, September 18, 1990 beginning at 2 p.m. to consider the following matters:

Summary Agenda:

No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

A. *Memorandum re:*
Proposed Amendments to the Bylaws of the Resolution Trust Corporation.

Discussion Agenda:

A. *Report re:*
Submission of Final Report regarding the Review of the 1988 FSLIC Assistance Agreements.

The meeting will be held in the Auditorium of the RTC Building located at 801—17th Street, NW., Washington, DC.

Requests for further information concerning the meeting may be directed to Mr. John M. Buckley, Jr., Executive Secretary of the Resolution Trust Corporation, at (202) 416–7282.

Dated: September 11, 1990.

Resolution Trust Corporation.

John M. Buckley, Jr.,

Executive Secretary.

[FR Doc. 90–21834 Filed 9–11–90; 4:57 pm]

BILLING CODE 6714–01–M

Corrections

Federal Register
Vol. 55, No. 179
Friday, September 14, 1990

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 3

[Docket No. 90-040]

RIN 0579-AA20

Animal Welfare; Standards

Correction

In proposed rule document 90-19223 beginning on page 33448 in the issue of Wednesday, August 15, 1990, make the following corrections:

On page 33492, in the first column, in the 23rd line, after "animals held for", add "quarantine. Several commenters requested that we define the word".

On page 33504, in the first column, in the fifth line from the bottom, "Current" should be added before "§ 3.85(b)".

On page 33505, in the first column, beginning in the 10th line, delete "that the nonhuman primates were provided water within that 4 hours before".

§ 3.3 [Corrected]

On page 33514, in the first column, in § 3.3(b), in the ninth line add "doors" between "windows" and "vents".

§ 3.7 [Corrected]

On page 33516, in the third column, in § 3.7(c)(4), in the sixth line "official" should read "officials".

§ 3.10 [Corrected]

On page 33517, in the first column, in § 3.10(a), on the 13th line "steam" should read "stream" and on the 15th line, "stream" should read "steam".

BILLING CODE 1505-01-D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Groundfish and Crab Fisheries of the Bering Sea and Aleutian Islands Area, Groundfish Fisheries of the Gulf of Alaska, and Pacific Halibut Fisheries Off the State of Alaska

Correction

In notice document 90-19964 beginning on page 34724 in the issue of Friday, August 24, 1990, make the following correction:

On page 34725, in the first column, the last line of the first full paragraph should read "effective in January 1992."

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 90N-0275]

Barr Laboratories, Inc.; Proposal To Refuse To Approve Abbreviated New Drug Applications for Conjugated Estrogrens Tablets; Opportunity for a Hearing

Correction

In notice document 90-19864 beginning on page 34613 in the issue of Thursday, August 23, 1990, make the following corrections:

1. On page 34616, in the second column, in the second complete paragraph, in the seventh line, the citation should read "21 U.S.C. 355(j)(7)(B)(i)".

2. On page 34617, in the first column, in the second paragraph, in the sixth line, "Bhavanani" should read "Bhavnani".

3. On page 34618, in the last line of the first column, "Director of" should read "Division of".

4. On the same page, in the third column, in the first complete paragraph, in the eighth line, the citation should read "21 U.S.C. 355(j)(3)(A)", and in the third from last line "21 U.C.S." should read "21 U.S.C.".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Program Announcement and Proposed Funding Priority for Cooperative Agreements for Area Health Education Center Programs

Correction

In notice document 90-21290 beginning on page 37562 in the issue of Wednesday, September 12, 1990, make the following correction:

On page 37563, in the second column, under **SPECIAL CONSIDERATION FOR FISCAL YEAR 1991** in the fifth line remove "disadvantaged".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No. 26327; Notice No. 90-21]

RIN 2120-AD59

Operation Over the High Seas and Within the North Atlantic Minimum Navigation Performance Specification Airspace

Correction

In proposed rule document 90-20793 beginning on page 36592 in the issue of Wednesday, September 5, 1990, in the first column, under "**DATES**", "January 3, 1990" should read "January 3, 1991".

BILLING CODE 1505-01-D

federal register

Friday
September 14, 1990

Part II

Department of Justice

Bureau of Prisons

28 CFR Part 524

Control, Custody, Care, Treatment and Instruction of Inmates; Central Inmate Monitoring; Final Rule

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 524

Control, Custody, Care, Treatment and Instruction of Inmates; Central Inmate Monitoring

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: In this document the Bureau of Prisons is amending its rule on Central Inmate Monitoring. The Bureau of Prisons monitors and controls the transfer, temporary release, and community activities of certain inmates who present special needs for management. Changes in this amendment include a clarification of the two types of Witness Security Cases, changes in eligibility criteria, clarification of clearance procedures, and nomenclature and editorial changes. This amendment is intended to update provisions of the Central Inmate Monitoring program and to ensure the continued safe and orderly running of Bureau institutions.

EFFECTIVE DATE: September 14, 1990.

ADDRESSES: Office of General Counsel, Bureau of Prisons, HOLC Room 760, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Roy Nanovic, Office of General Counsel, Bureau of Prisons, phone (202) 307–3062.

SUPPLEMENTARY INFORMATION: The Bureau of Prisons is amending its rule on Central Inmate Monitoring. A final rule on this subject was published in the **Federal Register** May 20, 1982 (47 FR 22002) and was amended in the **Federal Register** June 11, 1984 (49 FR 24105). For the convenience of the reader, the entire text of the rule is being published. A summary of the changes follows.

In the second sentence of § 524.70, the word "approval" is revised to read "clearance" to reflect Bureau procedure. In § 524.71 the phrase "Community Programs Managers" is revised to read "Community Corrections Managers" to reflect that change in title. In § 524.72, paragraph (a) is revised to incorporate the provisions of former paragraphs (a) and (b). Former paragraphs (c) through (i) of § 524.72 become paragraphs (b) through (h). New § 524.72(b) is revised to remove the reference to RICO conviction and to raise the dollar figures for monetary value of the offense used to determine eligibility from $1,000,000 and $500,000 to $5,000,000 and $1,000,000 respectively. In § 524.72(e) the heading "Disruptive groups" is revised to read "Security threat groups", the phrase "any penal" is replaced by "either state or federal penal", and in the last sentence the word "disruptive" is revised to read "security threat". These terminology changes specify more accurately the basis for this central inmate monitoring assignment. New § 524.72(g) is revised to include assignment for inmates for whom there is no identifiable threat, but who are to be separated at the request of the Federal Judiciary or Federal prosecutors. New § 524.72(h) is revised to include assignment for members of a terrorist group with a potential for violence, and also to revise the phrase "paragraphs (a)–(h)" to read "paragraphs (a)–(g)".

In § 524.73(a) the phrase "Community Programs Manger" is revised to read "Community Corrections Manager". To reflect current Bureau procedure, § 524.73(a) specifies that classification takes effect when proper notification is made. This ordinarily means when appropriate entries have been made into the Bureau's computer system. Section 524.73(b) identifies the case manager as the person responsible for ensuring notification is made to the affected inmate. This had been the responsibility of the institution's CIM coordinator. This paragraph now also specifies that witness security cases will be notified through a commitment interview. In § 524.73(b), the phrase ", with the original form placed in the inmate privacy folder" is removed to reflect current Bureau procedure. Former paragraph (c) of § 524.73 is designated as paragraph (d), and a new paragraph (c) is added which specifies that unsentenced inmates in pre-trial custody do not require notification. Inmates in pre-trial custody may receive a classification for reasons of security. Notification to the inmate of this classification serves no practical purpose, as it is made solely for management purposes and has no adverse effect on these inmates. For example, an unsentenced inmate's access to community activities remains under the control of the court. In new paragraph (d), references to interim and final classification are removed in order to reflect current Bureau procedure. References in this paragraph (d) to placing the original form in the inmate privacy folder are also removed.

Section 524.74 on CIM classifications is revised to incorporate provisions of former §§ 524.74 and 524.75 on final and interim CIM classifications, and specific references to final and interim classifications are deleted from the revised section. This reflects current Bureau procedures. Paragraph (a) of new § 524.74, is revised to state that an inmate's participation in the Department of Justice Witness Security Program is voluntary. Paragraph (d) of new § 524.74 derives from paragraph (a) of former § 524.75, and states that the Central Office is the reviewing authority for all future separation cases for witness security cases. Paragraph (e) of new § 524.74 allows for the classification of pre-trial inmates as central inmate monitoring cases. The intent of such classification is to provide for the protection of designated pre-trial inmates. Paragraph (f) of new § 524.74 derives from paragraph (d) of former § 524.75, and further specifies that an inmate not notified of a change in the classification by the reviewing authority within 60 days from the date of the initial notification may consider the CIM classification final. Paragraph (b) of former § 524.75 is no longer necessary because Bureau procedure does not include provision for interim classification. Appeal procedures referred to in paragraph (b) are now covered in new § 524.77. Paragraph (c) of former § 524.75 is incorporated into new § 524.74(d).

Former § 524.76 is redesignated as § 524.75. New § 524.75 is amended in paragraph (a) by revising the word "approval to read "clearance", in paragraph (b)(1) by adding the parenthetical phrase "(including satellite camp, except as provided for in paragraph (e)(1) of this section)", in paragraph (b)(2) by revising the phrase "community treatment centers" to read "community corrections centers," and in paragraph (d) by revising the phrase "Inmate Monitoring Branch" to read "Inmate Monitoring Section", and includes "escorted trips" as requiring Central Office clearance. Paragraph (e) of former § 524.76 is modified as new § 524.75(e)(1) and now specifies the Warden may give clearance for transfer of sole separation cases to satellite camp of the Warden's institution, paragraph (f) of former § 524.76 is now covered in new § 524.75(c), (d) and (e)(4), paragraph (g) of former § 524.76 is incorporated into new § 524.75(f), paragraph (h) of former § 524.76 is incorporated into new § 524.75(e)(2) and (f), and paragraph (i) of former § 524.76 is removed as this procedure is no longer necessary, since new § 524.75(c) sets forth the standard for clearance. Section 524.75(e)(3) allows the Warden to give clearance for local furlough medical trips (day) for state prisoners and separation cases, and § 524.75(e)(5) allows the Warden to give clearance for temporary release for local one day writs to the United States Marshals for witness security cases. New § 524.75(g) specifies that inmates in pretrial status,

who are classified solely under the separation assignment, only require review by the Warden or designee for temporary or permanent releases.

In new § 524.76 (formerly § 524.77), the first sentence of paragraph (a) is revised to eliminate overly specific details relating to program review. The intent of the paragraph is unchanged. Paragraph (b) of new § 524.76 is revised to clarify that participation in the Department of Justice Witness Security Program is voluntary, and to incorporate the nomenclature change for the Central Office Inmate Monitoring Section. In new § 524.77 (formerly § 524.78), references to interim and final classifications are removed to reflect current Bureau procedure, and in the last sentence the word "complaints" is revised to read "appeals" for the sake of clarity. New § 524.77 also provides that witness security cases may choose to address their concerns directly to the Inmate Monitoring Section, Central Office, rather than use the Administrative Remedy Procedure.

In new § 524.78 (formerly § 524.79), the heading is revised to read "CIM classification of recommitted offenders", and references to parole/mandatory release violation or new conviction are removed as being redundant. In paragraph (c) of new § 524.78, the case manager is identified as the person responsible for ensuring the inmate is provided notification of classification actions, and the reference to interim classification is deleted.

