CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 523–0161.

Kenneth R. Mason,

Secretary.

August 24, 1987.

[FR Doc. 87–20229 Filed 8–28–87; 5:06 am]

BILLING CODE 7020–02–M

INTERNATIONAL TRADE COMMISSION

TIME AND DATE: Wednesday, September 9, 1987 at 10:00 a.m.

PLACE: Room 117, 701 E Street NW., Washington, DC 20436

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda
2. Minutes
3. Ratifications
4. Petitions and Complaints
5. Inv. 701–TA–288, 289 and 731–TA–381, 382 (Preliminary) (Certain Granite from Italy and Spain)—briefing and vote.
6. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 523–0161.

Kenneth R. Mason,

Secretary.

August 25, 1987.

[FR Doc. 87–20230 Filed 8–28–87; 5:06 PM]

BILLING CODE 7020–02–M

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of August 31, September 7, 14, and 21, 1987.

PLACE: Commissioners' Conference Room, 1717 H Street, NW., Washington, DC.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of August 31

Wednesday, September 2

10:30 a.m.
Affirmation/Discussion and Vote (Public Meeting)
a. Revision to the General Statement of Policy and Procedures for Enforcement Action
b. Shoreham—Intervenor Motion to Admit New Contention on Medical Services for Contaminated Injured Individuals
c. Licensing Board Decision in Radiology Ultrasound Nuclear Consultants, P.A. (Tentative)
d. Review of ALAB–867 (Jurisdiction Over Kress Creek) (Tentative)

Thursday, September 3

2:00 p.m.
Briefing on Status of Decommissioning Activities (Public Meeting)

Week of September 7—Tentative

Wednesday, September 9

2:00 p.m.
Briefing on Performance of Sandia Containment Tests (Public Meeting)

Thursday, September 10

2:00 p.m.
Discussion of Integration of AEOD Reports into the Regulatory Process (Public Meeting)
3:30 p.m. Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of September 14—Tentative

Monday, September 14

10:00 a.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6)
2:00 p.m.
Briefing on the Status of Peach Bottom (Public Meeting)

Thursday, September 17

10:00 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of September 21—Tentative

Tuesday, September 22

2:00 p.m.
Briefing on the Integrated Safety Assessment Program (ISAP) (Public Meeting)

Thursday, September 24

2:00 p.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Note.—Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

TO VERIFY THE STATUS OF MEETINGS CALL (RECORDING) (202) 634–1498.

CONTACT PERSON FOR MORE INFORMATION: Robert McOsker (202) 634–1410.

Andrew L. Bates,

Office of the Secretary.

August 27, 1987.

[FR Doc. 87–20223 Filed 8–28–87; 4:33 pm]

BILLING CODE 7590–01–M

Corrections

Federal Register
Vol. 52, No. 170
Wednesday, September 2, 1987

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. 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.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[AD-FRL 3215-1]

Standards of Performance for New Stationary Sources; Determination of Carbon Monoxide Emissions in Certifying Continuous Emission Monitoring Systems at Petroleum Refineries

Correction

In rule document 87-18598 beginning on page 30674 in the issue of Monday, August 17, 1987, make the following corrections:

PART 60—[CORRECTED]

Appendix A—[Corrected]

1. On page 30679, in the third column, in the last line of the column, "+ 10 percent" should read "± 10 percent".

2. On page 30680, in the third column, in paragraph 5.3, the 10th line should read "to 400-or 400-to 1000-ppm range. If any samples".

3. On page 30681, in the first column, in the second line, insert the word "Equation" after "using".

4. On the same page, Equation 10A-4 should appear as follows:

$$C = C_b (1 - F)$$

5. On the same page, in the second column, under "Bibliography", in paragraph 4., in the second line, "Law" should read "Low".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 404

[Regulations No. 4]

Federal Old-Age, Survivors, and Disability Insurance; Wage Coverage

Correction

In rule document 87-18088 beginning on page 29659 in the issue of Tuesday, August 11, 1987, make the following correction:

On page 29663, in the first column, in the **Authority**, in the second line, "215(b)" should read "215(h)".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

Issuance of Acquiescence Rulings

Correction

In notice document 87-17945 beginning on page 29441 in the issue of Friday, August 7, 1987, make the following corrections:

1. On page 29442, in the second column, in the fifth line, insert "202" after "section".

2. On page 29443, in the first column, under **AR 86-19(11)**, in the first line under paragraph *Issue*, remove "be".

3. On the same page, in the first column, in footnote 6, in the seventh line, "(f) of (g)" should read "(f) or (g)".

4. On the same page, in the second column, in footnote 9, in the fourth line, "had" should read "has".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-030-07-4322-02]

Meeting; Carson City District Grazing Advisory Board

Correction

In notice document 87-18774 appearing on page 30962 in the issue of Tuesday, August 18, 1987, make the following correction:

In the first column, in the third line of the **SUMMARY**, the date should read "September 16,".

BILLING CODE 1505-01-D

Federal Register

Wednesday
September 2, 1987

Part II

Pension Benefit Guaranty Corporation

29 CFR Parts 2616 and 2617

Distress Terminations of Single-Employer Plans and Standard Terminations of Single Employer Plans; Proposed Rules

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 2616 and 2617

Distress Terminations of Single-Employer Plans and Standard Terminations of Single-Employer Plans

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Proposed rules.

SUMMARY: These regulations, when adopted, will replace the Pension Benefit Guaranty Corporation's regulations on Notice of Intent to Terminate and Determination of Plan Sufficiency and Termination of Sufficient Plans (29 CFR Parts 2616 and 2617), as modified by the Notice of Interim Procedures, 51 FR 12491 (April 10, 1986). Those regulations were, to a great extent, rendered obsolete by the enactment of the Single-Employer Pension Plan Amendments Act of 1986 ("SEPPAA"), which substantially changed the rules governing voluntary terminations of single-employer plans. Among other changes, SEPPAA created two distinct types of voluntary termination, "standard" and "distress". The notice of interim procedures summarized the new termination rules for both types of voluntary plan terminations. The effect of these regulations, when adopted, will be to replace that notice and prescribe, in Part 2617, all of the rules and procedures governing standard terminations and, in Part 2616, all of the rules and procedures for distress terminations.

DATE: Comments must be submitted by November 2, 1987.

ADDRESS: Comments should be addressed to Office of the General Counsel (Code 22500), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006. Comments will be available for public inspection at the PBGC's Communications and Public Affairs Department, Suite 7100, at the above address, between the hours of 9:00 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: J. Ronald Goldstein, Attorney, Corporate Policy and Regulations Department (Code 35100), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006; 202–778–8850 (202–778–8859 for TTY and TDD). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

Background

On April 7, 1986 the Single-Employer Pension Plan Amendments Act of 1986 ("SEPPAA"), amending the Employee Retirement Income Security Act, as amended ("ERISA" or the "Act"), became law. As part of the reform measures aimed at better protecting promised pension benefits and better controlling the costs of the single-employer insurance program under Title IV of ERISA, SEPPAA substantially altered the rules governing voluntary plan terminations. These new rules apply to all terminations initiated (*i.e.*, for which a notice of intent to terminate was filed) on or after January 1, 1986.

Under prior law, a plan administrator was free to terminate a single-employer plan at any time (subject to certain procedural requirements), without regard to the degree to which plan benefits were funded. Upon the termination of an underfunded plan, participants' benefits were protected by Title IV only to the extent of their guaranteed benefits; participants lost their right to any additional benefits to which they were entitled under the plan (*i.e.*, their nonforfeitable benefits) that were not funded.

Moreover, plan termination not only enabled a plan sponsor to cut off its statutory obligation to fund participants' benefits, but also to shift all or a portion of the liability for guaranteed benefits to the single-employer insurance program. Plan sponsors that were able to continue in business and to continue providing pension coverage to their employees found that it was cheaper to terminate their underfunded plans, because their liability for the underfunding was limited by the net worth rule in ERISA section 4062. Thus under prior law, the single-employer insurance program wound up bearing the burdens of plan underfunding, often in cases where the plan sponsor was financially strong enough to sustain the costs of eliminating the underfunding. Further, participants whose nonforfeitable benefits exceeded PBGC guarantees lost benefits unless plan assets were sufficient to cover them.

SEPPAA changed all this and essentially transferred back to plan sponsors the liability for funding promised pension benefits when the plan sponsor is financially able to bear these costs. Under SEPPAA, the right to terminate a defined benefit plan is no longer unrestricted. Instead, most plan sponsors may terminate their plans only if the plans are able to satisfy "benefit commitments", which generally exceed PBGC guaranteed benefits. Failing this, a plan may be terminated only if the contributing sponsor that maintains the plan and the other members of its controlled group can demonstrate that they are in such poor financial condition, or that their costs of maintaining single-employer plans have become so burdensome, that they cannot, realistically, continue to maintain the plan for which termination is sought.

The first kind of plan termination is a "standard" termination, and the second a "distress" termination. Under SEPPAA section 11007, amending ERISA section 4041(a), a single-employer plan may be voluntarily terminated only in a standard or distress termination. Absent qualifying for one of these types of termination, a single-employer plan cannot voluntarily terminate.

It should be kept in mind, however, that SEPPAA does not affect a plan administrator's right to freeze a plan, although SEPPAA does impose certain new notice requirements pertaining thereto. Therefore, in cases where a plan administrator knows that a plan cannot, or is uncertain whether it can, qualify for either a standard or distress termination, the plan administrator may want to consider freezing the plan.

In addition to these very substantial changes to the substantive rules on plan termination, SEPPAA also changes many of the procedural rules. The new rules for standard terminations are set forth in amended ERISA section 4041(b) (amended by SEPPAA section 11008) and the rules for distress terminations are in amended section 4041(c) (amended by SEPPAA section 11009).

In order to reflect these new rules, the Pension Benefit Guaranty Corporation's two principal regulations dealing with the voluntary plan termination process, the rules on Notice of Intent to Terminate and Determination of Plan Sufficiency and Termination of Sufficient Plans (29 CFR Parts 2616 and 2617), need to be totally revised. In keeping with the structure of the SEPPAA amendments, the PBGC is now proposing to promulgate two new termination regulations, one dealing solely with distress terminations and the other with standard terminations. The distress termination rules will be codified in Part 2616 and the standard termination rules in Part 2617.

Most terminations under SEPPAA will be standard terminations. In addition, a number of the rules applicable to distress terminations are merely variants of the standard termination rules. For these reasons, the discussion that follows will deal first with standard terminations.

Standard Terminations—Statutory Rules

One of the goals of the Congress in promulgating the new termination rules was to simplify and expedite the PBGC's review of terminations under which the PBGC would not be called on to pay

guaranteed benefits, thereby permitting the faster distribution of plan assets to participants in those plans, as well as enabling the PBGC to devote more of its resources to those terminations that do impose liabilities on the plan termination insurance program. Thus, sections 11007 and 11008 of SEPPAA greatly reduce the PBGC's role in standard terminations, while at the same time increasing the statutory protections afforded plan participants and beneficiaries and enhancing their ability to protect their own rights. In developing proposed Part 2617, the PBGC has adhered to this Congressional intent and attempted to restrict its role in standard terminations to the minimum consistent with its statutory obligations.

Although the substantive requirements for standard terminations are new, many of the procedural rules are a codification of the PBGC's prior procedures for terminating sufficient plans. Therefore, the termination process described in SEPPAA section 11008, amended ERISA section 4041(b), will be familiar to most pension practitioners. (Statutory references hereinafter are to amended section 4041 unless stated otherwise.)

Pursuant to section 4041(b)(1), a plan may terminate in a standard termination only if:

(A) The plan administrator issues a 60-day advance notice of intent to terminate to affected parties other than the PBGC (as required by section 4041(a)(2));

(B) The plan administrator issues a termination notice to the PBGC and notices of benefit commitments to plan participants and beneficiaries (as required by section 4041(b)(2) (A) and (B));

(C) The PBGC does not issue the plan a notice of noncompliance under section 4041(b)(2)(C); and

(D) When the final distribution of assets occurs, plan assets are sufficient to satisfy all benefit commitments under the plan.

The requirement of a 60-day notice of intent to terminate to plan participants, beneficiaries and collective bargaining representatives derives from, but significantly modifies, the requirement in the PBGC's Notice of Intent to Terminate regulation that the plan administrator notify participants and retirees of a proposed termination on or before the date of filing the notice with the PBGC. Under amended section 4041(a)(2), however, the notice of intent to terminate is not filed with the PBGC and the recipients must receive personal notice. Instead of filing the notice of intent to terminate with the PBGC, the plan administrator must make a subsequent filing with the PBGC, referred to in Part 2617 as the "standard termination notice". The requirements for this notification to the PBGC (contained in section 4041(b)(2)(A)) essentially embody the PBGC's Enrolled Actuary and Plan Administrator Certification Program, making that program mandatory for all standard terminations.

The requirement of the issuance of notices of benefit commitments to plan participants and beneficiaries is new under SEPPAA and is discussed in greater detail later in this preamble. However, it is important at the outset to understand SEPPAA's new concept of "benefit commitments", since this concept is central to many of SEPPAA's most significant reformations of prior law.

"Benefit commitments" are those benefits which: (1) Are guaranteed by the PBGC under section 4022 of the Act; (2) would be guaranteed but for the limitations in section 4022(b); or (3) constitute early retirement supplements or subsidies or plant closing benefits, providing the participant or beneficiary has, prior to the plan termination date, satisfied the plan's conditions for entitlement to the benefit, but for the statutory exceptions (listed in the regulation). The legislative history of this provision indicates that the terms comprising the third portion of the definition are to be liberally construed. Benefit commitments include, for example, "30-and-out" benefits or post-termination cost-of-living adjustments, assuming, in both cases, that all conditions for entitlement to the benefit had been satisfied before plan termination. Benefit commitments do not, however, include benefits related to post-termination service or post-termination shutdowns. Thus, benefit commitments do not include all benefits protected by section 301(a) of the Retirement Equity Act under section 411(d)(6) of the Internal Revenue Code.

Title IV now protects participants' rights to their benefit commitments (although, as will be discussed later in this preamble, this protection is only partial in the case of distress terminations). Under amended section 4041, a "sufficient" plan is one that can satisfy all obligations for benefit commitments, rather than merely guaranteed benefits.

The provision for the PBGC's issuance of a "notice of noncompliance" is new under SEPPAA and constitutes a reversal of prior procedure. The PBGC must issue this notice (normally within 60 days after receipt of the standard termination notice) in order to stop a proposed standard termination, thereby prohibiting a plan administrator from making the final distribution of assets. Contrary to prior law, under SEPPAA the PBGC must take no formal action to authorize a final distribution of plan assets, but instead, must act only if it wishes to stop the distribution. (Of course, the PBGC's taking no action to stop a final distribution of assets does not imply that the termination and distribution satisfy the requirements of the Internal Revenue Code.) The PBGC will issue a notice of noncompliance if it determines that any of the notice requirements was not met, or that there is reason to believe that the plan is not sufficient for benefit commitments (section 4041(b)(2)(C)).

SEPPAA's final prerequisite to a standard termination is a significant departure from prior law, one intended to protect the single-employer insurance program. Previously, if a plan was sufficient for guaranteed benefits as of the proposed termination date and thereafter became insufficient, its earlier status was controlling. Thus, participants received the benefits to which assets were allocated as of the proposed termination date, and the PBGC made up the subsequent shortfall. This liability was borne by the PBGC without any commensurate liability for the plan sponsor.

Under SEPPAA, when a subsequent insufficiency (for benefit commitments) occurs, the proposed termination is nullified, and the plan continues as an ongoing plan. Thus, SEPPAA ensures that the obligation for funding promised benefits stays with the plan sponsor, rather than the insurance program. (As will be discussed later in this preamble, this same principle is incorporated in a slightly modified fashion under the distress termination rules as well.)

Finally, unless the PBGC issues a notice of noncompliance barring the termination, and assuming that the plan can in fact satisfy all benefit commitments, the plan administrator must close out the plan (section 4041(b)(2)(D)) in the same manner as under prior law. The plan administrator must also (as under prior practice) submit a post-distribution certification to the PBGC (section 4041(b)(3)).

Distress Terminations—Statutory Rules

As mentioned above, SEPPAA's restrictions on the termination of insufficient (for benefit commitments) plans constitute a major departure from prior law. In addition to meeting notice requirements similar to those applicable to standard terminations, qualification for a distress termination necessitates

demonstrating the requisite financial hardship.

Specifically, under section 4041(c)(1), a plan may terminate in a distress termination only if:

(A) The plan administrator issues a 60-day advance notice of intent to terminate to affected parties including the PBGC (as required by section 4041(a)(2));

(B) The plan administrator issues a subsequent termination notice to the PBGC, referred to in Part 2616 as the "distress termination notice", (as required by section 4041(c)(2)(A)); and

(C) The PBGC determines that the distress tests are satisfied in accordance with section 404.1(c)(2)(B).

Section 4041(c)(2)(B) both establishes the four statutory distress tests and prescribes their applicability. Under that provision, the contributing sponsor and each substantial member of its controlled group must satisfy at least one of the distress tests; they need not all satisfy the same distress test. The concept of a "substantial member" of a controlled group is new under SEPPAA and is defined as any member of a controlled group whose assets comprise at least five percent of the total assets of the entire controlled group. (It should be kept in mind that this concept of a substantial member of a controlled group is relevant only for purposes of satisfying the statutory distress tests. Employer liability under section 4062 of the Act still runs to all members of the contributing sponsor's controlled group.)

The four distress tests are as follows:

(1) Liquidation in bankruptcy—a person has filed or had filed against it, as of the termination date, a petition seeking liquidation under title 11, United States Code, or under a similar provision of state law, and, as of that date, the petition has not been dismissed.

(2) Reorganization in bankruptcy—a person has filed or had filed against it, as of the termination date, a petition seeking reorganization under title 11, or under a similar state law, or, as of that date, a case described in #1, has been converted to a reorganization proceeding; the case has not been dismissed, as of the termination date; and the plan termination is approved by the bankruptcy court or the appropriate state court.

(3) Inability to continue in business—a person demonstrates that, unless a distress termination occurs, the person will be unable to pay its debts and to continue in business.

(4) Unreasonably burdensome pension costs—a person demonstrates that its costs of providing pension coverage have become unreasonably burdensome solely as a result of declining employment of employees covered under all single-employer plans maintained by that person.

If the PBGC determines that the necessary persons meet at least one of these tests, and the aforementioned notice requirements are also satisfied, the plan may terminate in a distress termination. How this is effected depends on the degree to which plan benefits are funded. Under section 4041(c)(3)(B), the rules for implementing a distress termination are a hybrid of the rules applicable to standard terminations and the rules under prior law applicable to the termination of insufficient (for guaranteed benefits) plans.

If a plan can pay at least all guaranteed benefits, the PBGC will authorize the plan administrator to distribute all plan assets according to the same rules as under a standard termination (sections 4041(c)(3)(B) (i) and (ii)). If the plan assets are not sufficient to satisfy guaranteed benefits, the plan administrator may not take any further actions to implement the plan termination, and the PBGC will act under ERISA section 4042 to have a trustee appointed and will assume the obligation to pay guaranteed benefits (section 4041(c)(3)(B)(iii)).

As alluded to previously, SEPPAA modifies Title IV's employer liability rules in a number of significant ways in order to better protect the termination insurance program and plan participants and beneficiaries. Two of these changes are pertinent to the distress termination process.

First, since in some distress terminations plan administrators will be authorized to distribute plan assets, the possibility exists that a subsequent insufficiency for guaranteed benefits (or, less likely, a subsequent insufficiency for benefit commitments) may occur. When this happens, the original valuations and asset allocation are no longer controlling. Instead, SEPPAA provides for new valuations and a new allocation as of, generally, the date the subsequent insufficiency is discovered (sections 4062 (b)(1)(B) and (c)(1)(B)). Thus, the liability or loss associated with a subsequent shortfall is shared by the contributing sponsor (and its controlled group members), plan participants and the PBGC.

The second employer liability change pertinent to the termination process is the creation of liability for unfunded benefit commitments in excess of guaranteed benefits (section 4062(a)(2)). This liability equals the lesser of 15% of total benefit commitments or 75% of the unfunded benefit commitments in excess of guaranteed benefits. It affords plan participants some protection against a plan's inability to pay the benefits to which participants were entitled. In order to collect this liability and make payments to participants, SEPPAA creates a new "section 4049 trust". (Proposed Part 2616 set forth below does not deal with the establishment and operation of the section 4049 trust. That will be dealt with in a separate regulation.)

Because of the similarities between SEPPAA, particularly its standard termination rules, and prior rules for terminating plans, the discussion of the proposed regulations that follows does not summarize all of the regulations, but rather focuses on the new rules and discusses issues arising from them. It should be kept in mind that a number of the issues raised under the discussion of Part 2617 are applicable to distress terminations, as well.