Because these changes impose no further restrictions on inmates and deal with agency procedures designed to help ensure the continued protection of inmates, the Bureau finds good cause for exemption from the provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public comment, and delay in effective date. Members of the public may submit comments concerning this rule by writing the previously cited address. These comments will be considered, but will receive no response in the **Federal Register**. For ease of review, the entire text of the rule is being republished.

The Bureau of Prisons has determined that this rule is not a major rule for the purpose of E.O. 12291. After review of the law and regulations, the Director, Bureau of Prisons has certified that this rule, for the purpose of the Regulatory Flexibility Act (Pub. L. 96–354), does not have a significant impact on a substantial number of small entities.

List of Subjects in 28 CFR Part 524

Prisoners.

Dated: September 10, 1990.

J. Michael Quinlan,

Director, Bureau of Prisons.

Accordingly, pursuant to the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons in 28 CFR 0.96(q), subchapter B of 28 CFR chapter V is amended as set forth below.

SUBCHAPTER B—INMATE ADMISSION, CLASSIFICATION, AND TRANSFER PART 524—CLASSIFICATION OF INMATES

1. The authority citation for 28 CFR part 524 is revised to read as follows, and all other authority citations within the part are removed:

Authority: 5 U.S.C. 301; 18 U.S.C. 3521–3528, 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to conduct occurring on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to conduct occurring after that date), 5039; 21 U.S.C. 848; 28 U.S.C. 509, 510; 28 CFR 0.95–0.99.

2. Subpart F of 28 CFR part 524 is revised to consist of §§ 524.70 through 524.78 as follows:

Subpart F—Central Inmate Monitoring System

Sec.

Subpart F—Central Inmate Monitoring System

§ 524.70 Purpose and scope.

The Bureau of Prisons monitors and controls the transfer, temporary release (e.g., on writs), and community activities of certain inmates who present special needs for management. Such inmates, known as central inmate monitoring (CIM) cases, require Central Office and/or Regional Office clearance for transfers, temporary releases, or community activities recommended by the Warden. This monitoring is not for the purpose of precluding inmates classified as central inmate monitoring cases from transfers, from temporary releases, or from participation in community activities, when the inmate is otherwise eligible, but rather is to provide protection for all concerned and to contribute to the safe and orderly running of federal institutions.

§ 524.71 Responsibility.

Authority for actions relative to the Central Inmate Monitoring Program is delegated to the Assistant Director, Correctional Programs Division, to Regional Directors, and to Wardens. Each of these persons shall designate a CIM coordinator (for the Central Office, each Regional Office, and each institution, respectively). Community Corrections Managers are designated CIM coordinators for inmates confined at contract facilities.

§ 524.72 Central inmate monitoring assignments.

Central inmate monitoring cases are classified according to the following assignments.

(a) *Witness Security Cases:* Individuals who agree to cooperate with law enforcement, judicial, or correctional authorities, frequently place their lives or safety in jeopardy by being a witness or intended witness against persons or groups involved in illegal activities. Accordingly, procedures have been developed to ensure the safety of these individuals. There are two types of Witness Security Cases: Department of Justice (authorized by the Attorney General under Title V of Public Law 91–452) and Bureau of Prisons Witness Security Cases (authorized by the Assistant Director, Correctional Programs Division).

(b) *Sophisticated criminal activity:* Inmates who have been involved in sophisticated, large-scale criminal activity. Examples of sophisticated criminal activity include drug offenses, property offenses, white collar offenses, or a criminal history of involvement in such offenses. An inmate may be classified to this assignment when all the following minimum criteria are met:

(1) The offender was a principal figure or prime motivator in the criminal organization or activity from which substantial income or resources could be obtained; and

(2) The monetary value of the offense totaled $5,000,000 or more for drug offenses, and $1,000,000 or more for property offenses or white collar offenses. The realization of a lesser amount of net illicit gain by the inmate for property or white collar offenses does not mitigate the amount of loss or potential loss which may have been incurred by the victim(s).

(c) *Threats to government officials:* Inmates who have made threats to government officials or have been identified in writing by the U.S. Secret Service as requiring special surveillance.

(d) *Broad publicity:* Inmates who have received widespread publicity (for

example, national media coverage) as the result of their criminal activity or notoriety as public figures.

(e) *Security threat groups:* Inmates who belong to or are closely affiliated with groups (e.g., prison gangs), which have a history of disrupting operations and security in either state or federal penal (which includes correctional and detention facilities) institutions. This assignment also includes those persons who may not be confined in the same institution with a specified security threat group(s).

(f) *State prisoners:* Inmates, other than Witness Security cases, who have been accepted into the Bureau of Prisons for service of their state sentences. This assignment includes cooperating state witnesses and regular state boarders.

(g) *Separation:* Inmates who may not be confined in the same facility with other specified individuals who are presently housed in federal custody or who may come into federal custody in the future. Factors to consider in classifying an individual to this assignment include, but are not limited to, testimony provided by or about an individual (in open court, to a grand jury, etc.), and whether the inmate has exhibited aggressive behavior towards other specific individuals, either in the community or within the institution. This assignment also includes those inmates who have provided authorities with information concerning the unauthorized or illegal activities of others. This assignment may also include inmates for whom there is no identifiable threat, but who are to be separated from others at the request of the Federal Judiciary or Federal Prosecutors.

(h) *Special supervision:* Inmates who require special management attention, but who do not ordinarily warrant assignment in paragraphs (a)–(g) of this section. For example, this assignment may include an inmate with a background in law enforcement or an inmate who has been involved in a hostage situation. Others may include those who are members of a terrorist group with a potential for violence. Placement in this assignment may be made only upon the authorization of a Regional Director or the Assistant Director, Correctional Programs Division.

§ 524.73 Procedures.

Staff shall use the following procedures in making central inmate monitoring classifications:

(a) An inmate may be classified at any time as a central inmate monitoring case by a Community Corrections Manager or by appropriate staff at the Central Office, Regional Office, or institution. This classification takes effect when proper notification is made.

(b) The case manager shall ensure that the affected inmate is notified in writing as promptly as possible of the classification and the basis for it. Witness security cases will be notified through a commitment interview. The notice of the basis may be limited in the interest of security or safety. For example, in separation cases under § 524.72, notice will not include the names of those from whom the inmate must be separated. On the other hand, in sophisticated criminal activity cases under § 524.72, adequate notice shall include specific reference to the sophisticated criminal activity; that is, the crime or crimes for which the inmate was convicted, or explicit and reliable information of other sophisticated criminal activity. The inmate shall sign for and receive a copy of the notification form. If the inmate refuses to sign the notification form, staff witnessing the refusal shall indicate this fact on the notification form and then sign the form.

(c) Inmates in pre-trial custody do not require notification.

(d) When an inmate's name is ordered removed for any reason from the Central Inmate Monitoring System (for example, because the reviewing authority either disapproves the CIM classification or approves removal of a CIM classification based on new information), the appropriate staff member shall ensure that the relevant portions of the inmate central file are either removed or, when part of a larger document, are amended to clearly reflect removal of the CIM assignment. The form providing for notification of the central inmate monitoring classification, the summary sheet, supportive documentation, and the written basis for removal are to be retained in the inmate privacy file. Staff shall notify the inmate in writing of the removal of the specific CIM classification. The inmate shall sign for and receive a copy of this notification form. If the inmate refuses to sign the notification form, staff witnessing the refusal shall indicate this fact on the form and then sign the form.

§ 524.74 CIM classifications.

A CIM classification may be made where the basis for the classification is well established at the time of the initial review. The inmate is to be notified of the CIM classification(s) and of the right to appeal the classification(s) through the Administrative Remedy Procedure.

(a) Witness security cases are designated by the Central Office. An inmate's participation in the Department of Justice Witness Security Program is voluntary. A commitment interview and an admission and orientation interview are to be conducted with the witness security inmate to ensure that the inmate understands the conditions of confinement within the Bureau of Prisons. Central Office classification of an individual as a witness security case, under either the Department of Justice or Bureau of Prisons, does not require additional review, and overrides any other CIM assignment.

(b) State prisoners accepted into the Bureau of Prisons from state or territorial jurisdictions are designated by appropriate staff in the Central Office or Regional Office. All state prisoners are automatically included in the Central Inmate Monitoring System to facilitate designations, transfers, court appearances, and other movements. Central Office or Regional Office classification of an individual as a state prisoner does not require additional review.

(c) Designated staff in the Central Office or Regional Office may assign an inmate to any other CIM classification which they are authorized to make, based upon substantive information. Staff in the Central Office or Regional Office shall notify the appropriate institution CIM coordinator of the classification.

(d) A classification may be made at any level to achieve the immediate effect of requiring prior clearance for an inmate's transfer, temporary release, or participation in community activities. A review by designated staff is required to determine whether a sound basis exists for the classification. Staff making this initial classification shall forward to the reviewing authority complete information regarding the inmate's classification. Reviewing authorities for CIM classification are:

(1) Designated staff in the Central Office Inmate Monitoring Section who review classification decisions for all future separation assignments for witness security cases and for any combination of assignments involving a witness security case.

(2) The Warden who reviews CIM classification decisions for all separation assignments except for uncommitted separation.

(3) Designated staff in the Regional Office who review CIM classification decisions for all other central inmate monitoring assignments and for any combination of assignments, except for those involving a witness security case

(e) Pre-trial inmates may be classified as central inmate monitoring cases to effect appropriate security concerns

(e.g., separation, special security and special supervision). Designated staff at institutions are authorized to make these assignments, based upon substantive information.

(f) The reviewing authority shall examine the appropriateness of the CIM classification, ordinarily within 60 days of the date the inmate was initially notified of the classificiation. The reviewing autority shall notify the institution's CIM coordinator in writing of the outcome of the review. An inmate not notified of a change in the classification by the reviewing authority within 60 days from the date of the initial notification may consider the CIM classification final.

§ 524.75 CIM activities clearance.

(a) An inmate classified as a Central Inmate Monitoring case may not be transferred (except for medical emergencies), may not be given a temporary release, and may not participate in community activities without prior clearance from the appropriate reviewing authority.

(b) Clearance by the Central Office or Regional Office (depending upon CIM classification) is required prior to the inmate's participation in the following activities:

(1) Transfer to another federal facility (including satellite camp, except as provided for a in paragraph (e)(1) of this section);

(2) Transfer to non-federal facilities or contract community corrections centers (for continued service of federal sentence);

(3) Temporary release (e.g., on writ) to federal, state, and/or local jurisdictions;

(4) Furloughs;

(5) Escorted trips outside commuting distance of the institution; and

(6) Work or Study Release.

(c) Except as provided in the following paragraphs of this section, the Regional Director or designee shall be the clearance authority on all transfers, temporary releases, and participation in community activities for inmates assigned central inmate monitoring status.

(d) The Central Office Inmate Monitoring Section shall be the clearance authority on all transfers, temporary releases, escorted trips, and participation in community activities for witness security cases.

(e) The Warden may give clearance to CIM cases for the following activities:

(1) Transfer of sole separation cases to satellite camp of Warden's institution;

(2) Local escorted medical trips (other than witness security cases);

(3) Local furlough medical trips (day) for the following CIM assignments: state prisoners and separation cases;

(4) Local non-medical escorted trips for separation cases.

(5) Temporary release for local one day writs to the United States Marshals for witness security cases.

(f) The Warden may give clearance to transfer a CIM inmate, including witness security cases, to a local hospital for emergency medical care not available at the institution.