Finally, the PBGC notes that it is still reviewing these termination regulations, as well as others of its regulations (*e.g.*, Parts 2618 and 2619, dealing with the allocation of plan assets and the valuation of plan benefits, respectively) to determine what changes are necessary to conform the regulations to the requirements of the Retirement Equity Act ("REA"). For this reason, the sections in Parts 2616 and 2617 dealing with the form of benefit that must be provided upon plan termination and with the election of alternative forms have been reserved. Similarly, it should be understood that portions of Part 2619, which is referred to in several places both in this preamble and in Part 2616, will be revised in light of REA (and SEPPAA). The PBGC expects that these revisions will be completed before Parts 2616 and 2617 are made final. (Although, the various REA issues are not specifically addressed in this preamble, the PBGC welcomes public comment on the proper interaction of REA with ERISA Title IV.)

Part 2617—Standard Terminations

Section 2617.2 of the regulation on standard terminations defines several terms new under SEPPAA. The new term "benefit commitments" was discussed above. Also new is the term "affected parties". Among other uses, this term is used to describe the persons to whom a notice of intent to terminate must be issued. Since, in a standard termination, that notice is not given to the PBGC, § 2617.2 omits the PBGC from the statutory list of affected parties. It defines "affected party" as each plan participant, each beneficiary of a deceased participant, each alternate

payee under an applicable qualified domestic relations order, and each employee organization representing plan participants. For purposes of this regulation, "participant" is defined as it is defined under the PBGC's Payment of Premiums regulation (29 CFR Part 2610), except that the definition in § 2617.2 does not include deceased participants. (As under Part 2610, the definition also excludes participants whose benefits have been fully satisfied through the purchase from an insurer of an irrevocable commitment to provide the benefits.)

SEPPAA uses the terms "contributing sponsor" and "members of the contributing sponsor's controlled group" in lieu of the term "employer". For purposes of standard terminations, only the term "contributing sponsor" is relevant, and it is defined as the person who is responsible for meeting the minimum funding standards with respect to a plan. This definition does not deal with paragraph (B) of the statutory definition, which has no relevance to standard termination and is discussed in connection with distress termination.

Part 2617 uses an old term, "proposed termination date", in a slightly different manner than under prior law. The "proposed termination date" is the date so specified in the notice of intent to terminate and the standard termination notice filed with the PBGC. If these dates are different, the date in the standard termination notice is controlling. This might occur when, for example, a plan administrator decides that more time is needed to file the standard termination notice and therefore a later termination date must be proposed in that notice. (See discussion below on the time limits for filing a standard termination notice.) The proposed termination date specified in the termination notice may be later, but never earlier, than the date stated in the notice of intent to terminate.

The term "proposed termination date" is used throughout the regulation, rather than the term "termination date". This is because until the final distribution of assets in satisfaction of all benefit commitments occurs, the plan termination is contingent upon the plan's ability to actually satisfy all benefit commitments under the plan. When this final distribution occurs, then the proposed termination date becomes the actual termination date.

One of the other SEPPAA changes designed to better enable plan participants to protect their rights in the event of a proposed plan termination is set forth in section 4041(a)(3) and implemented by § 2617.5 of this proposed regulation. (Section 4041(a)(3) also applies to distress terminations, and therefore, the discussion that follows is relevant to those terminations as well.) Pursuant to section 4041(a)(3), the PBGC may "not proceed with a plan termination if the termination would violate the terms and conditions of an existing collective bargaining agreement". While the purpose of this provision seems rather straightforward, implementing it raises a host of questions.

By its terms this rule applies only to terminations that would violate "*existing* collective bargaining agreements" (emphasis added). Yet, in many cases when a collective bargaining agreement has expired, the parties continue to be obligated to adhere to the terms of the expired agreement. Should the protection afforded plan participants by section 4041(a)(3) continue to exist in these situations?

Other difficult problems involve the condition "if the termination would violate the . . . collective bargaining agreement". Obviously, whether this is the case will often be subject to dispute. Who is to make this determination? Labor-management relations law provides mechanisms for resolving such disputes, as do many collective bargaining agreements. This suggests that the PBGC should not attempt to make these determinations. But if it does not, does that mean that the PBGC must suspend processing of a plan termination whenever there is an assertion that the termination would violate an existing collective bargaining agreement? (Indeed, is a mere assertion adequate to invoke section 4041(a)(3), or must a party take some formal action, *e.g.*, initiate arbitration or file a lawsuit?) What if a challenge is frivolous on its face? Further, if the PBGC is not to make these determinations, how long may the suspension of a termination last? Must the suspension continue until the challenging party and the contributing sponsor have exhausted their judicial remedies and appeal rights?

The PBGC has considered these questions in developing the rules set forth in proposed § 2617.5 as discussed below (and proposed § 2616.5 in the distress regulation). The PBGC emphasizes, however, that this is a proposal only and urges interested persons to submit their views on these matters.

In brief, § 2617.5(a) of the proposed regulation provides that whenever the PBGC is advised, prior to the expiration of the time within which it may issue a notice of noncompliance, that a formal challenge (as described in § 2617.5(c)) has been initiated asserting that the plan termination violates the terms of an existing collective bargaining agreement, the PBGC will suspend the processing of the termination. The effect of a suspension is to stop the running of all time periods imposed by the Act and this regulation relevant to the termination. The suspension does not, however, nullify the notice of intent to terminate, nor negate its effects. Therefore, the prohibition in § 2617.4 against any distributions pursuant to the plan termination after issuance of the notice of intent to terminate remains in effect, and benefit accruals and vesting cease as of the proposed termination date. (As in any proposed termination, if the PBGC ultimately dismisses or nullifies the termination, accruals and vesting resume as of the proposed termination date.)

The methods of formally challenging a proposed termination described in § 2617.5(c) are methods available under labor relations law. This list is intended to be all inclusive. Whether or not any one of these avenues is available in a particular case depends on the terms of the collective bargaining agreement and/or applicable law. This regulation does not confer any new rights with respect to how or when a party may challenge a proposed plan termination under a collective bargaining agreement.

A suspension under § 2617.5 remains in effect until the final resolution of the challenge as described in § 2617.5(d). As with the types of formal challenges that may be initiated, this list is meant to be all inclusive. If the contributing sponsor prevails and wishes to continue the plan termination, the termination proceeding will be reactivated and all prior actions taken with respect to the termination shall be effective. If the challenge to the termination is sustained, the PBGC shall dismiss the termination proceeding and it shall be void *ab initio*.

Proposed § 2617.6 ("Requirement for annuities") contains a general rule that is very similar to the general rule under the PBGC's old sufficiency regulation. As noted earlier in this preamble, rules on exceptions to the annuity requirement and required annuity form have been reserved until the PBGC determines what changes are necessary to conform the regulation to the requirements under Title I of ERISA and the Internal Revenue Code that were added by the Retirement Equity Act.

Proposed § 2617.7 carries over from the existing regulation, with one important change, the rule permitting a contributing sponsor to make a commitment to make a plan sufficient.

Under a standard termination, of course, that commitment must be to fund all benefit commitments under the plan. However, § 2617.7 provides that if the contributing sponsor is the subject of a bankruptcy liquidation or reorganization proceeding, the commitment will be valid only if it is approved by the court before which the proceeding is pending. The purpose of this rule is to prevent a standard termination from going forward on the basis of a commitment that is not very likely to be honored.

Proposed § 2617.8 contains the rule on what constitutes "filing" of a document with the PBGC under this regulation. Under § 2617.8(a), a document is deemed filed with the PBGC on the date that it is received by the PBGC, providing it is received on a regular business day, no later than 4:00 p.m. Documents received at other times are deemed filed on the next regular business day. This change from prior practice is necessary because the old filing rule (postmark date) proved difficult to administer, and because the PBGC's time for reviewing proposed terminations is shorter under SEPPAA.

Section 4041(a)(2) provides that, at least 60 days prior to the proposed termination date, the plan administrator must provide each affected party with a notice of intent to terminate. This requirement is implemented by § 2617.12, which requires the plan administrator to issue (*i.e.*, either hand deliver or deposit with a mail or courier service) the notices by the stipulated date. (Section 2617.12 also provides that the notices may not be issued more than 180 days prior to the proposed termination date.) In other words, the earliest possible proposed termination date is the date the notices are issued plus 60 days. For example, a plan administrator who wished to terminate a plan on October 31, 1986, would have to issue all notices of intent to terminate no later than September 1, 1986; September 1 plus 60 days is October 31. The PBGC stresses this rule because this requirement cannot be waived. If a standard termination notice filed with the PBGC shows that the proposed termination date stated in the notice of intent to terminate did not comply with this rule, the PBGC will issue a notice of noncompliance voiding the proposed termination. In order to terminate the plan, the plan administrator would then have to begin the process again.

Because of the severity of this rule, § 2617.12(a) requires that the notices be "issued" by the appropriate date. To require actual delivery would, in the PBGC's judgment, place an unreasonable burden on the plan administrator in light of the consequences of noncompliance. The plan administrator is not responsible for the performance of the United States Postal Service or any other established delivery service. To require actual delivery of the notices by the appropriate date would mean that slower delivery than the plan administrator might reasonably have expected could defeat the plan termination. Moreover, the 60-day requirement (increased from 10 days under prior law) ensures that the affected parties will be advised of the proposed termination in time to challenge it if they so desire. (The PBGC notes that plan administrators may choose to use the same mailing for the notice of intent to terminate and the notice to interested parties required under ERISA section 3001, although these notices must be set forth in separate documents.)

Pursuant to section 4041(b)(2)(A), the plan administrator must file the standard termination notice with the PBGC "(a)s soon as practicable" after the issuance of the notices of intent to terminate. Notices of benefit commitments must be issued no later than the date on which the standard termination notice is sent (section 4041(b)(2)(B)). The PBGC is concerned that an "as soon as practicable" rule would be unadministrable, and therefore, § 2617.15(a) requires the plan administrator to file the standard termination notice no later than 60 days after the proposed termination date stated in the notice of intent to terminate (or, if later, the proposed termination date specified in the standard termination notice). For example, if the proposed termination date stated in the notice of intent to terminate was October 31, the standard termination notice would have to be filed with the PBGC no later than December 30; October 31 plus 60 days is December 30. (Tracking the statutory language, § 2617.13(a) requires that the notices of benefit commitments be issued no later than the date on which the standard termination notice is sent to the PBGC.).

The PBGC believes that this 60-day rule is necessary to avoid potential abuse of the termination process. Without the establishment of a fixed time period within which a plan administrator must proceed with a termination, the process could be used to effect a "deep freeze" of the plan (*i.e.*, the cessation of benefit accruals and vesting), while waiting for the most propitious time to carry out the termination and actually distribute plan assets in full satisfaction of all benefit commitments.

The PBGC also believes that this rule provides more than enough time (at least 120 days after issuance of the notices of intent to terminate) for plan administrators to issue the notices of benefit commitments and prepare and file the standard termination notice. The regulation does provide for a limited extension to complete the filing of a standard termination notice submitted within the requisite 60-day period (§ 2617.16(d)). Moreover, if the plan administrator finds that it is impossible to submit the standard termination notice within 60 days after the proposed termination date stated in the notice of intent to terminate, the plan administrator may set a later proposed termination date in the standard termination notice. However, in no event may the new proposed termination date be later than 180 days after the issuance of the notices of intent to terminate.

The PBGC stresses that it will not waive the filing date requirement. Filing a standard termination notice after the 60-day period (or failing to complete the submission within the time specified in § 2617.16(d)) will result in the PBGC's issuing a notice of noncompliance pursuant to § 2617.17.

One more time limit under the regulation bears mentioning. Section 4041(b)(2)(D) requires the plan administrator to begin the final distribution of assets "as soon as practicable" after the expiration of the period within which the PBGC may issue a notice of noncompliance. For the reasons stated in connection with the 60-day rule discussed above, the PBGC has decided that it should establish a fixed time frame for making the distribution. Accordingly, § 2617.18(a) requires the plan administrator to make the final distribution within 30 days after the expiration of the PBGC's review period.

The PBGC finds that the most common reason given by plan administrators for delaying the final distribution is that the plan has not received an IRS determination letter with respect to the termination. The PBGC, therefore, urges plan administrators to file their requests for determination letters early in the termination process, at or about or before the time they issue the notices of intent to terminate.

Where, despite the plan administrator's best efforts, it is not possible to distribute plan assets within the required period, the PBGC may extend the period under § 2617.18(e). A

request for extension must be filed before the expiration of the 30-day period and request an extension of a specific duration not to exceed 45 days. The PBGC will grant the extension only if it finds that the inability to distribute is not caused by the actions or inactions of the plan administrator or contributing sponsor.

In this connection, the PBGC notes that the existence of a claim against the contributing sponsor for due and unpaid contributions is not a valid reason for delaying the final distribution of assets, subject, of course, to the restriction that if the plan administrator cannot distribute assets in full satisfaction of all benefit commitments, the plan administrator may not proceed with the termination. Otherwise, the plan administrator shall make the distribution within the prescribed 30-day period and thereafter pursue the claim for the unpaid contributions. Amounts subsequently collected may be paid to participants and beneficiaries without regard to the annuity requirement in § 2617.6, since these are amounts in excess of benefit commitments.

Failure to distribute within the 30-day (or extended) period shall nullify the proposed termination, and the plan shall be an ongoing plan.

Another significant mechanism introduced by SEPPAA to enable plan participants and beneficiaries to better protect their rights in a plan termination is the requirement that participants and beneficiaries be issued notices of their benefit commitments at least 60 days prior to the final distribution. This notice serves two purposes. First, for benefits that may not or will not be paid in the plan's normal form, the notice must state the normal form under the plan and the factors used to convert to the alternative form (§ 2617.14 (d)–(f)). This will enable participants who have not made their benefit elections to make more informed elections, and it will enable all participants to question whether correct factors and assumptions are being used. In the past, the PBGC has received numerous inquiries from participants concerning a plan's interest assumptions (principally, the rate used for calculating lump sum benefits paid in lieu of annuities). Providing this data to participants before the final distribution of assets will enable participants to direct these concerns to their plan administrators before plan assets are distributed.

The second purpose of the notice of benefit commitments is to enable participants and beneficiaries to verify the personal data upon which the calculation of their benefits was based. Section 2617.14 (d)–(f) mandates that the notice contain the personal data (*e.g.*, participant's age, beneficiary's age, length of service, salary, etc.) used to compute the benefit commitments. Thus, participants will be able to correct any erroneous information prior to the plan's close out.

With respect to benefits of participants (or beneficiaries) in pay status as of the proposed termination date, § 2617.14(d) requires that the personal data be provided only to participants (or beneficiaries) who were in pay status one year or less as of that date. Requiring that this information be provided to all persons in pay status could create a tremendous administrative burden in many plans. Moreover, it seems unlikely that, after one year, there would be outstanding questions as to a person's correct benefit.

Finally, notices of benefit commitments will serve their intended function only if they are written in clear, simple language that the average participant or beneficiary can understand. Section 4041(b)(2)(B) specifically requires this. This rule is reiterated in § 2617.14(a) of the proposed regulation and further implemented by § 2617.14(b), which provides a special rule covering situations where a significant number of plan participants speak only the same non-English language.

The standard termination notice that must be filed with the PBGC under proposed § 2617.15 essentially combines Form 5310 (notice of intent to terminate) and Forms 444 and 445 (enrolled actuary and plan administrator certifications). While the PBGC is continuing the use of those forms (with appropriate modifications) during the start-up period under SEPPAA (although one-stop filing is no longer available), Part 2617 (and Part 2616) when issued in final form will supersede Forms 5310, 444 and 445. The information that must be submitted to the PBGC will be set forth in this regulation (see § 2617.15 (b) and (c)).

The PBGC has endeavored to keep the information requirements for the standard termination notice at the absolute minimum. In brief, the notice requires plan and contributing sponsor identifying information, statements verifying compliance with the notice of intent to terminate and notice of benefit commitments requirements, and data showing that the plan is sufficient for all benefit commitments. Data supporting the enrolled actuary's certification is not required; if the enrolled actuary's determination of sufficiency is incorrect, or for any other reason the plan proves to be unable to satisfy all benefit commitments, the proposed termination will be nullified (§ 2617.18(d)). Similarly, the proposed regulation does not prescribe the valuation methods to be used by the enrolled actuary. The enrolled actuary may use any reasonable methods and assumptions consistently applied that will accurately reflect the plan's ability to pay all benefit commitments on the date of distribution after allocating plan assets in accordance with Part 2618 of this subchapter. In addition, the PBGC notes that the rules in Part 2619 regarding the valuation of benefits to be paid as lump sums will apply.

Plan administrators who expect a termination to result in a reversion of residual assets to the contributing sponsor should bear in mind that certain information relating to such terminations that the PBGC used to request later in the termination process is now required to be submitted as part of the standard termination notice (§ 2617.15(e)). This information is needed so that the PBGC can (among other things) review the termination for consistency with the PBGC/DOL/IRS guidelines on asset reversions and also review any alternative method for allocating the reversion under a contributory plan. (The PBGC notes that its review with regard to the guidelines is limited to Title IV matters and does not extend to questions of compliance with Title I and the Internal Revenue Code.) The PBGC reminds plan administrators that a purported plan termination that is not consistent with the joint guidelines is not a termination under ERISA and the plan is an ongoing plan.

With respect to contributory plans under which the plan administrator proposes to allocate the reversion in a manner other than that prescribed in § 2618.31(b) of the Allocation of Assets regulation, § 2617.15(c)(3) requires that the plan administrator consent to a 60-day extension of the PBGC's time within which to issue a notice of noncompliance. This extension is needed to provide the PBGC with adequate time to review the proposed alternative allocation method. (In this connection, the PBGC notes that plans that are no longer, but once were, contributory plans and still retain any employee contributions are treated as contributory plans for all purposes under the allocation rules of Part 2618 and section 4044 of the Act.)

As mentioned earlier in this preamble, under SEPPAA the PBGC no longer must authorize the final distribution of plan assets in a standard termination, but instead, must prohibit the distribution if the termination does not comply with

the statute and this regulation. Accordingly, the PBGC will notify plan administrators of the date on which the PBGC's 60-day (or 120-day for certain reversion cases involving contributory plans) review period begins to run. Absent a suspension or extension of the 60-day (or 120-day) period, if a notice of noncompliance is not issued before the 61st (or 121st) day, the plan administrator is free to distribute plan assets; the PBGC will not issue anything authorizing the distribution.

If the PBGC issues a notice of noncompliance, the termination is nullified and the plan is an ongoing plan for all purposes (§ 2617.17(b)). However, the plan administrator may appeal the issuance of a notice of noncompliance in accordance with the rules prescribed in Subpart D of Part 2606, and the filing of an appeal automatically stays the effectiveness of the notice of noncompliance until the PBGC issues its decision on the appeal (§ 2617.17(c)). The stay avoids harm to the plan, the contributing sponsor and participants, that could arise from erroneously treating the plan as an ongoing plan if, for example, the plan were required to commence paying benefits to participants whose eligibility depends on plan continuation. If the PBGC revoked the notice of noncompliance and upheld the termination on appeal, recovery of such payments could be costly or impossible for the plan and, if successful, could impose hardship on the participants. The PBGC recognizes that if the appeal were denied, the automatic stay could have resulted in a delay in putting some eligible participants into pay status. The PBGC notes that this problem could be addressed in particular cases by making the notice of noncompliance effective immediately, without a right of appeal, as provided in 29 CFR 2606.23(b). Nevertheless, the PBGC requests comments on the appropriateness of the automatic stay provision.

The PBGC stresses that, even in the absence of a notice of noncompliance, the plan administrator may not make the final distribution if the plan cannot actually satisfy all benefit commitments (§ 2617.18(b)). When such a subsequent insufficiency occurs, the plan administrator must notify the PBGC immediately. If the plan administrator nevertheless makes the final distribution, the plan will be subject to restoration by the PBGC under ERISA section 4047 and an action may be brought against the plan administrator for violating ERISA.

Part 2616—Distress Terminations

Most of the definitions used in Part 2617 are also used in Part 2616, although some terms have slightly different meanings. For purposes of the distress termination regulation, the term "affected parties" includes the PBGC. Therefore, as noted earlier, in a distress termination, the notice of intent to terminate must be issued to the PBGC as well as to participants, beneficiaries and collective bargaining representatives.

The term "contributing sponsor" is defined to include the person responsible for meeting the funding standards with respect to a plan, as well as any person who is a member of the contributing sponsor's controlled group and was responsible for meeting the funding requirements with respect to the plan at a time when the person employed a significant number of the plan participants. The definition parallels the statutory definition and does not attempt to define what constitutes "a significant number of participants" for purposes of paragraph (B) of the statutory definition.