(g) Inmates in pre-trial status, who are classified solely under the separation assignment, only require review by the Warden or his designee for temporary or permanent releases.

§ 524.76 Review of CIM status.

(a) Except for witness security and state prisoner assignments, the Warden shall ensure that the status of an inmate's CIM assignment is considered at each program review. When staff believe that removal or modification of a CIM classification is appropriate, the institution's CIM coordinator and the appropriate reviewing authority are to be notified. Only the reviewing authority shall determine if removal or modification of the CIM classification is appropriate. The institution's CIM coordinator shall ensure that the inmate is notified of any decision made by the reviewing authority.

(b) Participation of an inmate in the Department of Justice Witness Security Program is voluntary. An inmate classified as a witness security case because of his participation in the Department of Justice Witness Security Program may request removal from this assignment at any time. Staff shall forward to the Central Office Inmate Monitoring Section a request by a witness security inmate for removal from the witness security program. An inmate may not be removed from the CIM assignment as a witness security case without the acknowledgement of the Department of Justice.

(c) A state prisoner accepted into the Bureau of Prisons from a state or territorial jurisdiction shall keep the CIM assignment "state prisoner" while solely in service of the state sentence.

§ 524.77 Appeals of central inmate monitoring classification.

An inmate may at any time appeal (through the Administrative Remedy Procedure) the inmate's classification as a central inmate monitoring case. Federal inmates housed in non-federal facilities do not have access to the Administrative Remedy Procedure. Inmates in this states who wish to appeal their CIM status may forward their appeals by private correspondence to the appropriate Regional Office. Inmates identified as witness security cases may choose to address their concerns directly to the Inmate Monitoring Section, Central Office, rather than use the Administrative Remedy Procedure.

§ 524.78 CIM classification of recommitted offenders.

An inmate who is recommitted to federal custody, who at the time of release was classified as a CIM case, shall retain this classification pending a review of the CIM status. Except for witness security cases, this review ordinarily is completed as part of the classification process. Review for witness security cases is completed by the Inmate Monitoring Section at the time that an institution is designated.

(a) When staff determine that the inmate's removal as a CIM case is appropriate, staff shall forward their recommendation, and the justification for this recommendation to the appropriate reviewing authority for a final decision on the CIM classification. The inmate retains the CIM classification pending a decision by the reviewing authority.

(b) When staff determine that modification (addition or deletion of one or more CIM assignments) of the CIM classification is appropriate, staff shall forward their recommendation, and the justification for this recommendation to the appropriate reviewing authority for a decision on modification of the CIM classification. The inmate retains the CIM classification pending a decision by the reviewing authority.

(c) When removal from, modification of, or continuation as a CIM case is indicated, or when a classification is effected, the case manager shall ensure that the inmate is provided notification of the action. The case manager shall also ensure that an inmate is provided notification of any subsequent decision by the rviewing authority to either modify or remove the inmate's CIM assignment.

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Friday
September 14, 1990

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 205

Guidelines for State Licensing of Wholesale Prescription Drug Distributors; Final Rule

21 CFR Part 205

Applicability to Blood and Blood Components Intended for Transfusion; Guidelines for State Licensing of Wholesale Prescription Drug Distributors

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 205

[Docket No. 88N-0258]

RIN 0905-AC81

Guidelines for State Licensing of Wholesale Prescripton Drug Distributors

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to implement those sections of the Prescription Drug Marketing Act of 1987 (PDMA) that require FDA to issue regulations setting forth guidelines for State licensing of wholesale drug distributors. The guidelines prescribe minimum standards, terms, and conditions for the storage and handling of prescription drugs for human use (hereinafter prescription drugs) and for the establishment and maintenance of records of their distribution. PDMA prohibits wholesale distribution of prescription drugs in interstate commerce unless the wholesale distributor is licensed by a State in accordance with these guidelines. In this rule, FDA has tentatively determined that PDMA does not apply to the distribution of blood and blood components intended for transfusion. In a separate notice elsewhere in this issue of the **Federal Register**, FDA invites further comment on this matter.

EFFECTIVE DATE: September 14, 1990.

FOR FURTHER INFORMATION CONTACT: Diane P. Goyette, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20657, 301-295-8049.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 13, 1988 (53 FR 35325), FDA published a proposed rule to issue guidelines for State licensing of wholesale drug distributors as required by the Prescription Drug Marketing Act of 1987 (Pub. L. 100-293, 102 Stat. 95). PDMA amends the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*) to provide, among other things, that no person may engage in the wholesale distribution in interstate commerce of drugs subject to section 503(b) of the act (21 U.S.C. 353(b)) (prescription drugs for human use), unless such person is licensed by the State in accordance with federally prescribed minimum standards. PDMA requires that these minimum standards be established in "guidelines" issued by FDA regulation. The guidelines must prescribe minimum standards, terms, and conditions for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distribution (21 U.S.C. 353(e)(2)).

The State licensing guidelines established by this regulation should not be confused with FDA guidelines issued under the agency's rules governing administrative practices and procedures (21 CFR 10.90). Guidelines issued under § 10.90 suggest procedures or present standards of general applicability that are not legal requirements, but that one can rely on as acceptable to FDA. Such guidelines allow persons to choose alternate courses of conduct that comply with the general standards or suggested procedures. In contrast, PDMA directs that the guidelines issued by this regulation "* * * shall *prescribe requirements* for the storage and handling of (prescription) drugs and for the establishment and maintenance of records of (their) distribution * * *" (emphasis added). Moreover, PDMA requires that wholesale drug distributors who distribute human prescription drugs in interstate commerce be licensed in accordance with the minimum requirements set forth in these guidelines (21 U.S.C. 353(e)(2)). Thus, the guidelines prescribed by this regulation are binding substantive rules that have the force and effect of law.

Unless express reference is made to guidelines issued under § 10.90 (as in paragraph 25, below), all references to guidelines in this document are made to these "Guidelines for State Licensing of Wholesale Prescription Drug Distributors" established under the requirements of PDMA.

The PDMA prohibition against interstate distribution of prescription drugs by persons who are not licensed by the State in accordance with these Federal guidelines takes effect 2 years after the date of publication of this final rule. Any person who distributes prescription drugs in violation of this prohibition is subject to imprisonment for not more than 10 years or a fine of not more than $250,000, or both (21 U.S.C. 333(b)(1)).

In developing the guidelines, FDA followed the recommendation of the House of Representatives' Committee on Energy and Commerce that it consider the "Model Regulations for Wholesale Drug Distribution" issued by the National Association of Boards of Pharmacy (NABP). FDA also considered the "Proposed Uniform Standards of Practice for Wholesale Drug Distribution," which have been adopted by the National Wholesale Druggists' Association (NWDA).

Additionally, FDA has carefully considered the approximately 50 comments received on the proposed rule. The comments came from members of Congress, trade associations, professional groups, individual pharmaceutical manufacturing firms, wholesale drug distributors, chain drug store companies, State boards of pharmacy, individual hospital and retail pharmacies, and pharmacists. Highlights of this final rule and the agency's economic analysis are followed by a summary and discussion of the comments in section VII below.

II. Highlights of the Final Rule

This final rule establishes guidelines for State licensing of wholesale prescription drug distributors as required under PDMA. The guidelines provide minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distribution. The guidelines ensure that all prescription drug wholesalers who distribute drugs in interstate commerce will operate according to these minimum standards while leaving States discretion to impose stricter licensing requirements. In response to comments and further internal deliberations, the final rule modifies certain provisions of the proposal to meet these objectives better. The major provisions of the final rule are summarized as follows:

1. *Scope.* The final rule applies to all wholesale distributors of human prescription drugs in interstate commerce.

2. *Definitions.* Section 205.3 sets forth definitions as they apply to this final rule. The distribution of drug samples by manufacturers' representatives, distributors' representatives, and the distribution of blood and blood components intended for transfusion by registered blood establishments are excluded from the definition of wholesale distribution in the final rule. These activities are, therefore, not subject to the licensing requirements under the guidelines.

3. *Wholesale drug distributor licensing requirement.* Section 205.4 of the final rule sets forth the requirement that a wholesale distributor conducting interstate transactions in a State be licensed by the State. This requirement is mandated by section 503(e)(2)(A) of the act.

4. *Minimum required information for licensure.* Section 205.5 of the final rule sets forth minimum information to be required from each licensing applicant.

5. *Minimum qualifications.* The final rule sets forth certain minimum qualifications for licensing under § 205.6. The agency believes that careful screening of applicants is necessary and prudent in reducing the opportunities for diversion of prescription drugs. State authorities must consider an applicant's history, which may reflect upon the applicant's ability to prevent drug diversion. Where granting a license would not be in the public interest, State authorities may deny a license to an applicant.

6. *Personnel.* The final rule establishes minimum personnel standards for licensees under § 205.7. Employees must be qualified by education and/or experience to perform their duties.

7. *Violations and penalties.* Section 205.8 of the final rule provides for suspension or revocation of licenses, and permits fines, imprisonment, or civil penalties upon conviction of violations of Federal, State, or local drug laws.

8. *Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.* The final rule sets forth the minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of records of their distributions. The final rule includes sections describing physical requirements of facilities where prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed. Such facilities must have certain characteristics, outlined in § 205.50(a) of the final rule, that make them suitable places for the storage of prescription drugs. Facilities must also have adequate security systems and be capable of ensuring a proper environment for the storage of prescription drugs.

a. *Wholesaler examination of incoming shipments of prescription drugs.* The final rule requires examinations of incoming and outgoing shipments to prevent acceptance of prescription drugs that are contaminated or otherwise unfit for distribution. The proposed section has been clarified in the final rule to limit the required inspection of incoming shipments of prescription drugs by wholesale distributors to a visual examination, adequate to reveal shipping container damage that would suggest damage to the contents. The final rule also deletes the requirement that the inspection of incoming shipments extend to an examination of the delivery vehicle.

b. *Handling of prescription drug products returned to the wholesale distributor.* Section 205.50(e) includes detailed instructions for the handling of returned, damaged, and outdated prescription drugs. The final rule permits the wholesaler to send back to the original supplier prescription drug products that have been returned to the wholesaler under circumstances that cast doubt on the product's integrity. This change is consistent with stated agency policy with regard to returned prescription drug products under PDMA.

c. *Recordkeeping requirements.* Section 205.50(f) sets forth recordkeeping requirements to ensure a high degree of accountability for all prescription drug transactions. Proposed § 205.50(f)(1) has been revised so that wholesale distributors are not required to include the expiration dates of prescription drugs in the records of their transactions under the final rule. Records must be retained for a period of 2 years following disposition of the prescription drug product under § 205.50(f)(2) of the final rule. Section 205.50(f)(3) of the final rule provides that records kept at the inspection site or immediately retrievable by computer or other means must be readily available for authorized inspection during the retention period. Those that are kept at another location must be made available within 48 hours of an authorized request.

d. *Written policies and procedures.* Section 205.50(g) sets forth minimum standards for the establishment and maintenance of written policies and procedures related to the receipt, security, storage, inventory, and distribution of prescription drugs. By following such pre-established procedures, a firm can better assure proper storage and distribution of prescription drugs on a consistent basis.

e. *Responsible persons.* Section 205.50(h) of the final rule requires the maintenance of lists of persons in responsible company positions. Such lists provide a deterrent to drug diversion.

f. *Compliance with Federal, State, and local law.* Section 205.50(i) of the final rule emphasizes that wholesale drug distributors must operate in compliance with all applicable laws and regulations.

g. *Salvaging and reprocessing.* Section 205.50(j) of the final rule states that wholesale drug distributors are subject to any applicable Federal, State, or local laws relating to salvaging or reprocessing. Salvaging and reprocessing operations can be very complex and are outside the scope of traditional wholesaler activities. Additional controls are therefore necessary to ensure that these operations are carried out in the appropriate fashion. Accordingly, § 205.50(j) of the final rule makes clear that FDA's current good manufacturing practice (CGMP) regulations for finished pharmaceuticals in 21 CFR parts 210 and 211 apply to wholesalers' salvaging and reprocessing operations.

III. Economic Analysis

FDA has examined the economic consequences of the changes implemented by the final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354).

As recommended by Congress, FDA consulted the NABP Model Regulations for Wholesale Drug Distribution in the development of the standards set by these guidelines. (See H. Rept. 100–76, p. 17.) The agency believes that the standards in these guidelines represent the norm of current practices and procedures among drug wholesalers and expects minimal incremental costs to occur when these standards become effective 2 years after the publication of this final rule. Any substantial costs that may arise will be attributable to the statute itself. Thus, this rule is not expected to produce economic consequences beyond those contemplated by the act. Accordingly, the agency concludes that this final rule is not a major rule as defined by Executive Order 12291. For similar reasons, the agency certifies, in accordance with the Regulatory Flexibility Act, that this final rule will not have a significant impact on a substantial number of small entities.

IV. Executive Order 12612; Federalism

Executive Order 12612 requires Federal agencies to carefully examine regulatory actions to determine if they would have significant impact on federalism. Using the criteria and principles set forth in the Order, the agency has considered the impact of this final rule on the States, on their relationship with the national government, and on the distribution of power and responsibilities among the various levels of government.

FDA is required by statute to issue this regulation to establish guidelines setting forth minimum standards for State licensing of wholesale prescription drug distributors. The regulation is to include minimum requirements for recordkeeping, storage, and handling of prescription drugs. States are affected to the extent that their wholesale distributors are not permitted to

distribute prescription drugs in interstate commerce unless they are licensed by the State in accordance with these guidelines. Under these guidelines, however, States are free to adopt standards that exceed the minimum requirements. They also maintain maximum administrative discretion, and can develop their own policies to achieve program objectives. States have had the opportunity to participate in the development of these guidelines through the notice and comment rulemaking process.

FDA certifies that it has examined this final rule, and while it may have some effect on federalism issues, for the reasons stated above, these effects are not significant and do not require an assessment under Executive Order 12612. Moreover, the agency's action is mandated by law; the agency has no discretion in carrying out its legal mandate by regulation.

V. Paperwork Reduction Act of 1980

This final rule contains information collections which have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 and assigned OMB control number 0910–0251. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Prescription Drug Marketing Act of 1987; Guidelines for State Licensing of Wholesale Prescription Drug Distributors.

Description: The reporting requirement includes the submission of certain descriptive information concerning each wholesale drug distributor (e.g., corporate address, contact person address) (§ 205.5). The recordkeeping requirements include establishing and maintaining inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs (§ 205.50(f) and (h)).

Description of respondents: State or local governments; businesses or other for-profit organizations; small businesses or organizations.

Estimated annual reporting and recordkeeping burden:

Section	Annual number of respondents	Annual frequency	Average burden per response (minutes)	Annual burden hours
202.5(a)	7,300	1	15	1,825
205.50(f) and (h)	7,300	1	20	2,434
Total				4,259

FDA, as a result of the comments received on the proposal, has deleted the provision in § 205.50(f)(1)(iii) requiring distributors to maintain records of expiration dates of prescription drugs. As reflected in the table above, this change will reduce the estimated burden from 30 minutes per response to 20 minutes, and from 3,650 annual burden hours to 2,434. There were no comments received on the Paperwork Reduction Act clearance submission or on the burden estimates.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a) (7), (8), and (10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Comments on the Proposed Rule

A. General Comments

1. Several comments addressed general issues raised by the proposed rule. Some comments questioned whether FDA should be regulating wholesale drug distributors, saying that regulations for State licensure of drug wholesalers should be left to the individual States. Other comments argued that the proposed rule is unnecessary and duplicative because State regulatory and private quality control systems already in place adequately address the goals of PDMA, and that the pharmacists' role in drug distribution precludes the need for wholesaler licensing by State or Federal authorities.

Section 503 of the act, as amended by PDMA, requires FDA to publish these State guidelines. It is not left to the agency's discretion (21 U.S.C. 353(e)(2)(B)). Moreover, the legislative history of PDMA reveals that Congress examined existing drug distribution systems, State licensing schemes, private quality control systems, and the role of pharmacists in meeting the goals of PDMA, and concluded that, although such programs might be individually effective, a national strategy was necessary to protect the public health.

These Federal guidelines set minimum standards for States to follow in designing their licensing systems. The guidelines assure that all wholesale drug distributors conducting business in interstate commerce will comply with the same minimum requirements. The agency believes that the guidelines leave States sufficient discretion to determine appropriate structures for the regulation of wholesale distributors conducting business in their States.

2. Some comments argued that the proposed guidelines should be modified or abandoned because they duplicate, and at times contradict, provisions of FDA's CGMP regulations (21 CFR parts 210 and 211).

The agency's CGMP regulations include provisions that are similar to some requirements in these guidelines. However, the CGMP regulations do not apply to the traditional activities of wholesale drug distributors (see 43 FR 45027), whereas these guidelines are expressly applicable to the traditional activities of wholesale drug distributors. FDA is unaware of any inconsistencies within its regulatory scheme that would dictate changes in these guidelines.

The provisions of this rule and other FDA regulations may have common elements, but the agency finds that this is appropriate. FDA finds that the guidelines are not only consistent with other Federal regulations, but complement the Federal scheme to enable FDA to have better control over the distribution of prescription drugs. The agency's views on the relationship between these guidelines and the current good manufacturing practice provisions of the act are discussed in paragraph 25 below.

3. Some comments discussed the economic impact of the proposed rule on wholesale distributors. Generally, these

comments contended that the proposed rule would impose substantial additional costs on wholesalers, without a corresponding benefit. Some comments estimated that new paperwork and personnel expenses would impose a burden. Other comments expressed concern that additional costs will force smaller, marginally profitable wholesale distributors out of business. The comments asserted that the proposed rule would impose many new procedural burdens on wholesale distributors that go beyond current practice and would be expensive to implement.

As noted earlier, the agency considered both the NABP "Model Regulations for Wholesale Drug Distribution" and the NWDA "Proposed Uniform Standards of Practice for Wholesale Drug Distribution" in developing these guidelines. Therefore, the agency believes that the guidelines represent the norm of current practice and procedure among drug wholesalers. The comments offered no examples of significant deviation from current procedures to bolster the general claim that implementation of these minimum requirements would have substantial economic consequences. Moreover, the comments suggested no specific changes in the proposed requirements to lessen the asserted economic impact.

When Congress passed PDMA, it determined that some changes should be made in the wholesale distribution system to protect the public from prescription drugs of questionable integrity. While some additional expenses are anticipated as these changes are implemented, the agency does not expect these minimum requirements to impose costs that are overly burdensome. The agency has reviewed this rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act and finds it satisfactory.

4. One comment asserted that compliance with the minimum standards set forth in the rule will greatly increase paperwork burdens. The comment also stated that the proposed guidelines governing the handling of prescription drugs, particularly those provisions dealing with destruction of returned or damaged prescription drugs, could have a significant effect on the human environment.

The agency has concluded that the standards described in these guidelines represent current procedure among responsible wholesale distributors. It is not expected that unreasonable, new paperwork burdens or significant effects on the human environment will be created.

5. One comment asked that FDA clarify its authority to enforce these guidelines.

These guidelines are minimum standards for State licensing of wholesale drug distributors. State licensing authorities are the primary agencies responsible for establishing and enforcing wholesaler licensing schemes in the States in accordance with the guidelines. FDA, however, will enforce section 503(e)(2)(A) of the act (21 U.S.C. 353(e)(2)(A)), which prohibits wholesale distribution of prescription drugs in interstate commerce in a State, except by persons licensed by the State in accordance with these minimum guidelines.

This specific authority under PDMA does not replace or dimish the agency's authority over wholesalers under other statutory provisions, including the adulteration, misbranding, and new drug provisions of the act.

B. Scope

6. Two comments requested that manufacturers' distribution centers be specifically excluded from the scope of the licensing requirements because they are adequately governed by FDA's CGMP regulations.

FDA does not find it necessary to make the change requested. Congress intended that all wholesale distributors of human prescription drugs, with certain specific exceptions, be licensed according to these gudielines. Manufacturers' warehouses that are conducting wholesale distributions are wholesale distributors and are subject to the licensing requirements unless their activities fall under one of the specific exclusions defined under § 205.3(f) of the final rule.

7. Three comments addressed issues raised by application of these guidelines to the distribution and sale of blood and blood components by blood establishments and hospitals. Two of these comments requested clarification of PDMA's scope and urged FDA to "exempt" blood establishments from all of PDMA's provisions. The comments contended that application of PDMA to blood distributors would seriously disrupt the nation's blood services. The third comment suggested that the agency could, by notice and comment rulemaking, exempt blood and blood components from PDMA by declaring that they are not prescription drugs for PDMA purposes.

After considering these comments and reviewing PDMA's purpose and legislative history, FDA has tentatively determined that PDMA does not apply to blood and blood components intended for transfusion. However, in a notice published elsewhere in this issue of the **Federal Register**, FDA is inviting further comments on this matter.

PDMA, by its literal terms, applies to all drugs that are subject to section 503(b) of the act; that is, to all human prescription drugs. There is no doubt that blood and blood components intended for transfusion are prescription drugs. See, e.g., 21 CFR 606.121(c)(8)(i); 21 CFR 610.61(t). See also May 25, 1982, 47 FR 22518; August 1, 1981, 46 FR 40121. However, if PDMA, and particularly PDMA's restrictions on the resale of prescription drugs, were considered applicable to the distribution of such blood and blood components, the result would be to seriously impede the present blood distribution system, thereby substantially interfering with, and reducing, our nation's blood supply. Because application of PDMA to blood and blood components intended for transfusion would produce this untenable result, FDA believes that Congress did not intend to subject such blood and blood components to PDMA's provisions.

Moreover, the legislative history lacks any discussion of PDMA's application to blood and blood components intended for transfusion and also clearly shows that Congress intended that PDMA remedy problems associated with the distribution of those drugs that are popularly referred to as "medicines" or "pharmaceuticals." See, *e.g.*, Public Law 100–293, section 2 (1988) (Congressional Findings). As is discussed in further detail in the companion notice to this final rule that is published elsewhere in this issue of the **Federal Register**, blood and blood components intended for transfusion are unique drug products that are distributed in an entirely different way than other prescription drugs. For example, such blood and blood components are not promoted through samples and coupons. FDA believes that the fact that such blood and blood components are not part of the system of distribution and marketing that Congress intended to regulate under the terms of PDMA further signals that Congress did not intend to include blood and blood components intended for transfusion within the scope of PDMA.

Accordingly, FDA's tentative determination is to limit the scope of these guidelines so that they do not apply to blood and blood components intended for transfusion. This limitation is accomplished by amending the definitions in § 205.3 to add new paragraph (f)(8), which specifically excludes from the definition of "wholesale distribution" the sale, purchase, or trade of blood and blood

components intended for transfusion. FDA is also adding definitions of "blood" and "blood component" in § 205.3 of the final rule.