The term "proposed termination date" also is defined somewhat differently under proposed Part 2616. Under this regulation, the proposed termination date specified in the distress termination notice must be the same as the date specified in the notice of intent to terminate. The plan administrator may not move the proposed termination date to a later date. Because in most distress terminations the contributing sponsor and the members of its controlled group will be in bankruptcy or otherwise experiencing severe financial hardship, permitting the plan administrator to change the proposed termination date to a later date would pose a significant risk to the PBGC.

The definition of "substantial member of a controlled group" found in § 2616.2 creates a rebuttable presumption that every member of the contributing sponsor's controlled group as of the termination date is a "substantial member" (*i.e.*, owns five percent or more of the total gross assets of the controlled group) unless the plan administrator can prove otherwise to the PBGC's satisfaction. The PBGC believes that this is a reasonable and appropriate rule since it is the contributing sponsor and its controlled group members who are in possession of the data necessary to prove whether any person is a substantial member of the controlled group.

Moreover, since the determination of "substantiality" is the first major step in the PBGC's processing of a distress termination, it is important that the PBGC be able to make this finding quickly. Establishing this presumption will facilitate that process. As another means of expediting this process, gross assets ordinarily will be determined from book values.

The plan administrator may submit whatever information the plan administrator believes is relevant to the demonstration that a person is not a substantial member. However, at a minimum, this information must include consolidated (for parent/subsidiary controlled groups) or combined (for brother/sister controlled groups) financial statements and financial statements for each controlled group member that the plan administrator asserts is not substantial (§ 2616.14(b)). Proposed § 2616.14(b) also requires that these financial statements be submitted for each of the five years preceding the proposed termination date. This is to enable the PBGC to review the relationship (in terms of gross assets) between the specific controlled group members in question and the whole controlled group during the recent past.

Proposed § 2616.3 basically reiterates the statutory requirements for a distress termination. It should be noted, however, that § 2616.3(d)(1), which describes the first statutory distress test (section 4041(c)(2)(B)(i)), slightly modifies that test. Specifically, the regulatory provision includes both cases begun as bankruptcy liquidations and cases begun as bankruptcy reorganizations and subsequently converted to liquidations. The latter group is not included in the statutory provision. This is an apparent oversight, since the statute does take account of cases begun as bankruptcy liquidations and subsequently converted to reorganizations (section 4041(c)(2)(ii)).

The distress tests, as set forth in § 2616.3(d), require, as does the statute, that a distress test be satisfied as of the plan termination date. Section 2616.14 (the section dealing with the distress termination notice) provides, however, that the plan administrator demonstrate satisfaction of the distress tests as of the proposed termination date. The reason for this is simple: at the time a distress termination notice is filed, the plan termination date will not have been established. This apparent inconsistency or gap in the statute raises a series of difficult questions.

With respect to distress terminations, SEPPAA does not change the statutory rules on establishment of a termination date. Section 4048(a)(2) (former section 4048(a)(1)) provides that in a distress termination, the termination date is "the date established by the plan

administrator and agreed to by the corporation". Section 4048(a)(4) (former section 4048(a)(3)) provides that when "no agreement is reached between the plan administrator and the corporation", the termination date is "the date established by the court". It was clear under prior law that the PBGC did not have to agree to the termination date proposed by the plan administrator. It was also clear that under these rules a "retroactive" termination date (*i.e.*, a termination date earlier than the date 10 days after the filing of a notice of intent to terminate) could be established.

If the PBGC does not agree to the termination date proposed by the plan administrator and another date is agreed to (or established by a court), would this mean that the plan administrator would have to prove satisfaction of the distress tests as of the new termination date? What if the contributing sponsor and the substantial members of its controlled group do not qualify for distress as of the new termination date? Should there, perhaps, be two termination dates in distress terminations: (1) The termination date proposed by the plan administrator, which would be the date used for determining satisfaction of the distress tests; and (2) the termination date established in accordance with section 4048 (a)(2) or (a)(4), which would be the date used for all other purposes, *e.g.*, for establishing participants' benefit commitments and guaranteed benefits?

Also, it may be argued that, although SEPPAA did not change the pertinent provisions of section 4048, the establishment of a retroactive termination date is inconsistent with SEPPAA's greater emphasis on advance notice to plan participants and beneficiaries of a proposed termination. In other words, the greater rights ostensibly afforded participants and beneficiaries by amended sections 4041 (a)(2) and (c)(1)(A) are largely vitiated if those provisions mean only that the date stated in the notices of intent to terminate must be 60 days later than the date the notices are issued, and not that the actual termination date agreed to by the plan administrator and the PBGC must be at least 60 days after the notice.

On the other hand, concluding that section 4048 no longer authorizes the establishment of retroactive termination dates appears inconsistent, not only with the express language of section 4048, but with SEPPAA's purpose of providing greater protection to the termination insurance program. The purpose of establishing a retroactive termination date in any case is to protect the insurance program. The PBGC, therefore, tentatively has concluded that retroactive termination dates continue to be authorized under ERISA in limited circumstances.

The PBGC specifically requests that interested members of the public comment on these questions. The PBGC is considering a wide range of options, including those suggested above, and will consider any others that members of the public might suggest.

Proposed § 2616.5, like its counterpart under proposed Part 2617, provides for the suspension of a distress termination proceeding if there is a challenge under a collective bargaining agreement to the proposed termination. Under § 2616.5, however, the proceeding is only suspended at the point where the PBGC would otherwise issue a notice of inability to determine sufficiency or a distribution notice authorizing a plan administrator to distribute plan assets. Regardless of when a challenge to the termination is initiated, the plan administrator must still perform all actions required by the proposed regulation, up to and including submission of the distress termination notice.

There are a number of reasons for this requirement. Principal among them is that the suspension of a potential distress termination increases the possibility, present in most distress terminations, of harm to participants and of losses to the termination insurance program. Therefore, in such cases the PBGC will need to determine whether it should involuntarily terminate the plan under ERISA section 4042. (The initiation of a challenge to a proposed voluntary termination in no way limits the PBGC's authority under section 4042 to initiate a plan termination proceeding.) Normally, the PBGC would need the information that is submitted as part of the distress termination notice to make this decision.

In addition, this requirement also ensures that during the pendency of the challenge, the plan administrator is not paying benefits in excess of estimated guaranteed, or if greater, estimated Title IV benefits. (Proposed § 2616.4 sets forth the rules concerning benefit payments during the termination proceeding.) This minimizes the risk to retirees of benefit recoupment by the PBGC should the plan termination occur. If the challenge is successful and the plan does not terminate, all withheld amounts will be immediately payable with interest (§ 2616.5(b)(1)).

As under prior law, proposed Part 2616 permits a contributing sponsor to make a commitment to make its plan sufficient for guaranteed benefits (§ 2616.7). However, since the contributing sponsor will frequently be involved in either a bankruptcy liquidation or reorganization, any commitment by such a contributing sponsor must receive the approval of the court. Without the court's approval, a commitment is not valid under § 2616.7. If the contributing sponsor does not honor its commitment, and the PBGC is required to trustee the plan and assume the obligation to pay guaranteed benefits, the PBGC may take any necessary actions to enforce the commitment. The contributing sponsor's obligations under the commitment are distinct from and may be enforced separately from any claims the PBGC might have for unpaid contributions or employer liability under ERISA section 4062.

Section 2616.7 provides for a commitment to make a plan sufficient only for guaranteed benefits, not for all benefit commitments. While a commitment for the greater amount would be permissible under Part 2616, the PBGC does not anticipate that a contributing sponsor that qualifies for a distress termination would have the financial ability to make the plan sufficient for benefit commitments. Moreover, if the contributing sponsor were able to do so, it would be simpler and less costly to terminate the plan in a standard termination under Part 2617.

The PBGC notes in this regard that a plan administrator contemplating a distress termination, who believes that the plan may be able to satisfy all benefit commitments, might want to initiate both a distress and a standard termination. Similarly, if the plan administrator is uncertain whether the distress tests can be satisfied and the contributing sponsor would be willing, if necessary, to fund all benefit commitments, the plan administrator might want to initiate both types of termination. This approach would enable a plan to retain its proposed termination date if it fails to qualify for one type of termination and chooses to proceed with the other. If the PBGC finds that a proposed termination fails to meet the applicable requirements, that termination cannot be "converted" into the other type of termination in order to preserve the original proposed termination date.

The rules discussed under standard terminations pertaining to the issuance of the notice of intent to terminate and the establishment therein of the proposed termination date are the same under proposed Part 2616 (§ 2616.12). The PBGC will review a notice of intent to terminate promptly upon its receipt to

verify compliance with these rules. If, based on the notice, it appears that the rules were not satisfied, the PBGC will advise the plan administrator that the proposed termination is nullified (§ 2616.12(c)). This will enable the plan administrator to avoid some of the expense and effort of completing and filing the distress termination notice.

It is possible, however, that even where the notice of intent to terminate indicates compliance with § 2616.12, this may not, in fact, be true. Therefore, in order to give the other affected parties the opportunity to demonstrate non-compliance to the PBGC, § 2616.12(b) provides that the PBGC's approval of a notice of intent to terminate at this stage of the termination process is merely tentative. The PBGC's final ruling on this issue will be made after submission of the distress termination notice, at which point the PBGC must determine whether all of the requirements for a distress termination have been satisfied.

As with the filing of a standard termination notice and for the same reason, a distress termination notice must be filed no later than 60 days after the proposed termination date (§ 2616.14(a)). The distress termination notice is a combination of the plan administrator and enrolled actuary certifications required for a standard termination and the participant data schedules previously required by Form 5310, plus information evidencing satisfaction of the distress criteria. Even though more information must be submitted for the distress termination notice, the PBGC believes that the 60-day rule provides adequate time to the plan administrator. For one thing, in a distress termination the plan administrator will not have to issue notices of benefit commitments (except in the rare case of a plan that is sufficient for benefit commitments). Further, prior to issuing the notices of intent to terminate, the plan administrator should have ascertained whether the distress criteria could be met and what evidence was available to demonstrate satisfaction of the criteria. Finally, the proposed regulation (§ 2616.14(d)) permits the plan administrator to defer the submission of the participant data schedules until after the PBGC has reviewed the distress termination notice and advised the plan administrator that the plan may terminate.

The information called for under proposed § 2616.14(b) to demonstrate satisfaction of the distress criteria is, with one exception, very similar to the information called for under the PBGC's Notice of Interim Procedures (51 FR 12491 (April 10, 1986)), which prescribes temporary procedures for plan terminations under SEPPAA prior to the promulgation of these new regulations. (The one significant departure from the interim procedures involves the information showing which persons are substantial members of the controlled group. This issue, including the information that must be submitted, was discussed previously.) The PBGC has not as yet had sufficient experience with proposed distress terminations to be able to refine or improve the information requirements. It is hoped that by the time the final Part 2616 is drafted, it will be possible to do so.

The plan data and benefit data that must be submitted under § 2616.14 (c) and (d) are similar to the data called for under prior law, although some additional information reflecting SEPPAA's new provisions is now required. For example, § 2616.14(c)(4) provides that whenever the contributing sponsor or any member of its controlled group is, on or after the proposed termination date, the subject of a proceeding described in § 2616.3(d)(1) or (d)(2), *i.e.*, a bankruptcy liquidation or reorganization proceeding, the plan administrator must submit copies of all motions, memoranda, notices or other filings made in those proceedings with respect to the plan. Prior to termination, a plan administrator is required to file these documents with the PBGC pursuant to the reportable events regulation (29 CFR Part 2615). (The PBGC notes, however, that the reportable events regulation is applicable only until the filing of a notice of intent to terminate. This is inadequate under SEPPAA, since the PBGC no longer receives that notice in a standard termination and the notice of intent to terminate for a distress termination contains little of the information required in a notice of intent to terminate under prior law. Accordingly, the PBGC will soon be amending Part 2615 to make it applicable until the proposed termination date specified in a notice of intent to terminate.)

The most significant changes in the plan and benefit data that must be submitted pertain to information on a plan's benefit commitments. Under SEPPAA, it is necessary in a distress termination for the enrolled actuary to value, and allocate plan assets to, benefit commitments, as well as guaranteed benefits. Likewise, the PBGC must determine whether the plan is funded for guaranteed benefits and for benefit commitments. Complying with these added requirements according to the prior rules and procedures for processing insufficient plan terminations would create substantially more work for both enrolled actuaries and the PBGC. Furthermore, in those cases where a distress termination is actually more like the termination of a sufficient plan (*i.e.*, in those cases where the plan is able to satisfy at least all guaranteed benefits), much of this work would be pointless. Accordingly, the PBGC is proposing rules that are an amalgam of the prior valuation rules for sufficient and insufficient plans and the rules for demonstrating plan sufficiency.

Under proposed § 2616.14(c)(6), which prescribes the rules for the enrolled actuary certification, the valuation date and methods used depend on whether the plan is sufficient for benefits in priority categories 1–4. If the plan is not, then benefits are valued pursuant to Part 2619, Subpart C, as of the proposed termination date. If the enrolled actuary will certify that the plan is sufficient for all benefits in categories 1–4, then benefits may be valued under Subpart B of Part 2619 (*i.e.*, by obtaining a qualifying bid from an insurer), using an assumed distribution date. If the plan, though sufficient for all benefits in categories 1–4, is not sufficient for all benefit commitments, the enrolled actuary will need to value each participant's total benefit commitments, as of the proposed termination date in accordance with Subpart C of Part 2619, so that employer liability for the unfunded benefit commitments can be determined. Nevertheless, permitting the use of a qualifying bid for valuation purposes in the circumstances described will significantly reduce the time required for (and therefore the cost of) plan valuations in a number of distress terminations.

These proposed valuation rules for plans that are sufficient for guaranteed benefits depart from the statutory rules in section 4041(c)(2)(A), which require that all values be computed as of the proposed termination date. Termination date valuations are logical and workable for plans that are insufficient for guaranteed benefits. However, this is not the case with respect to other plans, since other plans make a final distribution of plan assets. Thus, termination date values are unimportant because (as in a standard termination) it is the ability to actually distribute assets, in this case, in satisfaction of all guaranteed benefits, that is controlling. If the plan administrator is unable to do so, there is a subsequent insufficiency, the PBGC will trustee the plan and proceed under section 4042, and the valuation date moves forward to the

date of the subsequent insufficiency, sections 4041(c)(3)(C)(ii) and 4062 (b)(1)(B) and (c)(1)(B). (The rules on subsequent insufficiencies are discussed in greater detail later in this preamble.)

In addition, for plans that the PBGC will not need to trustee, there is really no need to require the time-consuming and expensive calculation of guaranteed benefits. The amount of outstanding benefit commitments (which forms the basis for the calculation of employer liability) is determined by comparing total benefit commitments to benefits to which assets are allocated. (Therefore, where a distribution is made, outstanding benefit commitments should be determined based on the benefits actually distributed.) Moreover, for purposes of the PBGC's determination of whether to issue a distribution notice, a qualifying bid as of a proposed distribution date will normally be better proof of a plan's ability to satisfy all guaranteed benefits as of some future distribution date than would a valuation performed under the PBGC's assumptions as of the proposed termination date. (Of course, eliminating the obligation to submit a valuation of guaranteed benefits does not relieve the plan administrator from the duty to ensure that each participant and beneficiary actually receives full guaranteed benefits.)

For these reasons, the PBGC proposes to adopt the valuation rules discussed above. However, the PBGC specifically requests that interested persons submit their views on this issue.

The requirements pertaining to the participant data schedules (§ 2616.14(d)) parallel the valuation rules. For example, when the enrolled actuary certifies that plan assets are sufficient for all benefits in categories 1–4 and a qualifying bid is obtained, the participant data schedules need not show each participant's guaranteed benefits. Instead, the schedules must show the value of each participant's monthly benefit commitments and monthly benefit to which assets were allocated (*i.e.*, the value of the monthly benefit covered by the qualifying bid). In other respects, the participant data schedules require the same information as under prior practice.

The PBGC emphasizes that if the enrolled actuary certifies that a plan is sufficient through priority category 4, but the plan is not in fact able to distribute assets in satisfaction of all guaranteed benefits, the enrolled actuary will be required to perform another valuation, pursuant to Subpart C of Part 2619, and to prepare new participant data schedules (§ 2616.17(b)(1)).

Finally, in the unlikely event that a plan is sufficient for all benefit commitments, the participant data schedules need not be submitted since neither the PBGC nor a section 4049 trustee will be paying any benefits under the plan. However, since in this event the completion of the plan termination is essentially the same as in a standard termination, the plan administrator will have to issue notices of benefit commitments in accordance with § 2617.13 and 2617.14 (§ 2616.14(e)).

After determining that a plan qualifies for a distress termination (§ 2616.15), the PBGC will instruct the plan administrator as to how the plan is to be closed out (§ 2616.16), based on the enrolled actuary's findings as to the level of the plan's sufficiency. If the plan is insufficient for guaranteed benefits, all the rules and procedures under prior law apply (with potentially greater liability to the PBGC under section 4062(b)), and, in addition the PBGC will decide whether to establish a section 4049 trust and appoint a trustee. This trustee collects for the section 4049 trust any employer liability payments for the unfunded benefit commitments, and the amounts collected are paid to plan participants. Liability to the section 4049 trust is the lesser of 15% of total benefit commitments or 75% of the unfunded benefit commitments in excess of guaranteed benefits (ERISA section 4062(c)) and is paid over time according to negotiated terms. Thus, while the amounts of participants' guaranteed benefits and benefit commitments are fixed as of the plan's termination date, the total payments (if any) participants will receive pursuant to the termination may not be known for several years.

While SEPPAA provides for the establishment of a section 4049 trust in all cases where a plan is insufficient for benefit commitments, the PBGC believes that in some cases it will be obvious from the outset that the purposes of the trust cannot be realized. Since most distress terminations will occur because of the bankruptcy of the contributing sponsor and the other members of its controlled group, the collectibility of amounts due the section 4049 trust pursuant to section 4062(c) is highly speculative. Even where some amounts might be collectible, the costs attendant thereto may be unreasonable. In addition, there will be costs to the PBGC associated with creating the trust and appointing a trustee, and these costs would be reimbursed only if the trustee is able to collect some of the section 4062(c) liability. Therefore, the PBGC is considering whether to establish a section 4049 trust only in those cases where it is reasonable to do so given the likelihood and potential costs of collection. The PBGC specifically requests public comment on this issue.

If the enrolled actuary's certification indicates that a plan can pay at least all guaranteed benefits, the PBGC will, generally, issue a "distribution notice". The exception to this rule is the case in which a plan's sufficiency for guaranteed benefits is dependent on its collecting all or part of a claim against the contributing sponsor for due and unpaid contributions, and the enrolled actuary is unable to certify that, in his or her belief, the necessary amounts will be collected before the proposed distribution date. In this event, the PBGC will trustee the plan without regard to whether it is sufficient for guaranteed benefits. The purpose of this is to enable the PBGC to pursue collection of the claim for unpaid contributions, since it is the PBGC, through its guarantee obligations, that is at risk in the event the claim is not collected. It is emphasized that, for all other purposes, (for example, allocating plan assets or computing employer liability) a claim for due and unpaid contributions is treated as any other plan asset. (As under the standard termination regulation, in a case where a plan administrator is authorized to distribute plan assets and there is an outstanding claim for unpaid contributions, it is the plan administrator's duty to pursue that claim. The distribution of assets, however, should not be delayed pending liquidation of the claim.)

In a distress termination, unlike in a standard termination, a subsequent insufficiency for guaranteed benefits (or, less likely, a subsequent insufficiency for benefit commitments) does not nullify the termination. It does, however, move the valuation date for all purposes forward to the date that the plan administrator notifies the PBGC of the subsequent insufficiency or the date on which the PBGC, on its own initiative, discovers the subsequent insufficiency (§ 2616.17 (b) and (d)). (In the case of a plan that had been sufficient for all benefit commitments, the valuation date becomes the date of distribution.) Thus, during the period between the termination date and the date of distribution, the risk of loss if a plan goes from being sufficient for guaranteed benefits (or benefit commitments) to insufficient for guaranteed benefits (or benefit commitments) is shared by the contributing sponsor, plan participants and beneficiaries and the PBGC.

This rule derives from ERISA section 4062 (b)(1)(B) and (c)(1)(B), which

provides for moving the valuation date forward for purposes of determining employer liability in the case of a subsequent insufficiency. Equitable treatment of all the involved parties suggests that the valuation date used for determining employer liability must also be used for determining the value of guaranteed benefits payable by the PBGC and of benefit commitments payable to participants and beneficiaries.

Finally, a finding by the PBGC that a plan does not qualify for a distress termination nullifies the proposed termination and all actions taken to effect it are void *ab initio*. However, plan sponsors, plan administrators and plan participants should bear in mind that in cases where it appears that benefit payments to retirees are in jeopardy or that the PBGC's risk of loss is increasing, the PBGC may act to terminate a plan involuntarily under ERISA section 4042.