If further comments on this issue in response to the companion notice persuade FDA to include distribution of blood and blood components intended for transfusion in these guidelines, FDA will amend the guidelines to cover such blood and blood components.

C. Definitions

8. On its own initiative, the agency has changed the definition of "prescription drug" in proposed § 205.3(c) (now § 205.3(e)) by removing the reference to State law. The applicability of these guidelines is limited to wholesale distributions in interstate commerce of drugs that are "prescription drugs" under section 503(b) of the act.

9. Several comments addressed proposed § 205.3, which sets forth definitions of terms to be used in the wholesaler licensing regulations. One comment requested clarification of the meaning of "under common control" as used in proposed § 205.3(d)(4) (now § 205.3(f)(4)).

Neither PDMA nor its legislative history defines the term "under common control" which is used in section 503(c)(3)(B)(iii) of the act (21 U.S.C. 353(c)(3)(B)(iii)). The term, however, has been used in other Federal regulatory schemes which were in use at the time PDMA was enacted into law. Both the Security Exchange Commission and the Environmental Protection Agency define "common control" to mean the power to direct or cause the direction of the management and policies of a person or an organization, whether by the ownership of stock, voting rights, by contract, or otherwise. See 17 CFR 230.405, 40 CFR 66.3(f). FDA has included this definition in this final rule.

10. A number of comments perceived a conflict between the definitions of "wholesale distribution" (proposed § 205.3(d)) and "wholesale distributor" (proposed § 205.3(e)). The comments noted that chain drug warehouses are specifically included in the definition's list of "wholesale distributors" while intracompany sales are specifically excluded from the scope of the definition of "wholesale distribution." The comments contended that the business of chain drug warehouses is generally limited to intracompany distribution of products, namely, to retail stores that are under common ownership or within a corporate structure. The comments stated that these activities should be considered "intracompany sales," and thus should be excluded from "wholesale distribution" and the licensing requirements of the regulations.

The agency does not find the definitions of "wholesale distribution" and "wholesale distributor" to be inconsistent. A "wholesale distributor" is any person who "engages in wholesale distribution of prescription drugs." The legislative history includes a discussion of the scope of the definition of "wholesale distribution" for the purposes of these guidelines. It was clearly the intent of Congress to require licensing of the wholesale distributions of human prescription drugs by chain drug warehouses (see H. Rept. 100–76, p. 17).

Some chain drug warehouses may limit distribution of prescription drug products to subdivisions within a corporate structure, and those distributions would fall under the "intracompany sales" exception and not be considered wholesale distributions under § 205.3(f). A chain drug warehouse that sells prescription drugs to a franchised store or to establishments outside the corporate umbrella, however, would be engaging in wholesale distribution, as defined in § 205.3(f) of this final rule, and its distributions in interstate commerce would be subject to the licensing requirements.

11. Several comments suggested that the distribution of prescription drug samples by manufacturers' representatives and distributors' representatives be specifically excluded from the definition of "wholesale distribution" and thus from the licensing requirement. The comments argued that licensing persons who distribute prescription drug samples is inconsistent with the intent of PDMA and would make the current practice of sample distribution by representatives virtually impossible.

Other comments argued that manufacturers' and distributors' representatives should be licensed and be required to store and handle samples in accordance with the guidelines or the guidelines will fail to assure that prescription drugs are stored properly in all cases.

After considering the comments and reviewing PDMA's purpose and legislative history, FDA has determined that the distribution of prescription drug samples by manufacturers' representatives and distributors' representatives, done in accordance with other applicable provisions of the act, is not "wholesale distribution" within the meaning of § 205.3(f) of these guidelines and will not be subject to licensing under this final rule. FDA believes that this result is consistent with a congressional intent to establish a separate, comprehensive regulatory scheme designed specifically for prescription drug samples.

The licensing of manufacturers' representatives and distributors' representatives as wholesalers would go beyond the intent of PDMA. PDMA was enacted to address certain problems in the human drug distribution system that Congress believed threatened the integrity of the nation's prescription drug supply. Wholesale distribution of drugs and sample distribution by manufacturers' representatives and distributors' representatives were two of the areas where Congress believed more controls were necessary. However, PDMA addressed these two areas in somewhat different ways.

In the case of wholesale distribution, Congress sought to improve storage and handling practices and accountability by requiring that wholesale distributors of human prescription drugs be licensed under State licensing requirements that meet prescribed minimum Federal standards. The legislative history suggests that Congress expected these licensing standards to be based on the NABP "Model Regulations for Wholesale Drug Distribution," a model inapplicable to the control of sample distribution. (H. Rept. 100–76, p. 17.) Moreover, the House Report also indicates that Congress intended the licensing requirement to be confined to "* * * distribution by chain drug warehouses, wholesale drug warehouses, and all sellers of prescription drugs in wholesale quantities to persons or firms other than the consumer or patient." (H. Rept. 100–76, p. 17.) The reference in the House Report supports a conclusion that PDMA's licensing provisions are not intended to cover the distribution of prescription drug samples, which, by statutory definition, are never sold (section 503(c)(1) of the act; 21 U.S.C. 353(c)(1)).

Congress chose a different method of regulation with regard to the distribution of prescription drug samples. These requirements are set forth in section 503(d) of the act, and establish express and comprehensive provisions governing the storage, handling, distribution, and disposition of prescription drug samples by manufacturers, their distributors, and representatives. The scope and specificity of these provisions indicate that Congress determined that sample distributions be conducted under this separate regulatory scheme. Section 503(d) and the legislative history of

PDMA contain no suggestion that any additional regulatory scheme, such as licensing prescription drug sample distribution as wholesale activity, was either necessary or contemplated by Congress.

Accordingly, the agency is adding § 205.3(f)(7) to the final rule, excluding the distribution of prescription drug samples by manufacturers' representatives and distributors' representatives from the "wholesale distribution" definition and the licensing requirements.

Because sample distribution by manufacturers' representatives and distributors' representatives will not be subject to State licensing in accordance with these guidelines, the agency does not intend that such sample distribution be subject to the storage and handling requirements of these guidelines. The agency disagrees with the contention of some comments that excluding such sample distribution from these storage and handling requirements will prevent prescription drugs from being properly stored in all cases. Under section 503(d)(3)(B) of the act, manufacturers and distributors must store prescription drug samples under conditions that will maintain their stability, integrity, and effectiveness, and take measures to assure that their prescription drug samples are kept free of contamination, deterioration, and adulteration. Manufacturers and distributors are thus responsible for the proper handling of prescription drug samples throughout their distribution.

12. One comment asked if those entities excluded from the "wholesale distribution" definition in proposed § 205.3(d) (1) through (8) would also be excluded from the storage, handling, and recordkeeping requirements of § 205.50.

The guidelines require only those persons engaged in the wholesale distribution in interstate commerce of prescription drugs to be subject to the guidelines' minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of records of the distribution of such drugs. By definition, therefore, the entities involved in the transactions listed in § 205.3(f) (1) through (8) of the final rule are not wholesale distributors under PDMA and are not subject to other provisions of the guidelines. Of course any person engaged in manufacturing, processing, packing, or holding of a drug is subject to all pertinent provisions of the act, including the current good manufacturing practice provisions of section 501(a)(2)(B) of the act (21 U.S.C. 352(a)(2)(B)).

13. A number of comments suggested that the definition of "wholesale distributor" be expanded to include manufacturers' representatives, sales agents, doctors, various kinds of clinics, and others. The comments asserted that addition of these categories to the definition would make the regulations more specific and all-inclusive and would assure compliance with storage and labeling requirements wherever prescription drugs are handled.

Section 205.3(g) of the final rule defines "wholesale distributor" to include anyone engaged in wholesale distribution of prescription drugs. The list of wholesale distributors enumerated in the guidelines is not exhaustive, but, as it clearly states, only illustrates the type of persons or firms who could, depending on the nature of their activity, be considered wholesale distributors under these provisions. The determinative consideration is the nature of the activity, not whether the entity is listed among the examples. If an activity is wholesale distribution and is not excluded under § 205.3(f) of the final rule, then the person engaged in the distribution is a wholesale distributor and his or her activity in interstate commerce must be licensed. FDA concludes that no purpose would be served by adding to the examples given in § 205.3(g).

14. One comment suggested that the phrase in proposed § 205.3(e) (now 205.3(g)), which included "retail pharmacies that conduct wholesale distributions" in the definition of wholesale distributors, be clarified. The comment asked that more guidance be given to determine when a retail pharmacy would be conducting wholesale distributions requiring licensure.

The nature of the operations of a retail pharmacy determines when it is a wholesale distributor. If its activities fit the definition of wholesale distribution and do not fall under any of the exclusions, the guidelines provide that the retail pharmacy is a wholesale distributor and must be licensed as such.

15. Another comment pointed out that the definition of "wholesale distributor" lists both "manufacturers" and "manufacturers' warehouses" as examples. The comment asked if both could be required to obtain licensure under the guidelines. The comment added that requiring a manufacturer to obtain licensure in a State if its warehouse is already licensed would be redundant, costly, and wasteful.

Both a manufacturer and its warehouse could be required to obtain a license as wholesale distributors under these guidelines if both are engaged in wholesale distributions as defined in § 205.3(f) of the final rule, and if the licensing State has no single license provision as permitted by § 205.5(b). Under § 205.5(b), States can set up a system permitting a single license for a business entity operating more than one facility in a State. Under such a system, one license would suffice for the regulation of a manufacturer and its warehouse, but both facilities would be subject to all of the licensing requirements.

D. Wholesale Drug Distributor Licensing Requirement

16. Several comments addressed the wholesale drug distributor licensing requirement described in proposed § 205.4. One comment asserted that the concept of interstate shipment is essential to the licensing requirement, but was not included in the section of the proposed guideline.

FDA does not agree that interstate shipment is a key element of the wholesaler licensing requirement under PDMA. The statute says that "(n)o person may engage in the wholesale distribution in interstate commerce (of prescription drugs) * * * in a State unless such person is licensed by the State in accordance with * * *" these guidelines (21 U.S.C. 353(e)(2)(A)). A product may be in interstate commerce before it has been shipped from one State to another. For example, a product manufactured in one State from components made in other States is in interstate commerce even if the finished product is shipped only within the State of manufacture. While FDA does not find interstate shipment to be an essential part of the licensing requirement, the agency does not find it necessary to otherwise clarify the licensing requirement by revising § 205.4 of the final rule to more closely reflect the statutory language. As revised, the final rule requires all wholesale distributors of prescription drugs who engage in interstate commerce in a State to be licensed by the State.

17. Numerous comments addressed the second sentence of proposed § 205.4. As proposed, that section said that the "mere shipment of prescription drugs into the State does not necessarily require licensing." Several comments argued that the word "necessarily" should be deleted from the sentence because it changes the meaning of the licensing requirement from that intended by Congress, as revealed in the legislative history of PDMA. Many other comments argued that the entire second

sentence of proposed § 205.4 should be removed from the final rule. These comments contend that the sentence could undermine the efforts of several States that currently license all wholesale drug distributors who ship prescription drugs into the State.

Proposed § 205.4 was derived from the discussion of the wholesale drug distributor licensing requirement in the legislative history accompanying PDMA. That discussion states, in pertinent part, that—

> Subparagraph 503(e)(2)(A) is intended to ensure that any person or firm engaging in the wholesale distribution of pharmaceuticals to any person or firm for resale shall be licensed in the state in which it does business and that the state licensing requirements meet certain minimum standards. The mere shipment of pharmaceuticals into a state would not trigger the requirement that the distributor be licensed in that state. However, the operation of a facility from which a wholesaler makes shipments outside the state would trigger the licensing requirement with respect to the state in which the facility is located.
>
> (H. Rept. 100–76, p. 17)

The legislative history indicates that when the Congress used the words "in the State" in section 503(e)(2)(A) of the act, it was referring to the physical location of the facility from which a wholesaler makes shipments. Thus, PDMA only requires that wholesalers who have a facility in a State be licensed by that State, and that wholesalers who have their facility outside the State, but who ship into the State, need not be licensed by that State pursuant to PDMA. However, States are free to require the licensing of any wholesaler who ships into the State, even if the wholesaler does not have a facility in the State, subject to all pertinent constitutional constraints. But the failure of such out-of-State wholesalers to have such a State license would not be a violation of section 503(e)(2)(A) of the act. The agency has concluded that the changes made to § 205.4 indicate the proper scope of PDMA, and that the second sentence of the proposed § 205.4 was unclear and is unnecessary.

E. Minimum Required Information for Licensure

18. Several comments discussed the provisions pertaining to minimum information required for licensure in proposed § 205.5. Some comments asserted that certain information required by § 205.5(a) is burdensome and unnecessary, because it is already a matter of public record. The comments contended that the State licensing authority is not entitled to have this information and that it is of no value to the State for the purpose of licensing. A few comments recommended that § 205.5(a) be revised to indicate that only information relating directly to activities conducted in the licensing State be required.

The agency has reviewed the information requirements and finds that the information does not go beyond the minimum necessary for a State licensing authority to enforce its licensing system. Furthermore, because the information is readily available in corporate records, it will not be overly burdensome for a wholesale distributor seeking licensure to supply it to the State.

The information required for licensure, described in § 205.5(a) of the final rule, goes no further than information that is pertinent to activities within the licensing State. In designing its licensing scheme, however, each state is free to require such additional information as it finds appropriate.

19. Several comments recommended against the single licensing provision in proposed § 205.5(b) that would allow a State to issue a single license to a business entity operating more than one wholesale distribution facility within the State. This section also allows a State to issue a single license to a parent entity that has divisions or affiliate companies conducting wholesale distributions at more than one location within the State. The comments argued that separate licenses would provide better accountability and more effective application of sanctions.

The agency disagrees. In cases where a State chooses to include a single licensing provision in its wholesaler licensing scheme, other sections of these guidelines will assure that all of the wholesale distribution facilities subject to the license are adequately regulated. Section 205.5(a) (1) through (4) requires that comprehensive information about the identity, nature, and location of a business be submitted to obtain a license. This information must include names and addresses of contact persons for all facilities used by the licensee. The agency believes that this information will provide a sufficient guarantee of accountability and effective application of sanctions under a single licensing provision. States are, of course, free to design single licensing schemes with other guarantees or to choose not to provide for single licensing at all.

20. Two comments recommended that proposed § 205.5(b) be amended to allow for license reciprocity. Under this plan, a State could grant wholesale distributor licenses based on reciprocal agreements with other States having comparable licensing requirements. The comments are concerned that States may refuse to license by reciprocity if the issue is not addressed in these guidelines.

Reciprocal licensing arrangements between State licensing authorities have traditionally been a matter within the exclusive discretion of the States. This final rule does not prohibit States from allowing license reciprocity with other States, and FDA would not discourage such cooperative arrangements, but the agency declines to include a reciprocal licensing provision in these minimum guidelines.

21. Two comments objected to proposed § 205.5(c), which states that the State licensing authority shall be notified of any changes in the information required under § 205.5(a) within 5 days of the change. Both comments found the 5-day time period to be unreasonably short. One comment suggested a 30-day reporting period, while the other argued that an annual report of such changes would be sufficient.

The agency is removing the 5-day notice requirement in § 205.5(c) and leaving the determination of the time period up to the State licensing authority. The State licensing authority receives and maintains the information required under § 205.5(a) and is thus in the best position to determine appropriate time frames for notification of changes in this information.

F. Qualifications of Personnel

22. One comment asserted that proposed § 205.6(b), which describes the right of a State licensing authority to deny a license that would not be "in the public interest," is too vague and should be removed.

FDA has provided a general—"in the public interest"—standard for the State licensing authority to deny a license. A State may choose to further define what it believes to be "in the public interest." The agency, however, declines to do so in these minimum guidelines.

23. Some comments objected to proposed § 205.7, which sets forth minimum personnel standards for licenses. The comments found the proposed minimum personnel standards to be an "unwarranted intrusion" into the right of wholesalers to choose their own employees. They recommended that § 205.7 be removed, saying that the requirement that personnel employed in wholesale distribution meet certain minimum education and experience standards goes beyond the intent of PDMA.

The agency disagrees with the contention that requiring a minimum education and training level for personnel employed in wholesale distribution is overly intrusive, inappropriate for these guidelines, or beyond the intent of Congress. The guidelines do not specify the kinds of education and experience required for personnel. Rather, the impact of the guidelines is to assure that personnel have an acceptable level of proficiency to carry out the licensing requirements. The agency believes that it is reasonable and appropriate to require that personnel involved in the handling, recordkeeping, and distribution of prescription drugs be competent to perform these important tasks.

G. Violations and Penalties

24. One comment suggested that removing the words "or any felony" from proposed § 205.8(a) would make the section on violations and penalties "more fair." The comment believed that the language in this section of the proposed rule could allow suspension or revocation of a wholesaler license for the criminal act of a single employee or for a felony involving a business that is completely separate and distinct from the corporation's wholesale distribution operation.

The agency believes that the determination of grounds for suspension or revocation of wholesaler licenses is a matter more appropriately left to the discretion of the State licensing authority. The agency is removing the words "or any felony" from § 205.8(a) of the final rule.

On its own initiative, FDA is revising proposed § 205.8(b), which sets forth the requirement that State licensing laws provide for suspension and revocation of licenses for violations of the licensing provisions. As proposed, § 205.8(b) implied that even insignificant or minor technical violations of wholesaler licensing laws could be the basis for suspension and revocation of licenses. As a minimum licensing requirement, FDA intended that significant or consistent infractions of State licensing provisions would be necessary to justify suspension and revocation of licenses. States are free to impose stricter requirements, but FDA should not do so. FDA is removing the word "any" from this section in the final rule to convey more accurately the agency's intended meaning, and is stating that State licensing laws shall provide for suspension or revocation of licenses "where appropriate," considering the facts of the violation in question.

H. Minimum Requirements for the Storage and Handling of Prescription Drugs

1. General Comments

25. Several comments objected to the reference to "current good manufacturing practices" in the introductory paragraph to proposed § 205.50. The comments asserted that the agency lacks the authority to impose such requirements on wholesale drug distributors. One comment contended that current good manufacturing practices are "not applicable to the proposed guidelines," and added that making them applicable would be beyond FDA's statutory authority. Another comment stated that the reference to current good manufacturing practices reflected the agency's "confusion." The comment argued that the agency is only entitled to regulate wholesaler operations in "housekeeping and stockkeeping" matters. The comment added that wholesalers deal only with drugs in containers sealed by the manufacturer, so wholesale distributors could not be subject to manufacturing standards.

FDA agrees that it may be confusing to refer, in § 205.50, to "current good manufacturing practices." The provision has been revised accordingly. FDA disagrees, however, that it lacks authority to apply current good manufacturing practice requirements to wholesalers, or that its authority over wholesalers extends only to "housekeeping and stockkeeping matters." Section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)) provides that a drug shall be deemed to be adulterated if "* * * the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to * * * current good manufacturing practice * * *." This section, through the operation of section 301(k) of the act (21 U.S.C. 331(k)), applies to drug wholesalers, retailers, pharmacies, and hospitals, as well as to manufacturers.

While the statutory current good manufacturing practice provisions of the act apply to wholesalers, FDA has not yet issued specific CGMP regulations covering traditional wholesaler activities. (FDA has previously stated that the CGMP regulations set forth in 21 CFR part 211 do not apply to wholesalers engaging in activities that are traditional to those establishments (see 43 FR 45027)). In the absence of specific CGMP regulations governing wholesaler activities, FDA advises that the minimum requirements in § 205.50 of these guidelines may be relied upon by wholesalers to meet applicable obligations under section 501(a)(2)(B) of the act. FDA intends, in the near future, to issue a guideline under § 10.90 of its procedural regulations (21 CFR 10.90), describing acceptable current good manufacturing practices for wholesalers that reflect the approach taken in this final rule.

26. Two comments made the general claim that the storage and handling provisions in proposed § 205.50 are too specific and restrictive. The comments argued that wholesale distributors should be free to choose systems and facility designs that will achieve the goals of PDMA.

The agency disagrees. Congress directed FDA to establish guidelines to "assure uniform standards covering the proper storage and handling of pharmaceuticals by wholesale distributors without regulatory duplication at the State and Federal level," and recommended consideration of the NABP model guidelines for licensing wholesalers in developing this guideline. (H. Rept. 100-76, p. 17). The storage and handling provisions of § 205.50 are responsive to this Congressional direction.

2. Facilities

27. Some comments asserted that proposed § 205.50(a)(3), which says that wholesale distribution facilities must have a designated area for the quarantine of outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs, is burdensome and would result in inefficient use of space by wholesale distributors. One comment stated that this problem could be minimized by specifying that one quarantine area for all substandard goods would be sufficient to comply with the minimum standards. Another comment suggested that deficient products could be identified and isolated by means of computerized inventory control, which would prevent inadvertent shipment without requiring separate quarantine space.

The agency has removed the word "separate" from § 205.50(a)(3), to clarify that a single quarantine area for outdated, damaged, deteriorated, misbranded, and adulterated prescription drugs is permissible. States can, of course, impose quarantine requirements that are stricter than this minimum guideline.

The agency does not believe that a computer-controlled quarantine system, which does not provide for physical separation of the drugs, is appropriate. A contaminated or adulterated prescription drug product is quarantined not only to ensure that it will not be

distributed to the consumer, but also to prevent it from coming into contact with other drugs it might contaminate. The agency has no knowledge of computer or other systems that would be as effective as physical separation in achieving these goals. In addition, the comments have not shown that providing a physical space for the separation of damaged goods would be burdensome.

28. One comment asked for clarification of the phrase "opened or used outside the care, custody, or control" as used in the description of quarantine procedures required under proposed § 205.50(a)(3). The comment is concerned that the phrase could be interpreted to require quarantine of prescription drugs in circumstances where there has been no compromise of the physical integrity of the drug.

The agency is removing this phrase from the final rule. Section 205.50(a)(3) of the final rule requires that prescription drugs whose immediate containers have been opened or apparently damaged must be quarantined. It is not necessary that there be actual injury to a drug product for quarantine to be required. A suggestion of product damage—such as a dirty or broken immediate product container—would trigger the quarantine requirement.

29. Another comment stated that repackaging facilities should be listed under § 205.50(a) to ensure that storage and labeling standards envisioned by PDMA will be complied with at all facilities where prescription drugs are handled.

The agency does not agree that it is necessary to add repackaging or other facilities under § 205.50(a). These provisions apply to all "wholesale distributors," specifically to any facility that stores, handles, warehouses, or holds prescription drugs for wholesale sale. The provisions thus have a broad application that clearly includes repackaging facilities.