Miscellaneous Amendments to Other PBGC Regulations

Several provisions in these regulations contradict or modify provisions in other PBGC regulations not mentioned earlier. For example, § 2617.17(c) establishes the right of a plan administrator to appeal the issuance of a notice of noncompliance. The PBGC's administrative appeals regulation (Part 2606) currently does not include this authority. Similarly, other provisions in proposed Parts 2616 and 2617 affect Parts 2615 and 2623 of the PBGC's regulations. In the interests of simplicity, all provisions that would require amendments to Parts 2606, 2615 and 2623 are discussed in this document. PBGC expects to make conforming amendments in the other regulations upon issuance of Parts 2616 and 2617 in final form (or perhaps prior thereto).

E.O. 12291 and the Regulatory Flexibility Act

The PBGC has determined that these proposed regulations are not "major rules" for the purposes of Executive Order 12291, because they will not have an annual effect on the economy of $100 million or more; or create a major increase in costs or prices for consumers, individual industries, or geographic regions; or have significant adverse effects on competition, employment, investment, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. These proposed rules would, if adopted, merely implement the statutory procedures and requirements governing voluntary pension plan terminations.

Under section 605(b) of the Regulatory Flexibility Act, the PBGC certifies that these rules will not have a significant economic impact on a substantial number of small entities. Traditionally pension plans with fewer than 100 participants have been treated as small plans. Seventy-five percent of these plans are defined contribution plans and are not covered by PBGC regulations. Only about 88,000 small plans are covered by the PBGC's single-employer insurance program. Of these, about 6 percent (5,600 plans or about 1.5 percent of all small pension plans) terminate each year and would be covered by the proposed regulations.

Public Comments

The PBGC urges interested parties to submit comments and suggestions on these proposed regulations. Comments should be addressed to: Director, Corporate Policy and Regulations Department (35100), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006. Written comments will be available for public inspection at the above address, Suite 7100, between the hours of 9:00 a.m. and 4:00 p.m. Comments should include the commenter's name and address, and give reasons for any recommendation. This proposal may be changed in light of the comments received.

List of Subjects in 29 CFR Parts 2616 and 2617

Employee Benefit plans, Pension insurance, Pensions, Reporting requirements.

In consideration of the foregoing, the PBGC proposed to revise Parts 2616 and 2617 of Subchapter C of Chapter XXVI, Title 29 of the Code of Federal Regulations as follows:

PART 2616—DISTRESS TERMINATIONS OF SINGLE-EMPLOYER PLANS

Subpart A—General Provisions

Sec.

Subpart B—Distress Termination Process

Appendix—Agreement for Commitment to Make Plan Sufficient for Guaranteed Benefits.

Authority: Secs. 4002(b)(3), 4041 and 4044, Pub. L. 93-406, 88 Stat. 1004, 1020 and 1025, as amended by secs. 403(1), 40(d) and 402(a)(7), Pub. L. 96-364, 94 Stat. 1299, 1301 and 1302, and by secs. 11007 and 11009, Pub. L. 99-272, 100 Stat. 244 and 248 [29 U.S.C. 1302(b)(3), 1341 and 1344].

Subpart A—General Provisions

§ 2616.1 Purpose and scope.

(a) *Purpose.* This regulation sets forth the rules and procedures for terminating a single-employer pension plan in a distress termination. Under the Single-Employer Pension Plan Amendments Act of 1986 ("SEPPAA"), a single-employer plan may be voluntarily terminated only in a "standard" or a "distress" termination, and then only if the termination satisfies the statutory requirements for the type of termination sought. The plan termination rules in SEPPAA apply to all plan terminations initiated by the plan administrator or the Pension Benefit Guaranty Corporation ("PBGC") on or after January 1, 1986. This regulation supersedes the PBGC's Notice of Intent to Terminate regulation (29 CFR Part 2616) and includes new rules governing the notice of intent to terminate for distress terminations, as well as other new substantive and procedural requirements pertaining to those terminations. [The rules for the notice of intent to terminate in a standard termination are now included in new Part 2617.] Subpart A of this regulation contains the various general rules and requirements relating to distress terminations. Subpart B sets forth the specific steps that a plan administrator must follow in order to terminate a plan in a distress termination.

(b) *Scope.* This part applies to any single-employer plan covered under ERISA section 4021(a) and not excluded by section 4021(b) that files a notice of intent to terminate in a distress termination on or after [effective date of part].

§ 2616.2 Definitions.

For purposes of this part:

"Act" means the Employee Retirement

Income Security Act of 1974, as amended by the Multiemployer Pension Plan Amendments Act of 1980 and the Single-Employer Pension Plan Amendments Act of 1986.

"Affected party" means, with respect to a single-employer plan, each participant, each beneficiary of a deceased participant, each alternate payee (as defined in section 206(d)(3)(K) of the Act) under an applicable qualified domestic relations order (as defined in section 206(d)(3)(B)(i)), each employee organization representing participants, and the PBGC. However, in connection with any notice required under this part, if an affected party has designated in writing another person to receive the notice, then any reference to the affected party shall be deemed to refer to the designated person.

"Benefit commitments" means those benefits that: (1) Are guaranteed under section 4022 of the Act; (2) would be guaranteed but for the limitations in section 4022(b); or (3) constitute early retirement supplements or subsidies or plant closing benefits, provided the participant or beneficiary has, prior to the plan termination date, satisfied all of the conditions under the plan to establish entitlement to the benefits, except for the satisfaction of a formal application, retirement, completion of a required waiting period subsequent to application for benefits, or designation of a beneficiary.

"Contributing sponsor" means, with respect to a single-employer plan, the person responsible for meeting the minimum funding requirements under section 302 of the Act or section 412 of the Internal Revenue Code of 1954, and any person that is a member of the contributing sponsor's controlled group and was responsible for meeting the funding requirements with respect to the plan at a time when the person employed a significant number of the plan participants.

"Distress termination notice" means the notice filed with the PBGC pursuant to section 4041(c)(2)(A) of the Act and § 2616.14 of this part that contains information demonstrating satisfaction of the distress criteria and also provides various plan and participant data including, but not limited to, an enrolled actuary's certification of the level of benefits funded under the plan.

"Insurer" means a company authorized to do business as an insurance carrier under the laws of a state or the District of Columbia.

"Multiple employer plan" means a single-employer plan maintained by two or more contributing sponsors that are not members of the same controlled group, under which all plan assets are available to pay benefits to all plan participants and beneficiaries.

"Notice of intent to terminate" means the notice to affected parties advising them of a proposed plan termination, as required by section 4041(a)(2) of the Act and § 2616.12 of this part.

"Participant" means any individual who is in employment covered by the plan and is earning or retaining credited service (including an individual who is below the integration level in a plan that is integrated with Social Security); any non-vested individual separated from employment who is earning or retaining credited service, excluding those individuals who have incurred a break in service of one year or the plan's break-in-service period, whichever is greater; and any individual who has retired or separated from employment and is either receiving benefits or entitled to begin receiving benefits in the future, excluding those individuals to whom an insurance company has made an irrevocable commitment to pay all the benefits to which the individual is entitled under the plan.

"PBGC" means the Pension Benefit Guaranty Corporation.

"Proposed termination date" means the date specified as such by the plan administrator in a notice of intent to terminate. A proposed termination date may not be earlier than the 60th day after the issuance of the notice of intent to terminate, nor later than the 180th day thereafter. The proposed termination date is used in the distress termination notice as the date for demonstrating satisfaction of the distress criteria, for determining participants' and beneficiaries' benefit commitments and guaranteed benefits, and for valuing plan benefits and assets in some cases.

"SEPPAA" means the Single-Employer Pension Plan Amendments Act of 1986.

"Single-employer plan" means any defined benefit plan (as defined in section 3(35) of the Act) that is not a multiemployer plan (as defined in section 4001(a)(3)).

"Substantial member of a controlled group" means a member of the contributing sponsor's controlled group whose gross assets (both tangible and intangible), as of the termination date, equal five percent or more of the total gross assets of the controlled group. Any member of the contributing sponsor's controlled group as of the termination date shall be deemed to be a substantial member for all purposes under this part, unless the plan administrator demonstrates to the satisfaction of the PBGC that the person's gross assets equal less than five percent of the controlled group's total gross assets.

"Termination date" means the date established pursuant to section 4048(a)(2) of the Act or, if applicable, section 4048(a)(4). The termination date is the date as of which a contributing sponsor and the substantial members of its controlled group (if any) must satisfy the distress criteria and the date for determining benefit commitments and guaranteed benefits.

§ 2616.3 Requirements for a distress termination.

(a) *Exclusive means of voluntary plan termination.* A plan may be voluntarily terminated by the plan administrator only in a standard termination or a distress termination. For a standard termination to occur, a plan must be able to discharge all of its obligations for benefit commitments and otherwise satisfy the requirements set forth in Part 2617 of this subchapter. A distress termination may occur only if all of the requirements set forth in paragraph (b) of this section are satisfied.

(b) *Requirements.* A plan may terminate in a distress termination only if—

(1) The plan administrator issues a notice of intent to terminate to affected parties in accordance with § 2616.12 at least 60 days before the proposed termination date;

(2) The plan administrator submits a distress termination notice to the PBGC in accordance with § 2616.14 no later than 60 days after the proposed termination date; and

(3) The PBGC determines that the contributing sponsor and each substantial member of its controlled group satisfy one of the distress criteria set forth in paragraph (d) of this section.

(c) *Effect of failure to satisfy requirements.* If any of the requirements of paragraph (b) of this section is not satisfied, any action taken to effect the plan termination shall be null and void, and the plan shall be an ongoing plan for all purposes. A plan administrator who still desires to terminate the plan shall initiate the termination process again from the beginning, starting with the issuance of a notice of intent to terminate. The PBGC retains its authority in any case to initiate a plan termination under section 4042 of the Act.

(d) *Distress criteria.* A contributing sponsor and each substantial member of its controlled group (as defined in § 2616.2) shall satisfy at least one of the following criteria in order for a distress termination to occur. The contributing sponsor and the substantial members of

the controlled group need not all satisfy the same test.

(1) *Liquidation in bankruptcy.* This criterion is met if, as of the termination date, a person has filed or had filed against it a petition seeking liquidation in a case under title 11, United States Code, or under a similar law of a state or political subdivision of a state, or a case described in paragraph (d)(2)(i) of this section has been converted to such a case, and, as of the termination date, the case has not been dismissed.

(2) *Reorganization in bankruptcy.* This criterion is met if—

(i) As of the termination date, a person has filed or had filed against it a petition seeking reorganization in a case under title 11, United States Code, or under a similar law of a state or a political subdivision of a state, or a case described in paragraph (d)(1) of this section has been converted to such a case;

(ii) The case has not been dismissed as of the termination date; and

(iii) The bankruptcy court or appropriate state court approves the termination.

(3) *Inability to continue in business.* This criterion is met if a person demonstrates to the satisfaction of the PBGC that, unless a distress termination occurs, the person will be unable to pay its debts when due and to continue in business.

(4) *Unreasonably burdensome pension costs.* This criterion is met if a person demonstrates to the satisfaction of the PBGC that the person's costs of providing pension coverage have become unreasonably burdensome solely as a result of declining covered employment under all single-employer plans for which that person is a contributing sponsor.

(e) *Non-recognition of certain actions.* If the PBGC finds that a person undertook any action or failed to act for the principal purpose of satisfying any of the criteria contained in paragraph (d) of this section, rather than for a reasonable business purpose, the PBGC shall disregard such act or failure to act in determining whether the person has satisfied any of those criteria.

§ 2616.4 Administration of plan during pendency of termination proceedings.

(a) *Prohibitions after filing notice of intent to terminate.* Beginning on the date that the plan administrator files with the PBGC (as defined in § 2616.8) a notice of intent to terminate, and unless and until the PBGC issues a distribution notice pursuant to § 2616.16 (b) or (c), the plan administrator may not—

(1) Distribute plan assets pursuant to, or take any other actions to implement, the termination of the plan;

(2) Pay benefits attributable to employer contributions, other than death benefits, in any form other than as an annuity;

(3) Use plan assets to purchase irrevocable commitments to provide benefits from an insurer; or

(4) Pay benefits in excess of a participant's benefit commitments under the plan.

(b) *Benefit payments on or after proposed termination date.* Notwithstanding paragraph (a)(4) of this section, beginning on the proposed termination date specified in the notice of intent to terminate, and unless and until the PBGC issues a distribution notice, the plan administrator may not make any benefit payments in excess of the greater of—

(1) A participant's estimated guaranteed benefit, determined pursuant to § 2623.6 of this subchapter; or

(2) A participant's estimated Title IV benefit, determined pursuant to § 2623.7 of this subchapter. For purposes of applying §§ 2623.6 and 2623.7, the term "section 4041(a) date of termination" used therein shall be replaced by the term "proposed termination date".

(c) *Failure to qualify for distress termination.* In any case where the PBGC determines, pursuant to § 2616.13(c) or § 2616.15(c), that the requirements for a distress termination are not satisfied, any benefits that were not paid pursuant to paragraph (a)(4) or (b) of this section shall be due and payable as of the date of the PBGC's determination, together with interest, from the date (or dates) on which the unpaid amounts were originally due, at the rate prescribed under Part 2610 in effect on that date (or dates).

(d) *Other administrative actions.* Except to the extent specifically limited by this section, the plan administrator shall continue to carry out the normal operations of the plan, such as putting participants into pay status, collecting contributions due the plan and investing plan assets.

§ 2616.5 Challenges to plan termination under a collective bargaining agreement.

(a) *Suspension of termination proceeding.* If, prior to the issuance by the PBGC of a notice of inability to determine sufficiency or a distribution notice pursuant to § 2616.16, the PBGC is advised that a formal challenge (as defined in paragraph (c) of this section) has been initiated asserting that the proposed termination violates the terms and conditions of an existing collective bargaining agreement, the PBGC shall suspend the termination proceeding and shall so advise the plan administrator in writing. The effect of the suspension shall be to stay the issuance by the PBGC of a notice of inability to determine sufficiency or a distribution notice. However, nothing in this paragraph relieves the plan administrator of the obligation to comply with § 2616.4 and to file a distress termination notice with the PBGC in the manner and within the time specified in § 2616.14.

(b) *Resolution of challenge.* Immediately upon the final resolution (as defined in paragraph (d) of this section) of the formal challenge to the termination, the plan administrator shall notify the PBGC in writing of the outcome of the challenge. If the validity of the proposed termination has been upheld, the plan administrator shall also advise the PBGC of whether the plan administrator wishes to continue the termination.

(1) *Challenge sustained.* If it has been determined that the proposed termination violates the collective bargaining agreement, the PBGC shall dismiss the termination proceeding, all actions taken to effect the plan termination shall be null and void, and the plan shall be an ongoing plan for all purposes. In this event, § 2616.4(c) shall apply, as of the date of the PBGC's dismissal, with respect to any benefits not paid pursuant to § 2616.4 (a)(4) or (b).

(2) *Termination sustained.* If it has been determined that the proposed termination does not violate the collective bargaining agreement and the plan administrator wishes to proceed with the termination, the PBGC shall reactivate the termination proceeding by sending a written notice thereof to the plan administrator. In that event, all actions taken to effect the termination prior to the suspension shall be effective, and the PBGC shall proceed to issue a notice of inability to determine sufficiency or a distribution notice, either with or without first requesting updated information from the plan administrator pursuant to § 2616.14(f).

(c) *Formal challenge to plan termination.* The occurrence of any of the following actions, asserting that the termination would violate the terms and conditions of an existing collective bargaining agreement, shall constitute grounds for the PBGC to suspend the termination proceeding:

(1) The commencement of any procedure specified in the collective bargaining agreement for resolving disputes under the agreement.

(2) The filing of a charge with the National Labor Relations Board alleging an unfair labor practice under section 8 of the National Labor Relations Act.

(3) The commencement of an action under section 301 of the National Labor Relations Act in a court of competent jurisdiction.

(d) *Final resolution of challenge.* For the purposes of this section, a formal challenge to a proposed termination shall be considered finally resolved when the parties involved in the challenge enter into a settlement that resolves the challenge or upon the issuance of a final, non-appealable order, as defined in this paragraph. Depending upon the type of action challenging the termination, any of the following constitutes a final, non-appealable order:

(1) An arbitrator's award that is neither appealed nor is review thereof sought within the time for filing such appeals or requesting review.

(2) An order of the National Labor Relations Board for which the Board does not petition for enforcement nor the person aggrieved petition for review within the time permitted for filing such actions.

(3) An order by a court of competent jurisdiction that is not appealed within the time limit for filing such appeals.

(4) When an appeal is taken from or a request for review is made concerning a decision described in paragraph (d)(1), (d)(2) or (d)(3) of this section, an order by a court of competent jurisdiction finally resolving the dispute.

(e) *Involuntary termination by the PBGC.* Paragraphs (a) and (b) of this section notwithstanding, the PBGC retains the authority in any case to initiate a plan termination in accordance with the provisions of section 4042 of the Act.

§ 2616.6 Requirement for annuities.

(a) *General rule.* Except as provided in paragraph (b) of this section, when a plan administrator distributes all plan assets pursuant to § 2616.18, any benefit to which assets are allocated pursuant to Part 2618 that is payable as an annuity under the provisions of the plan must be provided in annuity form through the purchase from an insurer of a single premium, nonparticipating (except in the case of a plan that is sufficient for all accrued benefits), nonsurrenderable annuity that constitutes an irrevocable commitment by the insurer to provide the benefits purchased.

(b) *Exceptions.* [Reserved]

(c) *Required form of annuity.* [Reserved]

§ 2616.7 Contributing sponsor's commitment to make plan sufficient for guaranteed benefits.

At any time prior to the filing with the PBGC of a distress termination notice, a contributing sponsor may make a commitment to contribute any additional sums necessary to make a plan sufficient for all guaranteed benefits, in order to enable the plan to distribute assets in full satisfaction of all guaranteed benefits. The commitment shall be in writing and be signed by the contributing sponsor and shall contain substantially the same provisions as the sample commitment in the appendix to this part. In addition, a commitment by a contributing sponsor that satisfies either the bankruptcy liquidation or reorganization distress criterion (§ 2616.3 (d)(1) or (d)(2)), shall be valid under this section only if it is approved by the court before which the liquidation or reorganization proceeding is pending. A commitment that meets the requirements of this section shall be considered a plan asset for all purposes under this part. In the event that a contributing sponsor fails to honor its commitment, rendering a plan insufficient for guaranteed benefits, the PBGC may bring an action to enforce the commitment.

§ 2616.8 Filings with the PBGC; time limits.

(a) *"Filing" defined.* Any document required or permitted to be filed with the PBGC under this part shall be deemed filed on the date it is received at the PBGC, providing it is received on a weekday, other than a Federal holiday, no later than 4:00 p.m. Documents received after 4:00 p.m. or on weekends or Federal holidays shall be deemed filed on the next regular business day.

(b) *How to file.* Any document being filed under this part may be delivered by mail or by hand to the PBGC's Case Classification and Control Division, Control Branch, Room 5300A (Code 25420), 2020 K Street NW., Washington, DC 20006.

(c) *Time limits.* If the last day of any period prescribed by this part for issuing or filing any notices or other documents or taking any other actions falls on a Saturday, Sunday or legal holiday, then the last day of the period shall be the next regular business day.

Subpart B—Distress Termination Process

§ 2616.11 Purpose and scope.

This subpart describes in detail the distress termination process. Sections 2616.12 and 2616.14 prescribe the contents of and the rules for issuing the two statutory notices that plan administrators must issue in a distress termination. The first notice, which is issued to all affected parties to begin the termination process, is the "notice of intent to terminate". The second notice, which is issued only to the PBGC, is the "distress termination notice". Sections 2616.15 and 2616.16 cover the PBGC's review of the proposed termination and the actions that the PBGC may take with respect to it. Sections 2616.17 and 2616.18 apply only to plans that are at least sufficient for guaranteed benefits and describe the actions the plan administrator must take to close out the plan.

§ 2616.12 Notices of intent to terminate.

(a) *General Rule.* At least 60 days and no more than 180 days prior to the proposed plan termination date, the plan administrator shall issue to each affected party (as defined in § 2616.2) a notice of intent to terminate containing all of the information specified in paragraph (d) of this section and, to the extent applicable, paragraph (e) of this section.

(b) *Method of issuance.* Notices of intent to terminate shall be issued individually to each affected party. The notice to the PBGC shall be filed in accordance with § 2616.8. The notices to the other affected parties shall be either hand delivered or delivered by first-class mail or courier service to the affected party's last known address.

(c) *When issued.* The notice of intent to terminate is deemed issued to the PBGC on the date on which it is filed (as defined in § 2616.8) and to the other affected parties on the date on which it is handed to the affected party or deposited with a mail or courier service.

(d) *Contents of notice.* Each notice of intent to terminate shall contain all of the following information (and the notice to the PBGC shall also contain the information described in paragraph (e) of this section):

(1) The name of the plan and of the contributing sponsor.