3. Security

30. Two comments argued that the security provisions described at proposed § 205.50(b) are too restrictive and suggested more general alternatives. One of the comments particularly objected to the requirement of an "internal alarm system," noting that other types of systems could be as effective for a given wholesale distribution business. The comment said that wholesale distributors should be free to choose the best alarm system for their facility.

The agency agrees that the requirement that the alarm system be "internal" is too specific and goes beyond the minimum standards to be set by these guidelines. The agency is thus removing this word from § 205.50(b) (2) and (3). Wholesale distributors can choose any alarm system design, consistent with State law and regulations, that is adequate to detect unauthorized entry into the facility and to protect the prescription drug inventory from theft and diversion. The type of alarm system that will satisfy this requirement will depend upon the characteristics of the facility, the wholesale operation, and the State's licensing law.

4. Storage

31. One comment asserted that the storage provisions at § 205.50(c) were too specific and suggested that they be removed. The comment argued that it should be "satisfactory" for FDA to require only that prescription drugs be stored at appropriate temperatures and under proper conditions.

The agency's obligation to impose reasonable storage requirements for prescription drugs goes beyond the general standard suggested by this comment. Congress has mandated that FDA set standards for the storage and handling of prescription drugs by wholesale distributors. These are meant to be minimum standards, but they must be adequate to serve as direction to States in setting up their licensing systems. General statements about "appropriateness" and "adequacy" do not offer sufficient direction to the States. The requirements of § 205.50(c) conform to the storage provisions of the NABP model guideline and, as discussed in paragraph 26, are in line with congressional intent.

32. One comment stated that the storage requirements in proposed § 205.50(c) should specifically exclude wholesale distributors from responsibility for the condition of prescription drugs during transport.

While FDA recognizes practical difficulties involved in maintaining proper storage and handling conditions for prescription drugs in transit, it believes that prescription drugs must be properly handled at all points in the distribution process. Drugs that are improperly handled at any point in the distribution process are subject to enforcement action under the adulteration and misbranding provisions of the act.

It should be noted, however, that the proposed rule does not place the responsibility for assuring proper storage conditions for prescription drugs in transit on the wholesale distributor. The guidelines require that incoming shipping containers be visually inspected by the wholesale distributor for obvious defects or problems caused by improper storage conditions in transit or at any other point in their distribution. Based on this inspection, the wholesale distributor can elect to accept or to refuse acceptance of prescription drugs that appear to be adulterated or misbranded. Responsibility for the condition of shipped drugs does not fall upon the wholesale distributor until acceptance is made.

33. A number of comments asked for clarification of the meaning of "room temperature" as used in the storage requirements in § 205.50(c)(1). The comment asked if FDA meant "controlled room temperature," as the term is used in the United States Pharmacopeia (USP), or "ambient" room temperature. The comments noted that maintaining a "controlled" room temperature would require more sophisticated equipment and higher utility outlays than "ambient" room temperature.

Properly stored prescription drugs must be protected from temperature extremes at all times. To ensure that this minimum standard is met, the agency is requiring that storage facilities be maintained at "controlled room temperature," which is defined in the USP as a temperature that is maintained between 15 and 30 °C (USP XXII (1990), p. 7). This requirement can be met using standard building thermostats and conventional heating ventilating, and air conditioning systems. The agency does not expect this minimum requirement to be burdensome or necessitate the purchase of sophisticated, expensive equipment.

34. A number of comments objected to the proposed requirement in § 205.50(c)(2) that temperature and humidity be recorded on manual, mechanical, electromechanical, or electronic equipment or logs. The comments asserted that this requirement was too costly and argued that current distribution systems include safeguards to ensure proper storage of the few prescription drug products requiring special treatment.

The agency disagrees with the claim that requiring records of storage conditions will impose unnecessary burdens on wholesale distributors. Section 205.50(c)(2), which describes the requirement, does so in very broad terms. The provision allows for operators of facilities to choose from a wide range of possible recording and documentation methods, as long as the choice is appropriate for their facility.

One of the listed choices is a "manual" procedure by which temperature and humidity information could be written in a log by an employee who reads a thermometer and hydrometer. This option is neither expensive nor burdensome. Other options are similarly reasonable in cost and operation.

5. Examination of Goods and Vehicles

35. Several comments concerned the proposed requirement in § 205.50(d)(1) that wholesalers inspect incoming prescription drugs and delivery vehicles. All of the comments recommended that the scope of any inspection be limited to obvious, apparent defects that can be discovered through a visual inspection. The comments cited the difficulty of determining transit conditions, and questioned the ability and expertise of personnel employed by the wholesale distributor to discover latent defects in vehicles or prescription drugs. The comments argued that requiring more in-depth inspections would be burdensome, costly, and could interfere with commercial relationships.

Some comments noted that a drug may be shipped in more than one vehicle and that only the last one would be available for inspection by the wholesaler. Inspection of this last vehicle would not assure that all transit vehicles were sound and protective of product integrity.

The agency generally agrees with these assertions and has modified the proposed inspection provisions in the final rule so that inspection of the delivery vehicle is no longer required, and inspection of incoming prescription drugs is limited to a visual examination of shipping containers. This inspection should be aimed at detecting damage that would suggest possible contamination of the container's contents. Some level of inspection must be conducted by wholesale distributors to identify the prescription drug and to remove obviously damaged drugs from the distribution system. Wholesale distributors must employ personnel who can perform such inspections.

Moreover, it is in the wholesale distributor's interest to employ personnel who have the ability and expertise to conduct inspections of incoming prescription drug shipments adequate to detect drugs that are not suitable for acceptance. One of the stated purposes of requiring inspection of incoming shipments is to provide an opportunity for wholesale distributors to refuse acceptance of prescription drugs that are unfit for distribution. Once the wholesale distributor has inspected the shipped drugs and elected to accept them, the distributor is responsible for the condition of the drugs. Until that time, the shipper or manufacturer remains responsible for delivering a prescription drug product in acceptable condition.

6. Returned, Damaged, and Outdated Prescription Drugs

36. Several comments addressed proposed § 205.50(e), which describes the obligations of wholesalers with respect to returned, damaged, and outdated prescription drugs. The comments found the entire section to be redundant because its subject matter is covered in other FDA regulations. The comments cited 21 CFR 211.204 and 211.208 as examples of regulations that make proposed § 205.50(e) unnecessary. These are the sections of FDA's CGMP regulations that pertain, respectively, to returned drugs and salvaged drug products.

As discussed previously in this document, the CGMP regulations set forth in 21 CFR part 211 apply to wholesale distributors only when they are engaged in activities that fall outside the scope of a traditional wholesale distribution practice (see 43 FR at 45027). A wholesaler who chooses to handle returned, damaged, or outdated drugs within the scope of traditional wholesale distribution practice is not subject to the CGMP requirements in 21 CFR part 211. Thus, the provisions of § 205.50(e) are not redundant with respect to these procedures. Of course, as stated in § 205.50(j) of this final rule, a wholesaler who engages in repackaging, salvaging, reprocessing, or other manufacturing activities is subject to the CGMP requirements in 21 CFR part 211.

37. Another comment suggested that § 205.50(e) be removed, saying the role that pharmacists play in the distribution of prescription drugs to consumers makes the provision unnecessary.

The requirements of this section are intended to prevent distribution of potentially adulterated or misbranded prescription drugs to consumers. FDA agrees that pharmacists play an important role in achieving this goal, but this does not replace the need for wholesale distributors to take measures, such as those described in proposed § 205.50(e), to remove prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated from wholesale distribution.

38. One comment recommended that proposed § 205.50(e)(2), which requires that prescription drugs in damaged containers be quarantined and physically separated from other drugs, be removed. The comment stated that the requirements of this section are adequately covered by proposed § 205.50(e)(1), which deals with quarantine of adulterated drugs.

The agency disagrees that proposed § 205.50(e)(2) is unnecessary and should be removed. Section 205.50(e)(1) states the requirement that adulterated drug products be quarantined, but does not specifically address the situation, described in § 205.50(e)(2), where damage to prescription drug product containers suggests that the quality of their contents has been compromised. The agency expects that this is the most common circumstance where quarantine is necessary and believes that it must be specifically addressed in the guidelines.

39. Another comment requested that "palletized bulk shipments" be specifically excluded from the container inspection requirement in proposed § 205.50(e)(2), because the language could be interpreted to mean that a prescription drug product would have been quarantined, destroyed, or returned the moment the outer seal of the bulk shipment is opened.

The agency has clarified § 205.50(e)(2) in the final rule to require quarantine when the prescription drug product is damaged or the condition of the sealed immediate or sealed secondary drug container suggests that the contents have been damaged. The guideline does not require quarantine when only the outer seal of a bulk shipment of prescription drug products is opened and this seal is not the immediate or secondary container of the product.

40. Several comments objected to the proposed requirements in § 205.50(e) for handling returned prescription drugs, finding them confusing and inconsistent within the proposal. The comments contend that unlike proposed § 205.50(e)(1) and (e)(2), proposed § 205.50(e)(3) does not allow for return of substandard prescription drugs to the manufacturer as an option for wholesale distributors. Other comments asserted that the requirements of proposed § 205.50(e)(3) were inconsistent with guidance given in FDA's August 1, 1988, letter on PDMA to regulate industry and other interested persons with regard to the handling of returned prescription drugs. That letter provided that hospitals, health care entities, or charitable institutions could destroy unwanted prescription drugs or return them to the manufacturer. The August 1, 1988, letter was supplemented by November 3, 1988, and January 26, 1990, letters that permitted these entities to return prescription drugs under certain specified circumstances.

The agency agrees and has added language to permit the return of

prescription drugs to the manufacturer or supplier under § 205.50(e)(3) of the final rule.

41. Several comments objected to the requirement in proposed § 205.50(e)(3) that wholesale distributors perform "examination, testing, or other investigation" to determine that a prescription drug meets standards of safety, identity, quality, strength, and purity before returning the product to their shelves. Other comments contended that reshelving of returned drugs products after examination and testing is inconsistent with PDMA because it allows such products to be redistributed. Some of the comments questioned the analytic capability of distributors to comply with the requirement, saying that most wholesale distributors do not now conduct such testing. One comment argued that the requirement could fairly be imposed on manufacturers, but not on wholesalers, and another recommended that only a visual examination be required, with further investigations performed by the manufacturer if the distributor's visual inspection suggested a problem.

PDMA was enacted to decrease the risk that counterfeit, adulterated, misbranded, subpotent, or expired prescription drugs will reach the American consumer. It would violate the purpose of PDMA to allow returned prescription drugs to be distributed to the public without certain assurances. It is not inconsistent with PDMA, however, to permit reshelving of returned drugs that have been shown, through adequate testing measures, to meet acceptable standards.

Section 205.50(e)(3) of the final rule offers several options for the disposition of returned prescription drugs. Under the provision, the wholesaler is allowed to send the returned drug back to the manufacturer, destroy the returned drug, or reshelve it if it meets the testing standards outlined. The wholesaler is not required to choose the testing alternative. If the testing alternative is chosen, the wholesale distributor may elect to have a qualified outside laboratory conduct the analysis if it does not have the appropriate in-house capability. If the wholesale distributor chooses to conduct the testing procedures, pertinent CGMP requirements must be followed, and analyses should be adequate to detect problems with the drug's safety, identity, strength, quality, and purity. The agency does not want to limit testing to a visual examination that could fail to detect potential problems.

7. Recordkeeping

42. Several comments objected to the requirement in proposed § 205.50(f)(1)(iii) that expiration dates be included in disposition records, saying that the requirement would be costly, burdensome, and unnecessary. The comment added that current procedures, such as pharmacists checking dates before dispensing prescription drugs, are adequate to keep expired drugs out of the distribution system as intended by PDMA.

The comments provide adequate evidence that maintaining records of expiration dates is not current standard business practice in the industry, and that incorporating the requirement into current practice may impose some unnecessary burdens on wholesale distributors. The agency is removing proposed § 205.50(f)(1)(iii) and will not require that wholesale drug distributors maintain records of expiration dates of prescription drugs at this time. FDA may impose the requirement in the future if experience with these guidelines suggests it is necessary.

Although not required at this time, the agency encourages keeping records of drug expiration dates. In the agency's view, drug disposition records that include expiration dates are more complete, better facilitate recalls, and help to ensure that outdated drug products are not distributed to American consumers.

43. Several comments questioned the requirement in proposed § 205.50(f)(2), which states that records of the disposition of prescription drugs by wholesale distributors must be available for inspection by authorized officials for a period of 2 years following the expiration dates of such drugs. The comments suggested several alternatives to associating the retention period to the expiration date of the drug.

As previously mentioned, FDA has removed proposed § 205.50(f)(1)(iii), which set forth the requirement that wholesale distributors maintain records of expiration dates of prescription drugs. FDA will therefore not require a record retention time period linked to the expiration date of the drug. Instead, the agency is changing the pertinent provision to establish a record retention period of 2 years following the date of disposition of the prescription drug product. FDA has concluded that this retention period is sufficient to enable the agency to respond to public health emergencies related to the distribution of prescription drugs. The agency anticipates that a vast majority of prescription drugs would be consumed, expired, or destroyed within this time.

44. Several comments objected to proposed § 205.50(f)(3), which established the 24-hour time period allowed for making records available to an authorized official. Calling the time period "unreasonable," the comments suggested it be changed to 72 hours. The comments claimed this would make the requirement consistent with other, unspecified FDA record production requirements.

The provision has been changed in the final rule to allow 2 working days for the production of records that are not kept at the inspection site and are not immediately retrievable by computer or other means. The agency finds this to be a reasonable and appropriate time frame, and is consistent with analogous record production requirements of other government agencies (see, for example, 21 CFR 1304.04).

8. Written Policies and Procedures

45. Some comments addressed the written policies and procedures requirements for licensed wholesale drug distributors in proposed § 205.50(g). The comments agreed that it is appropriate to require a procedure for distributing oldest stock first, but objected to the requirement that deviation from this procedure be justified and documented, arguing that this provision would add to recordkeeping burdens and operating costs.

The agency believes that consistent stock rotation practices, as contemplated in proposed § 205.50(g)(1), are an effective means of ensuring that outdated stock will not be distributed to the consumer. The agency agrees that documentation of deviations from proper stock rotation practices goes beyond minimum standards and has removed the documentation requirement from the final rule. The guidelines now permit deviations from proper stock rotation practices if the deviation is temporary and appropriate.

46. Several comments addressed the proposed provisions in § 205.50(g) (2) and (3) on recall procedures. One comment suggested removal of § 205.50(g)(3)(iii), which requires that there be a procedure for recall of a prescription drug that is to be replaced by a superior product or package design. The comment noted that such a product withdrawal has little to do with health and safety and should be handled at the discretion of the manufacturer and distributor.

The agency agrees that product withdrawals undertaken to enable a manufacturer to replace one packaging design with another for reasons other

than the promotion of public health and safety goes beyond the scope of this rulemaking. The final rule reflects this change.

47. Several other comments asserted that procedures currently followed by drug manufacturers, wholesale and retail drug distributors, and pharmacists have been quite effective in dealing with recalls. The comments contended that the recall procedures proposed in § 205.50(g) (2) and (3) would impose substantial economic burdens on wholesale distributors without offering any significant improvement in recall accuracy and should therefore be removed from the final rule.

The agency disagrees. The agency believes it necessary that all entities involved in the distribution of prescription drugs have procedures in place for the efficient handling of drug recalls. In this way, each party will be aware of its role in removing potentially dangerous products from the drug distribution system. While prescription drug manufacturers have a primary role in implementing a drug recall, other entities in the drug distribution system must share responsibility for ensuring that all drugs subject to recall are prevented from reaching the American consumer.

48. One comment asserted that the requirement in § 205.50(g)(3) that a wholesale distributor have procedures sufficient to handle "any crisis" is too vague. The comment suggested that the section describe specific procedures to follow in case of strike, fire, flood, and natural disaster or emergency.

Specific procedures for crisis situations, such as a strike, fire, flood, or other natural disaster, are best left to the individual States. It would not be appropriate for the agency to attempt to describe plans for handling specific kinds of crises.

49. Two comments questioned the expertise of the wholesale distibutor for making the determination, required in proposed § 205.50(g)(5)(i), that prescription drug stock in wholesale distribution has an expiration date that is sufficient for a drug to get to the consumer. Both suggested that it would be more appropriate for a pharmacist or physician to make such a judgment.

The agency agrees that making the determination required under proposed § 205.50(g)(5)(i) may require a degree of judgment that is beyond the expertise of wholesale distribution personnel. The agency has therefore removed this requirement from the final rule.

51. One comment objected to the 2-year retention requirement, under proposed § 205.50(g)(5)(ii), for documents relating to the disposition of outdated stock. The comment recommended that requiring retention for 1 year from the expiration of the prescription drug would be consistent with FDA's CGMP regulations in 21 CFR part 211.

A 2-year record retention requirement is consistent with the other record retention provisions in these guidelines, and the agency is not persuaded that the change recommended by this comment is appropriate.

9. Responsibility

52. One comment suggested that § 205.50(h) be amended to clarify whether manufactures could be "held liable" for using unlicensed wholesale distributors. This comment was not specific as to what kind of liability was of concern.

The liability of manufacturers for actions in tort is governed by State law and is beyond the scope of this rulemaking.

53. Another comment asserted that the requirement in proposed § 205.50(h) that a list of qualifications of management, directors, and others in charge be maintained is an "unnecessary police state intrusion and subject to a difference of opinion." The comment said that such a list is irrelevant to achieving the goals of PDMA and would be difficult and costly for State boards to administer.

The agency disagrees with the contention that the list of responsible persons required by this section is unnecessary or excessively burdensome. The agency expects that a majority of wholesale distribution businesses would have this information readily available. The information required in this list is minimum information necessary for administration of these guidelines by the State licensing authorities.

10. Compliance With Other Laws

54. Proposed § 205.50(i) required wholesale drug distributors to operate in compliance with all applicable laws and regulations, including local laws. Proposed section 205.50(j) required wholesale drug distributors to comply with only applicable Federal and State laws relating to salvaging and reprocessing, but did not require wholesale drug distributors to comply with local laws relating to salvaging and reprocessing. On its own initiative, FDA is amending § 205.50 to make paragraphs (i) and (j) consistent, and to make it clear that wholesale drug distributors must comply with local laws relating to salvaging and reprocessing.

This substantive rule is being made effective immediately upon publication. The agency has found that there is good cause for this immediate effective date (see 5 U.S.C. 553(d)(3)). PDMA provides that the licensing requirements for wholesale distributors mandated by section 503(e)(2)(A) of the act (21 U.S.C. 353(e)(2)(A)) will not go into effect until the expiration of 2 years after the date this regulation is promulgated and takes effect (see section 8(b)(2) of PDMA). States and wholesalers will have 2 years in which to conform their activities to this rule before any enforcement action could be taken by FDA. Thus, the normal 30-day delay in effectiveness is subsumed in the 2-year delay mandated by PDMA. There is no need to have the rule take effect 2 years and 30 days after publication, because the 2-year period provides ample time for the States and wholesalers to conform their activities to the requirements of this rule. In addition, Congress has indicated its interest in having this rule promulgated expeditiously (see section 8(a)(2) of PDMA). The waiver of the 30-day delay is consistent with the congressional desire that FDA promulgate this rule in a short time.

List of Subjects in 21 CFR Part 205

Drugs, Labeling, Manufacturing, Warehouses, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, chapter I, subchapter C of title 21 of the Code of Federal Regulations is amended by adding new part 205 to read as follows:

PART 205—GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

Sec.

Authority: Secs. 501, 502, 503, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 353, 371, 374).

§ 205.1 Scope.

This part applies to any person, partnership, corporation, or business firm in a State engaging in the wholesale

distribution of human prescription drugs in interstate commerce.

§ 205.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs.

§ 205.3 Definitions.

(a) *Blood* means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(b) *Blood component* means that part of blood separated by physical or mechanical means.

(c) *Drug sample* means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(d) *Manufacturer* means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(e) *Prescription drug* means any human drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(f) *Wholesale distribution* and *wholesale distribution* means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) The sale, purchase, or trade of blood and blood components intended for transfusion.

(g) "Wholesale distributor" means any one engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

§ 205.4 Wholesale drug distributor licensing requirement.

Every wholesale distributor in a State who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the State licensing authority in accordance with this part before engaging in wholesale distributions of prescription drugs in interstate commerce.

§ 205.5 Minimum required information for licensure.

(a) The State licensing authority shall require the following minimum information from each wholesale drug distributor as part of the license described in § 205.4 and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(5) The name(s) of the owner and/or operator of the licensee, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner, and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the State of incorporation; and

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(b) The State licensing authority may provide for a single license for a business entity operating more than one facility within that State, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within that State when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(c) Changes in any information in paragraph (a) of this section shall be submitted to the State licensing authority as required by such authority.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0251)

§ 205.6 Minimum qualifications.

(a) The State licensing authority shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the State:

(1) Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under Federal, State, or local laws;

(3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with requirements to maintain and/or make available to the State licensing authority or to Federal, State, or local law enforcement officials those records required under this section; and

(8) Any other factors or qualifications the State licensing authority considers relevant to and consistent with the public health and safety.

(b) The State licensing authority shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

§ 205.7 Personnel.

The State licensing authority shall require that personnel employed in wholesale distribution have appropriate education and/or experience to assume responsibility for positions related to compliance with State licensing requirements.

§ 205.8 Violations and penalties.

(a) State licensing laws shall provide for the suspension or revocation of licenses upon conviction of violations of Federal, State, or local drug laws or regulations, and may provide for fines, imprisonment, or civil penalties.

(b) State licensing laws shall provide for suspension or revocation of licenses, where appropriate, for violations of its provisions.

§ 205.50 Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

The State licensing law shall include the following minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

(a) *Facilities.* All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) *Security.* (1) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(i) Access from outside the premises shall be kept to a minimum and be well-controlled.

(ii) The outside perimeter of the premises shall be well-lighted.

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(2) All facilities shall be equipped with an alarm system to detect entry after hours.

(3) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) *Storage.* All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all stored drugs.

(d) *Examination of materials.* (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all incoming and outgoing prescription drugs.

(e) *Returned, damaged, and outdated prescription drugs.* (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) *Recordkeeping.* (1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 2 years following disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not

electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency.

(g) *Written policies and procedures.* Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the State licensing agency;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

(h) *Responsible persons.* Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) *Compliance with Federal, State, and local law.* Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(1) Wholesale drug distributors shall permit the State licensing authority and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) *Salvaging and reprocessing.* Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0251)

Dated: June 9, 1990.

James S. Benson

Acting Commissioner of Food and Drugs.

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