(2) The Employer Identification Number ("EIN") of the contributing sponsor and the Plan Identification Number ("PN"); if there is no EIN or PN, the notice shall so state.

(3) The name, address and telephone number of the person who may be contacted by an affected party with questions concerning the plan's termination.

(4) A statement that the plan administrator expects to terminate the plan on a specified proposed termination date (as defined in § 2616.2).

(5) A statement that the benefits under the plan are guaranteed by the

PBGC, including a brief description of what benefits are guaranteed (*e.g.*, if only a portion of the benefits are guaranteed because of the phase-in rule, this shall be explained), and that participants and beneficiaries may also receive a portion of the benefits to which each is entitled under the terms of the plan in excess of guaranteed benefits.

(6) For retirees only, a statement that their monthly (or other periodic) benefit amount may be reduced because of the plan's termination, but not below the amount guaranteed by the PBGC, or, if applicable, that the benefit amount may be reduced below the guarantee level if the benefits are subject to recoupment by the PBGC pursuant to Part 2623 of this subchapter.

(e) *Additional information for notice of intent to terminate filed with PBGC.* In addition to the information required under paragraph (d) of this section, the notice of intent to terminate that is filed with the PBGC shall contain the following:

(1) The name, address and telephone number of the plan administrator and of the plan administrator's duly authorized representative, if any.

(2) If premiums for the plan have been paid under another Employer Identification Number or Plan Identification Number, that EIN or PN.

(3) A statement of whether the plan is a multiple employer plan; if so, the names and EIN's of all contributing sponsors shall be given.

(4) The total number of plan participants (actives and retirees).

(5) The plan year ending date.

(6) The date (or latest date) on which the notices of intent to terminate were (or will be) issued to the other affected parties and a statement that they were (or will be) issued in accordance with § 2616.12.

(7) A statement of whether any participants or beneficiaries in pay status (or entitled to be in pay status) are not receiving their benefits, and whether the plan administrator expects to be able to pay all benefits when due during the 180-day period following issuance of the notices of intent to terminate.

(8) A list of all members of the contributing sponsor's controlled group, with the EIN of each, as of the proposed termination date and a statement of which distress test each is expected to satisfy; (if the plan administrator expects to demonstrate that any of these persons is not a substantial member of the controlled group, as defined in § 2616.2, the list shall so identify those persons and no distress test need be listed for them). If a petition seeking liquidation or reorganization under title 11, United States Code (or under similar law of a state or political subdivision thereof) has already been filed by or against the contributing sponsor or any member of its controlled group, a copy of the filed petition showing the court docket number shall also be submitted.

§ 2616.13 PBGC review of notice of intent to terminate.

(a) *General.* Upon receipt of a notice of intent to terminate, the PBGC shall review the notice to determine whether it was issued in accordance with § 2616.12 and shall advise the plan administrator of its determination, in accordance with paragraph (b) or (c) of this section, no later than the proposed termination date specified in the notice. The PBGC shall also review the notice, and may require the submission of additional information pursuant to paragraph (d) of this section, for the purpose of determining whether the PBGC should consider initiating an involuntary termination or the appointment of a trustee without an immediate termination under section 4042 of the Act.

(b) *Tentative finding of compliance.* If the PBGC determines that the issuance of the notices of intent to terminate appears to have complied with § 2616.12, it shall notify the plan administrator in writing of this tentative determination of compliance and that this determination will be made final or reversed after the PBGC has reviewed the distress termination notice filed pursuant to § 2616.14. The effect of this tentative determination is to allow the distress termination proceeding to continue.

(c) *Improper notice.* If the PBGC determines that the issuance of the notices of intent to terminate failed to comply with § 2616.12, it shall so notify the plan administrator in writing and advise the plan administrator that the proposed distress termination is null and void and that the plan is an ongoing plan for all purposes. In addition, the PBGC may require the plan administrator to submit the information prescribed by paragaph (d) of this section, in order to enable the PBGC to determine whether it should institute proceedings under section 4042.

(d) *Information on need to institute section 4042 proceedings.* Whenever a notice of intent to terminate indicates that there are currently benefits in pay status (or that should be in pay status) that are not being paid or that this is likely to occur within the 180-day period following the issuance of the notices of intent to terminate, or whenever the PBGC issues a determination under paragraph (c) of this section, or in any other case where the PBGC has any reason to believe that it may be necessary or appropriate to institute proceedings under section 4042 of the Act, it may require the plan administrator to submit the following information within a reasonable period of time specified in the request for the information.

(1) A copy of the most recent actuarial valuation of the plan.

(2) A statement of whether any funding waivers under section 303 of the Act or extensions of the amortization period under section 304 have been granted within the five years preceding the proposed termination date, and if so, the amounts involved, and whether any requests for waivers or extensions are currently pending, and if so, the amounts involved.

(3) Any other information that the PBGC determines that it needs in order to decide whether to institute termination or trusteeship proceedings pursuant to section 4042.

(e) *Appeal of determination that notice was improper.* A plan administrator may appeal the PBGC's determination under paragraph (c) of this section in accordance with the rules prescribed in Subpart D of Part 2606. The filing of an appeal automatically stays the effectiveness of the determination until the PBGC issues its decision on the appeal. However, a request for information by the PBGC under paragraph (c) of this section is not stayed by the filing of the appeal.

§ 2616.14 Distress termination notice.

(a) *General rule.* Except to the extent permitted by paragraph (d) of this section, no later than 60 days after the proposed termination date specified in the notice of intent to terminate, the plan administrator shall file with the PBGC, in accordance with § 2616.8, a "distress termination notice". The distress termination notice shall be clearly identified as such and shall contain the information described in paragraphs (b)–(d) of this section. Unless otherwise specified, all data and other information submitted shall be as of the proposed termination date.

(b) *Proof of distress.* In order to establish that the plan qualifies for a distress termination, the plan administrator shall submit the following:

(1) If applicable, the name and Employer Identification Number of each member of the contributing sponsor's controlled group that is not a substantial member of the controlled group and evidence demonstrating to the PBGC's satisfaction that such members are not

substantial. Such evidence shall in every case include—

(i) The controlled group's audited (or, if not available, unaudited) consolidated or combined (as applicable) financial statements for the most recent five years ending, prior to the proposed termination date, updated to show any material changes;

(ii) Audited (or, if not available, unaudited) financial statements for the five years ending prior to the proposed termination date (updated to show any material changes) for each member of the controlled group that the plan administrator asserts is not a substantial member; and

(iii) Any other relevant evidence.

(2) Identification of the distress test satisfied by the contributing sponsor and each substantial member (all members need not satisfy the same distress test).

(3) For the contributing sponsor and each substantial member of its controlled group, proof of satisfaction of a distress test, as follows:

(i) For the bankruptcy liquidation and reorganization tests, a copy of the filed petition showing the court docket number (unless this was submitted as part of the notice of intent to terminate), and for the reorganization test only, a copy of the order of the bankruptcy court or the appropriate state court approving the termination.

(ii) For the test of inability to stay in business without plan termination—

(A) Audited (or, if not available, unaudited) financial statements for the three most recent fiscal years ending prior to the proposed termination date, updated to show any material changes; if the person is undergoing (or has undergone) a partial liquidation, the financial statements must specify the data relating to the liquidating portion and estimated liquidation values and the source thereof shall be given;

(B) Projections of future revenues and expenses assuming both the continuation and the termination of the pension plan for which a distress termination is sought, for the next three fiscal years beginning with the year in which the plan would terminate; the projections that assume plan continuation must include estimated minimum funding contributions for each of those three years, and the projections that assume plan termination must include the projected termination liabilities to the PBGC, the section 4042 trustee and the section 4049 trust (amended section 4062 defines these liabilities);

(C) Certification by the person's chief financial officer or chief executive officer that all of the information submitted is accurate and complete to the best of that individual's knowledge, and that the person will not be able to continue in business without the plan termination;

(D) All recent (within the prior three years) financial analyses (if any) done of the person by an outside party, with a certification by the person's chief financial officer that the information on which the analysis was based was accurate and complete;

(E) All submissions (if any) made within the prior three years to a financial institution or investment banker in support of possible outside financing;

(F) A statement of whether any funding waivers under section 303 of the Act or extensions of the amortization period under section 304 have been granted within the five years preceding the proposed termination date, and if so, the amounts involved, and whether any requests for waivers or extensions are currently pending or planned, and if so, the amounts involved; and

(G) Any other relevant information.

(iii) For the test of unreasonably burdensome pension costs—

(A) The name and plan identification number of each single-employer defined benefit plan for which the person is a contributing sponsor;

(B) The latest Form 5500 Schedule B filed for each plan named in paragraph (b)(3)(iii)(A) of this section;

(C) For each plan named in paragraph (b)(3)(iii)(A) of this section, a plan census showing total, active and retired participants for the most recent five plan years ending prior to the proposed termination date; (these data may be provided by submitting the relevant Forms 5500 Schedules B);

(D) Audited (or, if not available, unaudited) financial statements of the person for the most recent five fiscal years ending prior to the proposed termination date, updated to show any material changes, with a breakout of the person's total pension costs (including any defined contribution plans) as a percentage of the person's total wage costs and a statement of the total costs per plan;

(E) A statement of whether any funding waivers under section 303 of the Act or extensions of the amortization period under section 304 have been granted within the five years preceding the proposed termination date, and if so, the amounts involved, and whether any requests for waivers or extensions are currently pending or planned, and if so, the amounts involved; and

(F) any other relevant information.

(c) *Plan data.* The plan administrator shall submit the following documents and information relating to the plan and its level of funding. Each item of information shall be numbered as the items are numbered in this paragraph.

(1) A copy of the executed plan document and any amendments thereto.

(2) A copy of any IRS determination letters.

(3) A statement of whether a formal challenge to the termination, as defined in § 2616.4(c), has been initiated, and if so, what action was initiated, by whom and on what date, and the current status of the challenge.

(4) If, as of the proposed termination date or thereafter, the contributing sponsor or any member of its controlled group is the subject of a proceeding described in § 2616.3 (d)(1) or (d)(2), copies of all motions, memoranda, notices or other filings in that proceeding with respect to the plan.

(5) A summary of plan participants and beneficiaries, showing the total numbers in each of the following categories:

(i) Retirees (including disability retirees) and beneficiaries receiving benefits.

(ii) Active participants eligible for normal retirement.

(iii) Active participants eligible for early (but not normal) retirement.

(iv) All other active participants vested before termination.

(v) All active, non-vested (before termination) participants.

(vi) Participants separated from service with deferred vested benefits.

(6) A certification by an enrolled actuary pursuant to paragraph (c)(6) (i), (ii), (iii) or (iv) of this section, as applicable. All values shall be as of the proposed termination date, except for benefits that are valued in accordance with Part 2619, Subpart B, in which event those benefits shall be valued as of a proposed distribution date that is no earlier than the proposed termination date.

(i) *Plan insufficient for guaranteed benefits.* If the plan is not sufficient for benefits in priority categories 1–4 of section 4044(a) of the Act as of the proposed termination date, the certification shall include the following:

(A) The value of the plan's assets valued in accordance with Part 2620;

(B) The actuarial present value of the plan's benefit commitments valued in accordance with Part 2619, Subpart C;

(C) The actuarial present value of the plan's benefits in priority categories 1–4 of section 4044(a) of the Act valued in accordance with Part 2619, Subpart C; and

(D) A statement that the plan is not sufficient for all benefits in priority categories 1–4.

(ii) *Plan sufficient for guaranteed benefits.* If the plan is sufficient for all benefits in priority categories 1–4 of section 4044(a), the certification shall include the following:

(A) The value of the plan's assets valued in accordance with Part 2620;

(B) The actuarial present value of the plan's benefit commitments valued in accordance with Part 2619, Subpart C;

(C) The actuarial present value of the plan's benefits that can be purchased from an insurer valued in accordance with Part 2619, Subpart B and a copy of the qualifying bid; and

(D) A statement that the plan is sufficient for all benefits in priority categories 1–4.

(iii) *Plan sufficient for benefit commitments.* If the plan is sufficient for all benefit commitments, the certification shall include the following:

(A) The value of the plan's assets valued in accordance with Part 2620;

(B) The actuarial present value of the plan's benefit commitments valued in accordance with Part 2619, Subpart B and a copy of the qualifying bid; and

(C) A statement that the plan is sufficient for all benefit commitments.

(iv) *Special rule for plans with claims for due and unpaid contributions.* Except as provided in the next sentence, if collection of any portion of a claim for due and unpaid contributions is necessary to make the plan sufficient for guaranteed benefits, then the enrolled actuary shall value the plan's assets and benefits in accordance with paragraph (c)(6)(i) of this section. If the enrolled actuary certifies that he or she believes that the amount needed to make the plan sufficient for guaranteed benefits will be collected prior to the proposed distribution date, then the enrolled actuary shall value the plan's assets and liabilities in accordance with paragraph (c)(6)(ii) of this section. In either case described in this paragraph, the certification shall also include a statement by the enrolled actuary of whether or not the plan is sufficient for guaranteed benefits.

(7) If the enrolled actuary certifies that the plan is not sufficient for benefits in priority categories 1–4 of section 4044(a), a description of the plan's funding arrangement, including copies of any executed group annuity or insurance contracts or trust agreements.

(8) A list of all plan assets, including, if applicable, a contributory sponsor's commitment made pursuant to § 2616.7.

(9) A certification by the plan administrator that the information submitted and statements made pursuant to paragraph (b) of this section and this paragraph and the information made available to the enrolled actuary are all accurate and complete.

(d) *Participant data schedules.* Within 20 days after receipt of the PBGC's determination under § 2616.15(b) that the requirements for a distress termination have been satisfied, the plan administrator shall file with the PBGC participant data schedules containing the information prescribed by this paragraph and shall certify that the information is accurate and complete. Each item of information shall be numbered as the items are numbered in this paragraph. (If desired, the plan administrator may submit the data required by this paragraph on computer tape after first obtaining from the PBGC the specifications therefor.)

(1) Name and last known address of each participant and beneficiary, including—

(i) Identification of any such persons who are officers or owner-employees; and

(ii) The percentage of the business owned by each.

(2) Sex and date of birth of each participant and beneficiary.

(3) For each participant, the date on which participation began and the date on which employment terminated, if that date is earlier than the proposed plan termination date.

(4) For each participant (including deceased participants whose beneficiaries are entitled to benefits under the plan), the specific data used to compute the participant's accrued benefit (*e.g.*, credited service, compensation, etc.) Social Security benefits, and the ages of the participant and beneficiary as of the earlier of the date of retirement or the proposed termination date.

(5) If the enrolled actuary has certified that the plan is sufficient for guaranteed benefits, with respect to each participant, the accrued monthly benefit, vesting percentage, amount, form, type (for benefits in pay status) and value of the monthly benefit commitments and the value of the monthly benefits to which assets are allocated pursuant to ERISA section 4044 and Part 2618 of this subchapter; for benefits in pay status, include the benefit commencement date. For purposes of this paragraph and paragraph (d)(6) of this section, benefit "type" means nature of benefit entitlement, *e.g.*, normal, early, or shutdown benefit, and benefit "form" means form of payment or annuity, *e.g.*, lump sum, period certain annuity or joint and survivor annuity. For joint and survivor benefits, include the benefit reduction, if any, for the participant and the percentage of the participant's benefit that continues to the survivor.

(6) If the enrolled actuary has certified that the plan is not sufficient for guaranteed benefits, with respect to each participant, the accrued monthly benefit, vesting percentage, amount, form, type (for benefits in pay status) and value of the monthly guaranteed benefit and of the monthly benefit commitments and the value of the monthly guaranteed benefit to which assets are allocated; for benefits in pay status, include the benefit commencement date, and for joint and survivor benefits, include the benefit reduction, if any, for the participant and the percentage of the participant's benefit that continues to the survivor.

(e) *Special rule for plans sufficient for benefit commitments.* In any case in which the enrolled actuary certifies that the plan is sufficient for all benefit commitments, the plan administrator need not submit the participant data schedules required under paragraph (d) of this section. However, in that event, prior to the date prescribed in paragraph (d) of this section for filing the schedules, the plan administrator shall issue to participants and beneficiaries described in 2617.13(b) notices of benefit commitments in accordance with §§ 2617.13 and 2617.14 and shall file with the PBGC, on or before the date prescribed in paragraph (d) of this section, a certified statement that the notices of benefit commitments were so issued.

(f) *Additional information.* The PBGC may in any case require the submission of any additional information that it needs to make the determinations that it is required to make under this subpart or to pay benefits pursuant to sections 4061 or 4049 of the Act.

§ 2616.15 PBGC determination of compliance with requirements for distress termination.

(a) *General.* Upon receipt of a distress termination notice, the PBGC shall determine whether the qualifications for a distress termination set forth in § 2616.3(b) have been met and shall notify the plan administrator in writing of its determination, in accordance with paragraph (b) or (c) of this section. The PBGC's determination shall be based on the information contained in the notice of intent to terminate and the distress termination notice, and on any information submitted by an affected party or otherwise obtained by the PBGC.

(b) *Qualifying termination.* If the PBGC determines that all of the requirements of § 2616.3(b) have been

satisfied, it shall so advise the plan administrator and shall also advise the plan administrator that participant data schedules must be submitted in accordance with § 2616.14(d).

(c) *Non-qualifying termination.* Except as provided in paragraph (c)(1) of this section, if the PBGC determines that the plan administrator failed to issue the notices of intent to terminate or the distress termination notice in accordance with § 2616.12 or § 2616.14, respectively, or that the distress criteria set forth in § 2616.3(d) were not met, it shall notify the plan administrator of this determination and the basis therefor. In addition, the notice shall advise the plan administrator of the effects of this determination, *viz.*, that the proposed termination is null and void, that all actions taken to cause or implement the termination are without effect, and that the plan is an ongoing plan for all purposes.

(1) If the basis for the PBGC's determination of non-qualification is that the plan administrator timely filed an incomplete distress termination notice, the PBGC shall notify the plan administrator of the missing items of information and advise the administrator that the information must be filed with the PBGC no later than the 60th day after the proposed termination date or the 20th day after the date of the PBGC notice, whichever is later.

(2) Failure to comply with the terms of a notice described in paragraph (c)(1) of this section shall nullify the proposed termination, and the PBGC shall so notify the plan administrator in accordance with paragraph (c) of this section.

(d) *Appeal of determination of non-qualification.* A plan administrator may appeal the PBGC's determination under paragraph (c) of this section in accordance with the rules prescribed in Subpart D of Part 2606. The filing of an appeal automatically stays the effectiveness of the determination until the PBGC issues its decision on the appeal.

§ 2616.16 PBGC determination of plan sufficiency/insufficiency.

(a) *General.* Upon receipt of the participant data schedules filed pursuant to § 2616.14(d) (or, where appropriate, the certification of issuance of notices of benefit commitments filed pursuant to § 2616.14(e)), the PBGC shall determine the degree to which the plan is sufficient and notify the plan administrator in writing of its determination in accordance with paragraph (b), (c) or (d) of this section.

(b) *Insufficiency for guaranteed benefits.* If the PBGC finds that it is unable to determine that a plan is sufficient for guaranteed benefits, it shall issue a "notice of inability to determine sufficiency" notifying the plan administrator of this finding and advising the plan administrator that—

(1) The plan administrator shall continue to administer the plan under the restrictions imposed by § 2616.4;

(2) The termination shall be completed under section 4042 of the Act; and

(3) Unless the PBGC has determined that all benefit commitments under the plan are guaranteed benefits under section 4022 of the Act, the PBGC will determine whether to establish a section 4049 trust with respect to the plan.

(c) *Sufficiency for guaranteed benefits.* Except as provided in paragraph (e) of this section, if the PBGC determines that a plan is sufficient for guaranteed benefits, but is unable to determine that the plan is sufficient for benefit commitments, it shall issue to the plan administrator a "distribution notice" instructing the plan administrator to distribute all plan assets in accordance with § 2616.18 and advising the administrator that the PBGC will determine whether to establish a section 4049 trust with respect to the plan. The PBGC may also require the plan administrator to submit any additional information needed to verify the amounts of participants' and beneficiaries' benefit commitments.

(d) *Sufficiency for benefit commitments.* If the PBGC determines that a plan is sufficient for benefit commitments, it shall issue to the plan administrator a "distribution notice" instructing the plan administrator to distribute all plan assets in accordance with § 2616.18.

(e) *Special rules for certain plans with claims for due and unpaid contributions.* If the PBGC finds that a plan would become sufficient for guaranteed benefits only if the plan collects all or a portion of a claim for due and unpaid contributions and the enrolled actuary did not certify that he or she believed the necessary amount would be collected prior to the proposed distribution date, the plan shall be treated like a plan described in paragraph (b) of this section.

(f) *Plan records.* The PBGC shall also advise the plan administrator that all records needed to compute the benefit commitments (if any) of each individual who is a plan participant or beneficiary as of the termination date (excluding those individuals who were in pay status for longer than one year as of that date), *e.g.*, records showing a participant's age, marital status, employment history, etc., shall be preserved for six years after the date of the post-distribution certification required under § 2616.18(c). These records shall be retained by either the plan administrator or the contributing sponsor.

§ 2616.17 Verification of plan sufficiency prior to close out.

(a) *General.* Prior to making the final distribution of plan assets, the plan administrator shall verify whether the plan is still sufficient, *i.e.*, is able to pay benefits, at the level determined by the PBGC, *i.e.*, guaranteed benefits or benefit commitments. If the plan administrator finds that the plan is no longer able to pay benefits at the level determined by the PBGC, then paragraph (b) or (c) of this section, as appropriate, shall apply.

(b) *Subsequent insufficiency for guaranteed benefits.* When a plan administrator finds that a plan has become insufficient for guaranteed benefits, the plan administrator shall promptly notify the PBGC in writing of that fact and may take no further action to implement the plan termination, pending the PBGC's determination and notice pursuant to paragraph (b)(1) or (b)(2) of this section.

(1) *PBGC concurrence with finding.* If the PBGC concurs with the plan administrator's finding, the distribution notice shall be void, and the PBGC shall issue the plan administrator a new notice in accordance with § 2616.16(b). In addition, the PBGC shall require the plan administrator to submit a new valuation, certified to by an enrolled actuary, of the benefit commitments and guaranteed benefits under the plan valued in accordance with Part 2619, Subpart C, as of the date of the plan administrator's notice to the PBGC.

(2) *PBGC non-concurrence with finding.* If the PBGC does not concur with the plan administrator's finding, it shall so notify the plan administrator in writing, and the distribution notice shall remain in effect.

(c) *Subsequent insufficiency for benefit commitments.* When a plan administrator finds that a plan has become insufficient for benefit commitments, the plan administrator shall immediately notify the PBGC in writing of this fact, but shall continue with the final distribution of assets in accordance with § 2616.18. If the PBGC does not agree with the plan administrator's finding, it shall take no action. If the PBGC does concur with the plan administrator's finding, it shall—

(1) Determine whether to establish a trust pursuant to section 4049 with respect to the plan; and

(2) Require the plan administrator to submit a new valuation, certified to by an enrolled actuary, of the benefit commitments valued in accordance with Part 2619, Subpart C, as of the final distribution date, and any additional information needed to verify the amounts of participants' and beneficiaries' benefit commitments.

(d) *Finding by PBGC of subsequent insufficiency.* In any case in which the PBGC finds on its own initiative that a subsequent insufficiency has occurred, paragraph (b)(1) or paragraphs (c)(1) and (c)(2) of this section, as appropriate, shall apply. In this event, the benefit commitments and, if applicable, guaranteed benefits shall be revalued as of the date of the PBGC's finding.

§ 2616.18 Close out of plan.

(a) *General.* When a plan administrator receives a distribution notice from the PBGC pursuant to § 2616.16 (c) or (d), and unless the plan administrator or the PBGC makes the finding described in § 2616.17(b), the plan administrator shall, within 30 days after receipt of the distribution notice, make the final distribution of plan assets in accordance with paragraph (b) of this section and thereafter shall file with the PBGC a post-distribution certification in accordance with paragraph (c) of this section.

(b) *Methods of final distribution.* The plan administrator shall distribute plan assets by purchasing annuities from an insurer, in accordance with § 2616.6(a), in satisfaction of all benefits that must be provided in annuity form under § 2616.6 to which assets are allocated in accordance with Part 2618, and by otherwise providing all benefits to which assets are allocated that need not be paid in annuity form under § 2616.6. With respect to annuity benefits, the plan administrator shall give to the participant or beneficiary the annuity contract or a certificate showing the insurer's name and address and clearly reflecting the insurer's obligation to provide the benefits purchased.

(c) *Post-distribution certification.* Within 30 days after the completion of the final distribution of assets, the plan administrator shall file with the PBGC a post-distribution certification containing the following information:

(1) The name and address of the insurer from which annuity contracts were purchased.

(2) A statement that plan assets were allocated in accordance with Part 2618.

(3) Unless all benefit commitments under the plan were paid, an addendum to the participant data schedules filed pursuant to § 2616.14(d) showing the amounts of the benefit commitments actually distributed to (or with respect to) each participant.

(4) If all benefit commitments under the plan were paid, the place or places where the plan records will be held.

(5) A certified statement that all information provided and statements made pursuant to this paragraph are true and complete.

Appendix—Agreement for Commitment To Make Plan Sufficient for Guaranteed Benefits

This agreement, by and between [title of Company] _____(the "Company") and the Pension Benefit Guaranty Corporation (the "PBGC") shall be effective as of the last date executed.

Whereas, the PBGC is a wholly owned government corporation created by the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 *et seq* (1982) (amended by Pub. L. No. 99-272 (1986), 100 Stat. 244) (the "Act"); and

Whereas _____ (the "Plan") is an employee pension benefit plan as described in section 3(2)(A) of the Act; and

Whereas the Company is [describe entity; e.g., corporation, partnership]; and

Whereas, the Company is a contributing sponsor of the Plan as described in section 4001(a)(13) of the Act, 29 U.S.C. § 1301(a)(13); and

Whereas, the Plan is covered by the termination insurance provisions of Title IV of the Act, 29 U.S.C. § 1301 *et seq;* and

Whereas, the Plan administrator has provided (or intends to provide) to each affected party a Notice of Intent to Terminate the Plan, pursuant to Section 4041(a)(2) of the Act, 29 U.S.C. § 1342(a)(2), and

Whereas, the Company wishes the Plan to be sufficient for all benefits described in section 4044(a) (1)–(4) of the Act, 29 U.S.C. 1344(a) (1)–(4) for purposes of Title IV of the Act, 29 U.S.C. § 1301 et seq; and

Whereas, the Company is not a debtor in a bankruptcy or other insolvency proceeding, and the Company does not anticipate that it will become a debtor in such a proceeding.

[Alternative Paragraph]

Whereas, the Company is a debtor in a bankruptcy or other insolvency proceeding and the court before which the proceeding is pending approves this commitment.

Now Therefore, the parties hereto agree as follows:

1. The Company promises to pay to the Plan, on or before the date prescribed for distribution of Plan assets by the Plan administrator, the amount necessary, if any, to ensure that, on the date the Plan administrator distributes the assets of the Plan, the Plan is able to provide all benefits described in section 4044(a) (1)–(4) of the Act, 29 U.S.C. § 1344(a) (1)–(4).

2. For the sole purpose of determining whether the plan is sufficient to provide all benefits described in section 4044(a) (1)–(4) of the Act, 29 U.S.C. 1355(a) (1)–(4), an amount equal to the amount described in paragraph 1 shall be deemed to be a Plan asset available for allocation among the participants and beneficiaries of the Plan, in accordance with section 4044 of the Act, 29 U.S.C. § 1344.

3. In the event that the Company fails to honor this commitment, the PBGC may bring an action to enforce the commitment.

4. In the event that the Plan administrator is unable to distribute the assets of the Plan to satisfy all benefits described in section 4044(a) (1)–(4) of the Act, 29 U.S.C. § 1344(a) (1)–(4), the PBGC may proceed to place the Plan into trusteeship in accordance with section 4042 of the Act, 29 U.S.C. § 1342.

5. This Agreement shall in no way relieve the company of its obligations—

(a) to pay contributions under the Plan;

(b) in the event of PBGC trusteeship, to pay any amount due to the PBGC under section 4062(b) of the Act, 29 U.S.C. § 1362; and

(c) in the event a trust is established pursuant to section 4041(c)(3)(B) (ii) or (iii) or section 4041(c)(3)(C) (i) or (ii) of the Act, 29 U.S.C. § 1341 (c)(3)(B) (ii) or (iii) or § 1341(c)(3)(C) (i) or (ii), to pay any amount due to the trust pursuant to section 4062(c) of the Act, 29 U.S.C. § 1362(c).

Date: _____

By: _____

Date: _____

PBGC By: _____

Knowingly and willfully making false, fictitious or fraudulent statements to PBGC is punishable under 18 U.S.C. § 1001.

PART 2617—STANDARD TERMINATIONS OF SINGLE-EMPLOYER PLANS

Subpart A—General Provisions

Subpart B—Standard Termination Process

Authority: Secs. 4002(b)(3), 4041 and 4044, Pub. L. 93-406, 88 Stat. 1004, 1020 and 1025, as amended by secs. 403(1), 40(d) and 402(a)(7), Pub. L. 96-364, 94 Stat. 1299, 1301 and 1302, and by secs. 11007 and 11009, Pub. L. 99-272,

100 Stat. 244 [29 U.S.C. 1302(b)(3), 1341 and 1344].

Subpart A—General Provisions

§ 2617.1 Purpose and scope.

(a) *Purpose.* This regulation sets forth the rules and procedures for terminating a single-employer pension plan in a standard termination. Under the Single-Employer Pension Plan Amendments Act of 1986 ("SEPPAA"), a single-employer plan may be voluntarily terminated only in a "standard" or a "distress" termination, and then only if the termination satisfies the statutory requirements for the type of termination sought. The plan termination rules in SEPPAA apply with respect to all plan terminations initiated by the plan administrator or the Pension Benefit Guaranty Corporation ("PBGC"), on or after January 1, 1986. This regulation combines the PBGC's regulations on Notices of Intent to Terminate and Determination of Plan Sufficiency and Termination of Sufficient Plans (29 CFR Parts 2616 and 2617), with appropriate changes to reflect SEPPAA's new rules for standard terminations. Subpart A of this regulation contains the various general rules and requirements relating to standard terminations. Subpart B sets forth the specific steps that a plan administrator must follow in order to terminate a plan in a standard termination.

(b) *Scope.* This part applies to the termination of any single-employer plan covered under ERISA section 4021(a) and not excluded by section 4021(b), for which a notice of intent to terminate is issued (or is required to be issued) on or after [effective date of part] and which is not terminated in accordance with the requirements for a distress termination under section 4041(c) of the Act and Part 2616 of this subchapter.

§ 2617.2 Definitions.

For purposes of this part:

"Act" means the Employee Retirement Income Security Act of 1974, as amended by the Multiemployer Pension Plan Amendments Act of 1980 and the Single-Employer Pension Plan Amendments Act of 1986.

"Affected party" means, with respect to a single-employer plan, each participant, each beneficiary of a deceased participant, each alternate payee (as defined in section 206(d)(3)(K) of the Act) under an applicable qualified domestic relations order (as defined in section 206(d)(3)(B)(i)), and each employee organization representing participants. However, in connection with any notice required under this part, if an affected party has designated in writing another person to receive the notice, then any reference to the affected party shall be deemed to refer to the designated person.

"Benefit commitments" means those benefits that: (1) Are guaranteed under section 4022 of the Act; (2) would be guaranteed but for the limitations in section 4022(b); or (3) constitute early retirement supplements or subsidies or plant closing benefits, provided the participant or beneficiary has, prior to the plan termination date, satisfied all of the conditions under the plan to establish entitlement to the benefit, except for the submission of a formal application, retirement, completion of a required waiting period subsequent to application for benefits or designation of a beneficiary.

"Contributing sponsor" means, with respect to a single-employer plan, the person responsible for meeting the minimum funding requirements under section 302 of the Act or section 412 of the Internal Revenue Code of 1954.

"Insurer" means a company authorized to do business as an insurance carrier under the laws of a state or the District of Columbia.

"Multiple employer plan" means a single-employer plan maintained by two or more contributing sponsors that are not members of the same controlled group, under which all plan assets are available to pay benefits to all plan participants and beneficiaries.

"Notice of benefit commitments" means the notice to participants and beneficiaries required by section 4041(b)(2)(B) of the Act and §§ 2617.13 and 2617.14 of this part that advises them of the minimum benefit entitlement of each in the event of a standard termination.

"Notice of intent to terminate" means the notice to affected parties advising them of a proposed plan termination, as required by section 4041(a)(2) of the Act and § 2617.12 of this part.

"Notice of noncompliance" means a notice issued to a plan administrator by the PBGC pursuant to section 4041(b)(2)(C) of the Act and § 2617.17 of this part advising the plan administrator that the requirements for a standard termination have not been satisfied and that the plan may not terminate.

"Participant" means any individual who is in employment covered by the plan and is earning or retaining credited service (including an individual who is below the integration level in a plan that is integrated with Social Security); any non-vested individual separated from employment who is earning or retaining credited service, excluding those individuals who have incurred a break in service of one year or the plan's break-in-service period, whichever is greater; and any individual who has retired or separated from employment and is either receiving benefits or entitled to begin receiving benefits in the future, excluding those individuals to whom an insurance company has made an irrevocable commitment to pay all the benefits to which the individual is entitled under the plan.

"PBGC" means the Pension Benefit Guaranty Corporation.

"Proposed distribution date" means the date chosen by the plan administrator as the tentative date for the final distribution of plan assets pursuant to a standard termination and the date used by the enrolled actuary for valuing plan assets and benefits. A proposed distribution date may never be earlier than the day following the last day of the PBGC's review period, as described in § 2617.16(b), nor later than the 30th day following the expiration of the review period.

"Proposed termination date" means the date specified as such by the plan administrator in a notice of intent to terminate or, if different, in the standard termination notice. If a plan terminates in a standard termination, this date becomes the termination date, and this is the date used by the enrolled actuary for determining participants' accrued benefits and benefit commitments under a plan. A proposed termination date may not be earlier than the 60th day after the issuance of the notice of intent to terminate, nor later than the 180th day thereafter.

"Single-employer plan" means any defined benefit plan (as defined in section 3(35) of the Act) that is not a multiemployer plan (as defined in section 4001(a)(3)).

"Standard termination" means the termination, in accordance with section 4041(b) of the Act and this part, of a single-employer plan that is able to pay all its benefit commitments.

"Standard termination notice" means the notice filed with the PBGC pursuant to section 4041(b)(2)(A) of the Act and § 2617.15 of this part advising the PBGC of a proposed standard termination and providing various plan data including, but not limited to, an enrolled actuary's certification of the plan's sufficiency for benefit commitments.

§ 2617.3 Requirements for a standard termination.

(a) *Exclusive means of voluntary plan termination.* Unless all the requirements for a distress termination set forth in section 4041(c) of the Act and Part 2616 are satisfied, a plan may be voluntarily terminated by the plan administrator

only in a standard termination. A standard termination may occur only if it meets all of the requirements set forth in paragraph (b) of this section.

(b) *Requirements.* A plan may terminate in a standard termination only if—

(1) The plan administrator issues a notice of intent to terminate to affected parties in accordance with § 2617.12 at least 60 days before the proposed termination date;

(2) The plan administrator files a standard termination notice with the PBGC in accordance with § 2617.15 no later than 60 days after the proposed termination date;

(3) The plan administrator issues notices of benefit commitments to plan participants and beneficiaries in accordance with §§ 2617.13 and 2617.14 no later than the date that the standard termination notice is sent to the PBGC;

(4) The PBGC does not issue a notice of noncompliance to the plan administrator pursuant to § 2617.17; and

(5) The plan administrator makes the final distribution of plan assets in accordance with § 2617.18, thereby satisfying all plan obligations for benefit commitments.

(c) *Effect of failure to satisfy all requirements.* If any of the requirements of paragraph (b) of this section are not satisfied, any action taken to effect the plan termination shall be null and void, and the plan shall be an ongoing plan for all purposes. A plan administrator who still desires to terminate the plan shall initiate the termination process again from the beginning, starting with the issuance of a notice of intent to terminate.

§ 2617.4 Administration of plan during pendency of termination proceedings.

Beginning on the date that the plan administrator issues the notice of intent to terminate and ending upon the expiration of the PBGC's review period referred to in § 2617.16(a) (generally 60 days after the filing with the PBGC of a complete standard termination notice), the plan administrator may not make any distributions to participants pursuant to or in furtherance of the plan's termination. This does not prohibit the plan administrator from carrying out the normal operations of the plan, such as putting participants into pay status, collecting contributions due the plan and investing plan assets.

§ 2617.5 Challenges to plan termination under a collective bargaining agreement.

(a) *Suspension of termination proceeding.* If, prior to the expiration of the PBGC's review period referred to in § 2617.16(a), the PBGC is advised that a formal challenge (as defined in paragraph (c) of this section) has been initiated asserting that the proposed termination violates the terms and conditions of an existing collective bargaining agreement, the PBGC shall suspend the termination proceeding. The effect of the suspension shall be to stop the running of all time periods specified in Title IV of ERISA or under this part relevant to the termination. However, the restriction prescribed by § 2617.4 shall continue in effect during the period of suspension. The PBGC shall notify the plan administrator in writing of the suspension.

(b) *Resolution of challenge.* Immediately upon the final resolution (as defined in paragraph (d) of this section) of the formal challenge to the termination, the plan administrator shall notify the PBGC in writing of the outcome of the challenge. If the validity of the proposed termination has been upheld, the plan administrator shall also advise the PBGC of whether the plan administrator wishes to continue or withdraw the proposed termination.

(1) *Challenge sustained.* If it has been determined that the proposed termination violates the collective bargaining agreement, the PBGC shall dismiss the termination proceeding, all actions taken to effect the plan termination shall be null and void, and the plan shall be an ongoing plan for all purposes.

(2) *Termination sustained.* If it has been determined that the proposed termination does not violate the collective bargaining agreement and the plan administrator wishes to proceed with the termination, the PBGC shall reactivate the termination proceeding by sending a written notice thereof to the plan administrator. In that event, the termination proceeding shall continue from the point where it was suspended, and all actions taken to effect the termination prior to the suspension shall be effective. Any time periods that were suspended shall resume running from the date of the PBGC's notice of the reactivation of the proceeding, and any time periods that had fewer than 15 days remaining shall be extended to the 15th day after the date of the PBGC's notice.

(c) *Formal challenge to plan termination.* The occurrence of any of the following actions, asserting that the termination would violate the terms and conditions of an existing collective bargaining agreement, shall constitute grounds for the PBGC to suspend the termination proceeding:

(1) The commencement of any procedure specified in the collective bargaining agreement for resolving disputes under the agreement.

(2) The filing of a charge with the National Labor Relations Board alleging an unfair labor practice under section 8 of the National Labor Relations Act.

(3) The commencement of an action under section 301 of the National Labor Relations Act in a court of competent jurisdiction.

(d) *Final resolution of challenge.* For the purposes of this section, a formal challenge to a proposed termination shall be considered finally resolved when the parties involved in the challenge enter into a settlement that resolves the challenge or upon the issuance of a final, non-appealable order, as defined in this paragraph. Depending upon the type of action challenging the termination, any of the following constitutes a final, non-appealable order:

(1) An arbitrator's award that is neither appealed nor is review thereof sought within the time for filing such appeals or requesting review.

(2) An order of the National Labor Relations Board for which the Board does not petition for enforcement or the person aggrieved petition for review within the time permitted for filing such actions.

(3) An order by a court of competent jurisdiction that is not appealed within the time limit for filing such appeals.

(4) When an appeal is taken from or a request for review is made concerning a decision described in paragraph (d)(1), (d)(2) or (d)(3) of this section, an order by a court of competent jurisdiction finally resolving the dispute.

(e) *Involuntary termination by the PBGC.* Paragraphs (a) and (b) of this section notwithstanding, the PBGC retains the authority in any case to initiate a plan termination in accordance with the provisions of section 4042 of the Act.

§ 2617.6 Requirement for annuities.

(a) *General rule.* Except as provided in paragraph (b) of this section, when a plan is closed out under § 2617.18, any benefit that is payable as an annuity under the provisions of the plan must be provided in annuity form through the purchase from an insurer of a single premium, nonparticipating (except in the case of a plan that is sufficient for all accrued benefits), nonsurrenderable annuity that constitutes an irrevocable commitment by the insurer to provide the benefits purchased.

(b) *Exceptions.* [Reserved]

§ 2617.7 Contributing sponsor's commitment to make plan sufficient.

At any time prior to the filing with the PBGC of a standard termination notice, a contributing sponsor may make a commitment to contribute any additional sums necessary to make a plan sufficient for all benefit commitments, in order to enable the plan to terminate in a standard termination. The commitment shall be in writing and be signed by the contributing sponsor, shall contain substantially the same provisions as the sample commitment in the appendix to this part, and shall be made to the plan. In addition, a commitment by a contributing sponsor that is the subject of a bankruptcy liquidation or reorganization proceeding, as described in § 2616.3 (d)(1) or (d)(2), shall be valid under this section only if it is approved by the court before which the liquidation or reorganization proceeding is pending. A commitment that meets the requirements of this section shall be considered a plan asset for all purposes under this part.

§ 2617.8 Filings with the PBGC; time limits.

(a) *"Filing" defined.* Any document required or permitted to be filed with the PBGC under this part shall be deemed filed on the date that it is received at the PBGC, providing it is received on a weekday, other than a Federal holiday, no later than 4:00 p.m. Documents received after 4:00 p.m. or on weekends or Federal holidays shall be deemed filed on the next regular business day.

(b) *How to file.* Any document being filed under this part may be delivered by mail or by hand to the PBGC's Case Classification and Control Division, Control Branch, Room 5300A (Code 25420), 2020 K Street NW., Washington, DC 20006.

(c) *Time limits.* If the last day of any period prescribed by this part for issuing or filing any notices or other documents or taking any other actions falls on a Saturday, Sunday or legal holiday, then the last day of the period shall be the next regular business day.

§ 2617.9 Maintenance of plan records.

All records (including the plan document) needed to compute the benefit commitments (if any) of each individual who is a plan participant or beneficiary as of the proposed termination date, excluding those individuals who have been in pay status for longer than one year as of that date, shall be preserved for six years after the date of the post-distribution certification required under § 2617.18(f). These records shall be retained by either the plan administrator or the contributing sponsor.

Subpart B—Standard Termination Process

§ 2617.11 Purpose and scope.

This subpart describes in detail the standard termination process. Sections 2617.12–2617.14 prescribe the contents of and the rules for issuing the two statutory notices that plan administrators must give to participants and beneficiaries in a standard termination. The first notice, which is issued to begin the termination process, is the "notice of intent to terminate." The second notice, which is issued prior to the PBGC's review of the termination request, is the "notice of benefit commitments." Section 2617.15 deals with the filing made with the PBGC, the "standard termination notice." Sections 2617.16 and 2617.17 cover the PBGC's review of the proposed termination and the actions that the PBGC may take with respect to it. Finally § 2617.18 prescribes the rules for closing out a plan in the absence of a notice of noncompliance.

§ 2617.12 Notice of intent to terminate.

(a) *General rule.* At least 60 days and no more than 180 days prior to the proposed plan termination date, the plan administrator shall issue to each affected party (as defined in § 2617.2) a notice of intent to terminate containing all of the information specified in paragraph (d) of this section. Failure to comply with this rule shall nullify the proposed termination.

(b) *Method of issuance.* The notice of intent to terminate shall be issued individually to each affected party. The notice shall be either hand delivered or delivered by first-class mail or courier service to the affected party's last known address.

(c) *When issued.* The notice of intent to terminate is deemed issued on the date in which it is handed to the affected party or deposited with a mail or courier service.

(d) *Contents of notice.* The notice of intent to terminate shall contain all of the following information:

(1) The name of the plan and of the contributing sponsor.

(2) The Employer Identification Number ("EIN") of the contributing sponsor and the Plan Identification Number ("PN"); if there is no EIN or PN, the notice shall so state.

(3) The name, address and telephone number of the person who may be contacted by an affected party with questions concerning the plan's termination.

(4) A statement that the plan administrator expects to terminate the plan on a proposed termination date (as defined in § 2617.2) that is either—

(i) A specific date set forth in the notice; or

(ii) A date to be determined that is dependent on the occurrence of some future event (such as the merger of the contributing sponsor with another entity). When an unspecified date is used, the notice shall state what the event is, generally when it is expected to occur, and when the termination will occur in relation to the other event.

(5) A statement that if the termination does not occur, the plan administrator will notify the affected parties of that fact.

(6) A statement that each affected party, other than the employee organization that represents plan participants, will be receiving a written notification of the benefits that the person will receive.

(7) For retirees only, a statement that their monthly (or other periodic) benefit amounts will not be affected by the plan's termination.

§ 2617.13 Issuance of notices of benefit commitments.

(a) *General rule.* No later than the date on which the plan administrator sends the standard termination notice to (or, if hand-delivered, files it with) the PBGC, as required by § 2617.15, the plan administrator shall issue to each plan participant and beneficiary described in paragraph (b) of this section a notice of that person's benefit commitments under the plan. The notice shall be in the form and contain the information specified in § 2617.14. Failure to comply with this rule shall nullify the proposed termination.

(b) *Persons entitled to notice.* A notice of benefit commitments shall be issued to all persons who, as of the proposed termination date, are participants in the terminating plan, and, in the case of a spin-off/termination, participants in the continuing plan. A notice of benefit commitments shall also be issued to all persons who are, as of that date, under the terminating plan or the continuing plan, beneficiaries of deceased participants or alternate payees under an applicable qualified domestic relations order. With respect to all other beneficiaries, notice to the participant shall constitute notice to that participant's beneficiary(ies).

(c) *Method of issuance.* A notice of benefit commitments shall be issued individually to each person described in paragraph (b) of this section. The notice shall be either hand-delivered or

delivered by first-class mail or courier service to the person's last known address.

(d) *When issued.* A notice of benefit commitments is deemed issued on the date it is handed to the recipient or deposited with a mail or courier service.

§ 2617.14 Form and contents of notices of benefit commitments.

(a) *Form.* A notice of benefit commitments shall be written in plain, non-technical English that is likely to be understood by the average participant or beneficiary. When technical terms must be used, their meaning shall be explained in non-technical language.

(b) *Foreign languages.* In the case of any plan described in paragraph (b)(1) or (b)(2) of this section, in addition to complying with paragraph (a) of this section, the notice of benefit commitments shall contain a statement, prominently displayed, in the foreign language (or languages) common to the non-English speaking plan participants advising them of how they may obtain assistance in understanding the notice. The assistance need not involve written materials, but shall be adequate to reasonably ensure that the participants and beneficiaries understand the information contained in their notices, and shall be provided through media and at times and places that are reasonably accessible to the participants and beneficiaries.

(1) *Small plans.* A plan described in this paragraph is any plan that covers fewer than 100 participants as of the proposed termination date, in which at least 25 percent of the participants speak only the same non-English language.

(2) *Other plans.* A plan described in this paragraph is any plan that covers 100 or more participants as of the proposed termination date, in which the lesser of 500 or 10 percent of the participants speak only the same non-English language.

(c) *Contents.* Each notice of benefit commitments shall contain the information specified in this paragraph. In addition, a notice shall contain the information described in paragraphs (d) through (f) of this section, depending on whether the benefit is in pay status and whether the participant has elected a benefit form as of the proposed termination date. If, as of the proposed termination date, the plan administrator is certain that the plan will be able to pay full accrued benefits to all participants, the information set forth in the notices may be for accrued benefits rather than benefit commitments, and each notice shall so state.

(1) The name of the plan and the Employer Identification Number ("EIN"); if there is no EIN, the notice shall so state.

(2) The name, address and telephone number of the person who may be contacted to answer questions concerning a participant's or beneficiary's benefit.

(3) The proposed termination date and, if applicable, a statement that this date is later than the proposed termination date given in the notice of intent to terminate.

(4) A statement that the amount of the benefit commitments set forth in the notice is an estimate, that under the proposed termination benefits paid will in no event be less than the estimate, and (where applicable) greater benefits may be paid if plan assets are adequate.

(d) *Benefits of persons in pay status.* A notice of benefit commitments to a participant or beneficiary in pay status as of the proposed termination date shall state—

(1) The amount and form of benefit payable as of the proposed termination date;

(2) The amount (if any) and form of benefit payable to a beneficiary upon the participant's death and the name of the beneficiary;

(3) The amount and date of any increase or decrease in the benefit scheduled to occur (or that has already occurred) after the proposed termination date and an explanation of the increase or decrease, including, where applicable, a reference to the pertinent plan provision; and

(4) For benefits of participants (or beneficiaries) in pay status for one year or less as of the proposed termination date, the specific personal data used to calculate the benefit commitments described in paragraphs (d)(1) and (d)(2) of this section, *e.g.*, participant's age at retirement, spouse's age, participant's length of service, etc., and including for Social Security offset benefits, the participant's actual or, if unknown, estimated Social Security benefit and for an estimated benefit, the assumptions used for the participant's earnings history.

(e) *Benefits of participants not in pay status but form and starting date known.* For benefit commitments payable with respect to a participant who is not in pay status as of the proposed termination date, but who has, as of that date, elected to retire, a notice of benefit commitments shall state—

(1) The amount and form of the benefit commitments payable as of the projected benefit starting date, and what that date is;

(2) The amount (if any) and form of benefit payable to a beneficiary upon the participant's death and the name of the beneficiary;

(3) If the age at which or form in which the benefit commitments will be paid differ from the age or form in which the participant's accrued benefit at normal retirement age is stated in the plan, the age or form stated in the plan and the age or form adjustment factors, including in the case of a lump sum benefit the interest rate, used to convert to the benefit described in paragraph (e)(1) of this section, with a reference to the pertinent plan provision;

(4) The specific personal data, as described in paragraph (d)(4) of this section, used to calculate the benefit commitments (other than a lump sum benefit) described in paragraphs (e)(1) and (e)(2) of this section, and, with respect to a benefit payable as a lump sum, the personal data used to calculate the underlying annuity; and

(5) When the benefit commitments will be paid in a lump sum, an explanation of how the interest rate is used to calculate the lump sum, a statement that the higher the interest rate used, the smaller the lump sum amount, and (if applicable) a statement that the lump sum amount given pursuant to paragraph (e)(1) of this section is an estimate because the applicable interest rate may change before the distribution date.

(f) *All other benefits of participants not in pay status.* With respect to all deferred benefits, other than those described in paragraph (e) of this section, a notice of benefit commitments shall state—

(1) The amount and form of the participant's benefit commitments at normal retirement age in the plan's normal form;

(2) The availability of any alternative benefit forms, including those payable to a beneficiary upon the participant's death either before or after retirement, and for any benefits to which the participant is entitled as of the proposed termination date that would be payable before normal retirement age, the amount and earliest benefit commencement date of such benefit and whether the benefit would be subject to future reduction;

(3) If the benefit commitments may be paid in a lump sum without the participant's consent, the amount of the lump sum and the interest rate used to calculate it;

(4) The specific personal data, as described in paragraph (d)(4) of this section, used to calculate the benefit commitments described in paragraph

(f)(1) of this section, and, with respect to a benefit that may be paid in a lump sum without the participant's consent, the personal data used to calculate the underlying annuity; and

(5) When the benefit commitments may be paid in a lump sum without the participant's consent, an explanation of how the interest rate is used to calculate the lump sum, a statement that the higher the interest rate used, the smaller the lump sum amount, and a statement that the lump sum amount given pursuant to paragraph (f)(3) of this section is an estimate because the applicable interest rate may change before the distribution date.

§ 2617.15 Standard termination notice.

(a) *General rule.* No later than 60 days after the proposed termination date specified in the notice of intent to terminate (or, if later, the proposed termination date specified in the notice required by this paragraph), the plan administrator shall file with the PBGC a "standard termination notice" containing the information prescribed in this section.

(b) *Contents of notice.* A standard termination notice shall be clearly identified as such and shall contain all of the information specified in this paragraph and, if the plan administrator expects the termination to result in the reversion of residual assets to the contributing sponsor, the information specified in paragraph (c) of this section, as well. Each item of information shall be numbered as the items are numbered in this paragraph and in paragraph (c) of this section.

(1) The name of the plan and of the contributing sponsor.

(2) The Employer Identification Number ("EIN") of the contributing sponsor and the Plan Identification Number ("PN"); if there is no EIN or PN, the notice shall so state; if premiums have been paid by the plan under another EIN or PN, that EIN or PN shall be given as well.

(3) The name, address and telephone number of the plan administrator and of the plan administrator's duly authorized representative, if any.

(4) A statement of whether the plan is a multiple employer plan; if so, the names and EIN's of all contributing sponsors must be given.

(5) The total number of plan participants (actives and retirees).

(6) The plan year ending date.

(7) The proposed termination date of the plan and, if earlier, the proposed termination date specified in the notice of intent to terminate.

(8) The date (or latest date) on which the notices of intent to terminate were issued and a statement that they were issued to each affected party in accordance with § 2617.12.

(9) The proposed distribution date.

(10) A statement that notices of benefit commitments were issued and the date or dates thereof, in accordance with §§ 2617.13 and 2617.14, to each person entitled to receive the notice pursuant to § 2617.13.

(11) A statement of whether a formal challenge to the termination, as defined in § 2617.4(c), has been initiated, and if so, what action was initiated, by whom and on what date, and the current status of the challenge.

(12) A statement of whether the contributing sponsor has made a commitment to make the plan sufficient, pursuant to § 2617.7.

(13) A statement of whether the termination will result in the reversion of residual assets to the contributing sponsor; if so, the information required by paragraph (c) of this section must also be submitted.

(14) A certification by an enrolled actuary of the information specified in this paragraph. The certification shall be signed by the enrolled actuary and shall show the enrolled actuary's identification number. All valuations done pursuant to this paragraph shall utilize reasonable methods and assumptions consistently applied, and all values given shall be as of the proposed distribution date, as defined in § 2617.2.

(i) The projected value of plan assets.

(ii) The projected actuarial present value of all benefit commitments (determined as of the proposed termination date).

(iii) A statement that the plan is projected to be sufficient for all benefit commitments.

(iv) A statement of whether the plan is projected to be sufficient for all accrued benefits and, if so, the projected actuarial present value of all accrued benefits (determined as of the proposed termination date).

(v) A statement of whether the termination is projected to result in a reversion of residual assets to the contributing sponsor, and if so, the projected amount of the reversion.

(15) A certification by the plan administrator that the information given and statements made pursuant to paragraphs (b)(1)–(b)(13) and, if applicable, paragraph (c) of this section and the information made available to the enrolled actuary are all accurate and complete.

(c) *Additional information for terminations resulting in asset reversions.* In any termination that will result in the reversion of residual assets to the contributing sponsor, the standard termination notice shall contain the following:

(1) A statement that the plan provides for a reversion of any residual assets to the contributing sponsor.

(2) A statement of whether the plan was involved in a spin-off or other transfer of assets or liabilities within the 36-month period preceding the proposed termination date.

(3) A statement of whether the contributing sponsor intends to cover substantially the same employees participating in the terminating plan in another (new or existing) defined benefit plan.

(4) With respect to a contributory plan, a statement of whether the plan administrator is requesting PBGC approval of an allocation method other than that prescribed in § 2618.31(b) of the PBGC's regulations; if so, the proposed allocation method must be submitted and the plan administrator shall consent to a 60-day extension of the PBGC's review period referred to in § 2617.16(a).

(5) A statement of whether the contributing sponsor intends to cover substantially the same employees participating in the terminating plan in a new or existing defined contribution plan.

(6) If an affirmative answer is made with respect to paragraph (c)(2) or (c)(3) of this section, a copy of the contributing sponsor's most recent annual report or audited financial statement.

§ 2617.16 PBGC action upon receipt of standard termination notice.

(a) *General.* Upon the filing of a standard termination notice containing all of the information required by § 2617.15 (b) and (c), the PBGC has (except as provided in paragraph (b) or (e) of this section or in § 2617.5) 60 days (or, in the case of a contributory plan involving a reversion of residual assets with respect to which the plan administrator proposes to use an allocation method other than that described in 29 CFR 2618.31(b), 120 days) to review the standard termination notice, determine whether or not to issue a notice of noncompliance pursuant to § 2617.17, and issue any such notice. If the PBGC does not issue a notice of noncompliance within this period, the plan administrator shall proceed to close out the plan in accordance with § 2617.18. The consequences of the issuance of a notice of noncompliance are set forth in § 2617.17.

(b) *Review period.* The 60-day (or 120-day) period referred to in paragraph (a)

of this section begins on the day following the filing of a complete standard termination notice and includes the 60th (or 120th) day. The PBGC and the plan administrator may agree in writing, prior to the expiration of the review period, to extend the period for an additional 60 days. More than one such extension may be made. Any extension may be made upon whatever terms and conditions are agreed to by the PBGC and the plan administrator.

(c) *Acknowledgment of complete standard termination notice.* Upon receipt of a standard termination notice containing all of the information required by § 2617.15 (b) and (c), the PBGC shall notify the plan administrator in writing of the date on which the notice was filed, so that the plan administrator may determine when the PBGC's review period will expire.

(d) *Incomplete standard termination notice.* Upon receipt of a standard termination notice that does not contain all of the information required by § 2617.15 (b) and (c), the PBGC shall return the notice and advise the plan administrator in writing of the missing items of information and that the complete standard termination notice must be filed no later than the 60th day after the proposed termination date or the 20th day after the date of the PBGC notice, whichever is later.

(e) *Authority to request additional information.* Whenever the PBGC has reason to suspect that any of the requirements of §§ 2617.12–2617.15 were not complied with, or in any case that will result in a reversion of residual assets to the contributing sponsor, the PBGC may require the submission of information supplementing that furnished pursuant to § 2617.15. A request for additional information under this paragraph shall be in writing and shall suspend the running of the PBGC's review period specified in paragraph (a) of this section. That period shall begin running again on the day following the filing of the requested information. If a plan administrator or contributing sponsor fails to submit information requested under this paragraph within the period specified in the PBGC's request, the PBGC may issue a notice of noncompliance in accordance with § 2617.17.

§ 2617.17 Notice of noncompliance.

(a) *General.* The PBGC shall issue to the plan administrator a written notice of noncompliance, within the period prescribed by § 2617.16(a), whenever it makes one of the determinations set forth in this paragraph. Any such determination shall be based on the information contained in the standard termination notice or in any supplemental submission under § 2617.16(e), or on information provided by any affected party or otherwise obtained by the PBGC.

(1) A determination that the plan administrator failed to issue notices of intent to terminate in accordance with § 2617.12.

(2) A determination that the plan administrator failed to issue notices of benefit commitments in accordance with §§ 2617.13 and 2617.14.

(3) A determination that the standard termination notice was not filed in compliance with § 2617.15.

(4) A determination that, as of the proposed distribution date, plan assets will not be sufficient to satisfy all benefit commitments under the plan.

(b) *Effect of notice of noncompliance.* The issuance of a notice of noncompliance terminates a standard termination proceeding. The effect of the notice is to nullify all actions taken to effect the plan termination and to render the plan an ongoing plan for all purposes. The notice of noncompliance is effective upon the expiration of the period within which the notice may be appealed under Part 2606 ("Rules for Administrative Review of Agency Decisions"). However, once the notice is issued, the plan administrator may take no further actions to terminate the plan until the notice is revoked pursuant to a decision by the PBGC on an appeal.

(c) *Appeal of notice of noncompliance.* A plan administrator may appeal the issuance of a notice of noncompliance in accordance with the rules prescribed in Subpart D of Part 2606. The filing of an appeal automatically stays the effectiveness of the notice of noncompliance until the PBGC issues its decision on the appeal.

(d) *Notice to affected parties.* Upon a decision by the PBGC on an appeal affirming the issuance of a notice of noncompliance or upon the expiration of the period within which the issuance of a notice of noncompliance may be appealed, the plan administrator shall notify the affected parties in writing that the plan is not going to terminate. The notices shall be delivered by first-class mail or by hand to the employee organization representing plan participants and to participants and beneficiaries who are in pay status. The notices to other participants and beneficiaries shall be provided in any manner reasonably calculated to reach those participants and beneficiaries. Reasonable methods of notification include, but are not limited to, posting the notice at participants' worksites or publishing the notice in an employee organization newsletter or newspaper of general circulation in the area or areas where participants and beneficiaries reside.

§ 2617.18 Close out of plan.

(a) *General rule.* Except as provided in paragraph (b) of this section, if the PBGC does not issue a notice of noncompliance within the period specified in § 2617.17, the plan administrator shall, within 30 days after the expiration of that period, make the final distribution of plan assets in accordance with paragraph (c) of this section. Thereafter, the plan administrator shall file with the PBGC the post-distribution certification required under paragraph (f) of this section.

(b) *Inability to pay all benefit commitments.* Prior to making the final distribution of plan assets, the plan administrator shall determine that plan assets are in fact sufficient to satisfy all benefit commitments under the plan. The plan administrator may not make any distribution of assets to effect the plan's termination if the assets are not sufficient. In the event of an insufficiency, the plan administrator shall promptly notify the PBGC.

(c) *Methods of final distribution.* The plan administrator shall distribute plan assets by purchasing annuities from an insurer, in accordance with § 2617.6(a), in satisfaction of all benefit commitments (or, if greater, benefits to which assets are allocated in accordance with Part 2618) that must be provided in annuity form under § 2617.6, and by otherwise providing all benefit commitments (or, if greater, benefits to which assets are allocated) that need not be paid in annuity form under § 2617.6. With respect to annuity benefits, the plan administrator shall give to the participant or beneficiary the annuity contract or a certificate showing the insurer's name and address and clearly reflecting the insurer's obligation to provide the participant's or beneficiary's benefit.

(d) *Failure to distribute within 30-day period.* Except as provided in paragraph (e) of this section, failure to make the final distribution of assets in accordance with paragraph (a) of this section, because of an insufficiency of plan assets as described in paragraph (b) of this section or for any other reason, shall nullify the termination. All actions taken to effect the plan's termination shall be null and void, and the plan shall be an ongoing plan for all purposes.

(e) *Extension of time for distribution.* If the plan administrator is unable to make the final distribution of plan

assets within the 30-day period for any reason other than an insufficiency described in paragraph (b) of this section, the plan administrator may make a written request to the PBGC for an extension of time within which to make the distribution. The request shall be filed with the PBGC prior to the expiration of the 30-day period, state the reason for the request, and provide a date certain no later than 45 days after the end of the 30-day period by which the distribution will be made if the extension is granted. The PBGC will grant an extension only if it is satisfied that the delay in making the distribution is not due to the actions or inactions of the plan administrator or the contributing sponsor, and that the distribution can in fact be complete by the date requested. In no event will the PBGC grant an extension of greater than 45 days.

(f) *Post-distribution certification.* Within 30 days after the completion of the final distribution of assets, the plan administrator shall file with the PBGC a post-distribution certification containing the following information:

(1) The name and address of the insurer from which annuity contracts were purchased.

(2) The place or places where the plan records will be held.

(3) A statement that plan assets were allocated in accordance with Part 2618.

(4) A statement that assets were distributed in accordance with paragraph (c) of this section.

(5) A certified statement that all information provided and statements made pursuant to this paragraph are true and complete.

Appendix—Agreement for Commitment To Make Plan Sufficient for Benefits Commitments

This agreement, by and between [title of company] _____ (the "Company") and _____ [title of plan] (the "Plan") shall be effective as of the last date executed.

Whereas, _____ (the "Plan") is an employee pension benefit plan as described in section (3)(2)(A) of the Act; and

Whereas the company is [describe entity; e.g., corporation, partnership]; and

Whereas, the company is a contributing sponsor of the Plan as described in section 4001(a)(13) of the Act, 29 U.S.C. § 1301(2)(13); and

Whereas, the Plan is covered by the termination insurance provisions of Title IV of the Act, 29 U.S.C. 1301 et seq.; and

Whereas, the Plan administrator has issued or intends to issue to each affected party a Notice of Intent to Terminate the Plan, pursuant to section 4041(a)(2) of the Act, 29 U.S.C. § 1341(a)(2), and

Whereas, the Company wishes the Plan to be sufficient for benefit commitments, as described in section 4001(a)(16) of the Act, 29 U.S.C. § 1301(a)(16), for purposes of Title IV of the Act, 29 U.S.C. § 1301 et seq.; and

Whereas, the parties understand that if the Plan is not able to satisfy all its obligations for benefit commitments it will not be able to terminate in a standard termination under section 4041(b) of the Act, 29 U.S.C. § 1341(b); and

Whereas, the Company is not a debtor in a bankruptcy or other insolvency proceeding, and the Company does not anticipate that it will become a debtor in such a proceeding.

[Alternative Paragraph]

Whereas, the Company is a debtor in a bankruptcy or other insolvency proceeding and the court before which the proceeding is pending approves this commitment.

Now Therefore, the parties hereto agree as follows:

1. The Company promises to pay to the Plan, on or before the date prescribed for distribution of Plan assets by the Plan administrator, the amount necessary, if any, to ensure that, on the date the Plan administrator distributes the assets of the Plan, the Plan is able to provide all benefit commitments.

2. For the sole purpose of determining whether the Plan is sufficient to provide all benefit commitments, an amount equal to the amount described in paragraph 1 shall be deemed a Plan asset available for allocation among the participants and beneficiaries of the Plan, in accordance with section 4044 of the Act, 29 U.S.C. § 1344.

3. This Agreement shall in no way relieve the Company of its obligations to pay contributions under the Plan.

Date: _____

By: _____

Company: _____

By: _____

Plan: _____

Issued in Washington, DC, this 25th day of August, 1987.

Kathleen P. Utgoff,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 87-19882 Filed 9-1-87; 8:45 am]

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September 2, 1987

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 886

Ophthalmic Devices; General Provisions and Classifications of 109 Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. 78N-3128]

Ophthalmic Devices; General Provisions and Classifications of 109 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 109 generic types of ophthalmic devices. The preamble to this final rule responds to comments received on the proposed regulations classifying these devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 2, 1987.

FOR FURTHER INFORMATION CONTACT: Richard E. Lippman, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7320.

SUPPLEMENTARY INFORMATION:

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A. Background

In the **Federal Register** of January 26, 1982 (47 FR 3694), FDA published proposed regulations containing general provisions applicable to the classification of ophthalmic devices and individual proposed regulations to classify 119 ophthalmic devices into one or more of three regulatory classes: class I (general controls), class II (performance standards), and class III (premarket approval). Of the 119 ophthalmic devices that were the subjects of the proposed regulations, FDA proposed to classify 45 devices into class I, 51 devices into class II, 4 devices into class III, and 19 devices into either class I or class II depending upon their construction.

In this final rule, FDA is classifying 109 devices, with 65 devices in class I, 33 in class II and 11 in class III. FDA has withdrawn the proposed regulation classifying one device, the fluorescein strip (Docket No. 78N-3150; 51 FR 40396) because the agency is regulating the fluorescein strip as a drug. Further, FDA is codifying the statutory classification into class III of nine transitional devices that were not required to be the subjects of proposed classification rules. FDA is also postponing classifications of certain devices that were the subjects of the proposed regulations. See the discussion below under "D. Devices Not Being Classified at This Time."

Elsewhere in this issue of the **Federal Register**, FDA is proposing to grant 55 ophthalmic devices an exemption from the requirement of premarket notification.

Classification of medical devices in commercial distribution is required by section 513 of the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c). The effect of classifying a device into class I is to require that the device meet the general controls applicable to all devices. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. For a class III device not considered a new drug before the amendments that either was in commercial distribution before May 28, 1976, or that is substantially equivalent to a device that was in commercial distribution before that date, each application for premarket approval must be submitted to FDA on or before March 30, 1990, or within 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. Devices that FDA previously regulated as new drugs, or newly offered devices that are not substantially equivalent to a device that was in commercial distribution before the amendments, are classified by statute into class III and already are required to have in effect an approved application for premarket approval. See section 520(1) of the act (21 U.S.C. 360j(1)).

The preamble to the proposed regulations described the development of the general provisions and the proposed regulations classifying ophthalmic devices and the activities of the Ophthalmic Devices Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of ophthalmic devices.

FDA provided a period of 60 days, later extended to 240 days (March 19, 1982; 47 FR 11879), for interested persons to submit written comments on the proposed regulations on ophthalmic devices. Summaries of the comments received and FDA's responses are discussed below.

In April 1985, H.R. 2177 (99th Cong., 1st Sess.) was introduced in the U.S. House of Representatives. The bill was a legislative proposal of the Department of Health and Human Services. Among other things, the bill would have (1) amended the act to eliminate the statutory category of class II, (2) made the establishment of a performance standard one of the several general controls that may be made applicable to a device, and (3) streamlined the procedure for establishing standards required by section 514 of the act. If legislation comparable to this bill becomes law, there would be only two categories of devices, class I (general controls) and class II (premarket approval, currently class III). Class II devices would be redesignated as class I devices. Because the proposed legislation contains transitional provisions that convert classifications under the current law to classifications under the proposed law, FDA is continuing to issue classification rules under the current law.

B. FDA's Priorities for Establishing Performance Standards

In the **Federal Register** of October 23, 1985 (50 FR 43060), FDA published a notice, "Policy Statement. Class II Medical Devices," announcing its policy for setting priorities for initiating proceedings to establish performance standards for medical devices classified into class II. Under the amendments, FDA is required to establish performance standards for class II devices. At this time, however, FDA does not have the resources to establish performance standards for all of the devices already classified (or being classified) in class II. Under the amendments, FDA is using the regulatory controls of class I to regulate a device classified into class II until a

performance standard is established under section 514 of the act (21 U.S.C. 360d) for the class II device.

In that notice, FDA announced it will consider the following factors when setting priorities for establishing performance standards for class II devices.

a. The seriousness of questions concerning the safety and effectiveness of the device; the risks associated with use of the device; the significance of a device to the public health; and the present and projected use of the device.

b. The recommendations of FDA's advisory committees.

c. The impact of an FDA guideline or recommendation.

d. The effect of a Federal standard or other regulatory controls under an authority other than the act.

e. The impact of voluntary standards.

f. The impact of activities authorized under the general controls provisions of the act.

g. The effect of dissemination of information and education efforts.

h. The sufficiency of voluntary corrective actions.

i. Valid scientific evidence developed since classification.

j. The existence of a petition for reclassification.

k. The impact of any other factors that affect a device's safety or effectiveness.

C. Changes in the Name of the Ophthalmic Device Advisory Committee

FDA has periodically reorganized its advisory panels for device classification. Most recently, on April 14, 1984, FDA established the Ophthalmic Devices Panel (the Panel) (see 49 FR 17446; April 24, 1984). The new panel performs the same functions with respect to ophthalmic devices as did its predecessors, the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel (1978–1984) and the Ophthalmic Devices Classification Panel (1976–1978).

D. Devices not Being Classified at This Time

FDA is postponing classification of certain, or all, versions of 36 proposed generic types of ophthalmic devices.

Although FDA proposed to classify the eye pad (Docket No. 78N–3265) (§ 886.4650) with ophthalmic devices, FDA intends to classify the device with general and plastic surgery devices using the same docket number. Thus, FDA is not classifying the eye pad at this time.

FDA proposed to classify the polymethylmethacrylate (PMMA) contact lens (Docket No. 78N–3277) (§ 886.5400) into class II. FDA is postponing the classification of the polymethylmethacrylate (PMMA) contact lens to obtain additional information on the device. After reopening the comment period on this proposed classification and reviewing available information, FDA will classify the device in a future issue of the **Federal Register.**

FDA is postponing the classification of the 34 ophthalmic devices listed below to review additional data on electrical safety. FDA is considering classifying each of these 34 devices into class I. FDA proposed to classify the battery-powered or manual versions of certain ophthalmic devices into class I and the AC-powered versions of each of the same devices into class II. FDA identified the manual or battery-powered and AC-powered versions of these proposed devices with the same docket number and same proposed section number. FDA is postponing the classification of the AC-powered version of each of 18 devices, but is classifying into class I the battery-powered or manual version of each of the 18 devices. Accordingly, when FDA publishes regulations classifying the 18 AC-powered ophthalmic devices whose classifications are being postponed, the agency intends to use the same docket numbers and section numbers to identify these classifications.

Section No.	Device
886.1050	Adaptometer (biophotometer).
886.1070	Anomaloscope.
886.1090	Haidinger brush.
886.1120	AC-powered ophthalmic camera.
886.1140	Ophthalmic chair (AC-powered).
886.1160	Color vision plate illuminator.
886.1250	Euthyscope (AC-powered).
886.1290	AC-powered fixation device.
886.1300	Afterimage flasher.
886.1340	Haploscope.
886.1350	Keratoscope (AC-powered).
886.1425	AC-powered lens measuring instrument.
886.1430	Ophthalmic contact lens radius measuring device.
886.1435	AC-powered Maxwell spot.
886.1450	Corneal radius measuring device.
886.1605	Perimeter (AC-powered).
886.1680	Ophthalmic projector.
886.1690	Pupillograph.
886.1700	Pupillometer (AC-powered).
886.1780	Retinoscope (AC-powered).
886.1810	Tangent screen (campimeter) (AC-powered).
886.1860	Ophthalmic instrument stand (AC-powered).
886.1870	Stereoscope (AC-powered).
886.1910	Spectacle dissociation test system (AC-powered).
886.1940	Tonometer sterilizer.
886.1945	Transilluminator (AC-powered).
886.4070	Powered corneal burr (AC-powered).
886.4250	Ophthalmic electrolysis unit (AC-powered).
886.4335	Operating headlamp (AC-powered).
886.4370	Keratome (AC-powered).
886.4855	Ophthalmic instrument table (AC-powered).
886.5820	Closed-circuit television reading system.
886.5900	Electronic vision aid (AC-powered).
886.5915	Optical vision aid (AC-powered).

Although the devices identified above are not classified in this final rule, for clarity these devices are listed below under "G. List of Ophthalmic Devices."

E. Safety of Light Emitted From Certain Ophthalmic Devices

FDA is aware of published data concerning possible risks of retinal damage from light emitted by the battery-powered and AC-powered ophthalmoscope (§ 886.1570), and the AC-powered slitlamp biomicroscope (§ 886.1850) devices (Refs. 9, 10, and 11). The agency believes that a need may exist for a range of light intensities to be available from these ophthalmic instruments to accommodate the differing needs of patients with clear ocular media and those of patients with hazy ocular media. The agency is currently conducting research to determine if the high levels of light intensity that may be needed to examine eyes of patients with hazy ocular media may exceed the existing safety guidelines for patients with clear ocular media (Ref. 12). When the results of this research are available and being prepared for publication, FDA will propose any appropriate actions necessary to provide reasonable assurance of the safety and effectiveness of these two light-emitting ophthalmic devices.

F. Changes in Classifications of Devices

Based on the comments received and on additional consideration of all information before the agency, FDA has placed eight devices in different classes from those originally proposed: the visual acuity chart (§ 886.1150), the ophthalmoscope (battery-powered) (§ 886.1570), the vitreous aspiration and cutting instrument (§ 886.4150), the phacofragmentation system (§ 886.4670), the magnifying spectacles (§ 886.5840), the spectacle frame (§ 886.5842), the prescription spectacle lens (§ 886.5844), and sunglasses (nonprescription) (§ 886.5850). If FDA's final classification of a device differs from FDA's proposed classification, the name of the device is identified with an asterisk (*) below under "G. List of Ophthalmic Devices."

FDA proposed that the battery-powered ophthalmoscope be in class I and the AC-powered ophthalmoscope be in class II (§ 886.1570). FDA has become aware of published data concerning possible risks of retinal damage from the ophthalmoscope, whether battery-powered or AC-powered. (See "E. Safety of Light Emitted from Certain Ophthalmic Devices.") Because of these possible risks, in this final rule FDA is classifying the battery-powered ophthalmoscope into class II. FDA now believes that the general controls of class I are insufficient to provide reasonable

assurance of the safety and effectiveness of the battery-powered ophthalmoscope and that establishment of a performance standard is necessary to provide such assurance. FDA believes that sufficient information is available to establish a performance standard for the battery-powered ophthalmoscope. FDA's reasons for changing the classification of the other seven devices are discussed below under "H. Summaries of Comments on Classification and FDA's Responses" (see paragraphs 3a, 4, 6, and 7). FDA does not believe that it is necessary to issue new proposed regulations concerning these decisions. The purpose of publishing a proposal and soliciting comments is to enable the agency to determine whether its proposed classification of a device was correct. After reviewing the comments submitted on a proposal, the agency may be persuaded that its proposed classification is incorrect. Persons interested in the classification process should, therefore, anticipate that in a final regulation a device may be placed in a class different from the one originally proposed. This possibility was specifically identified in the proposed general regulation for ophthalmic devices (see 47 FR 3694; January 26, 1982). Persons who disagree with the final classification of a device may petition for reclassification of the device under Subpart C of 21 CFR Part 860.

G. List of Ophthalmic Devices

The list below shows the section of the Code of Federal Regulations at which the device classification is being codified, the docket number of the corresponding proposed classification regulation, the classification of each device in the final rule, and an identification (yes or no) of whether public comments were received on the proposed classification regulation. If no comments were received, FDA is adopting the proposed regulation without a change in classification, unless specified otherwise in this rule. As mentioned above, the names of eight devices on this list whose final classifications are different from the classifications proposed for these devices are identified by asterisks (*).

Each of 36 devices whose final classification is being postponed is identified below as follows: The section number is in parentheses; the name of the device is identified with footnote "1"; and no classification is provided. (See "D. Devices Not Being Classified at this Time" for a description of FDA's reasons for postponing classification of these 36 devices.) Nine transitional devices identified below with footnote "2" were not the subjects of proposed regulations. FDA is codifying the statutory classification of these devices into class III. (See the discussion below under "K. Codification of Transitional Devices.")

SUBPART B—DIAGNOSTIC DEVICES

Section	Device name	Docket No.	Class	Comments
886.1040	Ocular esthesiometer	78N-3129	I	No.
(886.1050)	Adaptometer (biophotometer) [1]	78N-3130		Yes.
(886.1070)	Anomaloscope [1]	78N-3132		Yes.
(886.1090)	Haidinger brush [1]	78N-3133		Yes.
(886.1120)	AC-powered ophthalmic camera [1]	78N-3135		Yes.
886.1140	Ophthalmic chair	78N-3137	I	Yes.
(886.1140)	Ophthalmic chair (AC-powered) [1]	78N-3137		Yes.
886.1150	Visual acuity chart*	78N-3139	I	Yes.
(886.1160)	Color vision plate illuminator [1]	78N-3140		Yes.
886.1170	Color vision tester	78N-3141	I	No.
886.1190	Distometer	78N-3142	I	No.
886.1200	Optokinetic drum	78N-3143	I	No.
886.1220	Corneal electrode	78N-3144	II	Yes.
886.1250	Euthyscope	78N-3145	I	Yes.
(886.1250)	Euthyscope (AC-powered) [1]	78N-3145		Yes.
886.1270	Exophthalmometer	78N-3147	I	No.
(886.1290)	AC-powered fixation device [1]	78N-3148		No.
(886.1300)	Afterimage flasher [1]	78N-3149		Yes.
886.1320	Fornixscope	78N-3151	I	No.
886.1330	Amsler grid	78N-3152	I	No.
(886.1340)	Haploscope [1]	78N-3295		Yes.
886.1350	Keratoscope	78N-3153	I	Yes.
(886.1350)	Keratoscope (AC-powered) [1]	78N-3153		Yes.
886.1360	Visual field laser instrument	78N-3155	II	Yes.
886.1375	Bagolini lens	78N-3156	I	No.
886.1380	Diagnostic condensing lens	78N-3157	I	No.
886.1385	Polymethylmethacrylate (PMMA) diagnostic contact lens	78N-3158	II	Yes.
886.1390	Flexible diagnostic Fresnel lens	78N-3159	I	No.
886.1395	Diagnostic Hruby fundus lens	78N-3160	I	No.
886.1400	Maddox lens	78N-3161	I	No.
886.1405	Ophthalmic trial lens set	78N-3162	II	Yes.
886.1410	Ophthalmic trial lens clip	78N-3163	I	No.
886.1415	Ophthalmic trial lens frame	78N-3164	I	No.
886.1420	Ophthalmic lens guage	78N-3165	I	No.
(886.1425)	AC-powered lens measuring instrument [1]	78N-3166		Yes.
(886.1430)	Ophthalmic contact lens radius measuring device [1]	78N-3167		Yes.
(886.1435)	AC-powered Maxwell spot [1]	78N-3168		Yes.
(886.1450)	Corneal radius measuring device [1]	78N-3169		Yes.
886.1460	Stereopsis measuring instrument	78N-3170	I	No.
886.1500	Headband mirror	78N-3171	I	No.

SUBPART B—DIAGNOSTIC DEVICES—Continued

Section	Device name	Docket No.	Class	Comments
886.1510	Eye movement monitor	78N-3172	II	Yes.
886.1570	Ophthalmoscope*	78N-3175	II	Yes.
886.1605	Perimeter	78N-3178	I	Yes.
(886.1605)	Perimeter (AC-powered) [1]	78N-3178		Yes.
886.1630	AC-powered photostimulator	78N-3181	II	Yes.
886.1640	Ophthalmic preamplifier	78N-3182	II	Yes.
886.1650	Ophthalmic bar prism	78N-3184	I	No.
886.1655	Ophthalmic Fresnel prism	78N-3185	I	No.
886.1660	Gonioscopic prism	78N-3186	I	No.
886.1665	Ophthalmic rotary prism	78N-3187	I	No.
886.1670	Ophthalmic isotope uptake probe	78N-3188	II	Yes.
(886.1680)	Ophthalmic projector [1]	78N-3189		Yes.
(886.1690)	Pupillograph [1]	78N-3190		Yes.
886.1700	Pupillometer	78N-3191	I	Yes.
(886.1700)	Pupillometer (AC-powered) [1]	78N-3191		Yes.
886.1750	Skiascopic rack	78N-3193	II	Yes.
886.1760	Ophthalmic refractometer	78N-3194	II	Yes.
886.1770	Manual refractor	78N-3195	I	No.
886.1780	Retinoscope	78N-3196	I	Yes.
(886.1780)	Retinoscope (AC-powered) [1]	78N-3196		Yes.
886.1790	Nearpoint ruler	78N-3198	I	No.
886.1800	Schirmer strip	78N-3199	I	No.
886.1810	Tangent screen (campimeter)	78N-3200	I	Yes.
(886.1810)	Tangent screen (campimeter) (AC-powered) [1]	78N-3200		Yes.
886.1840	Simulatan (including crossed cylinder)	78N-3206	I	No.
886.1850	AC-powered slitlamp biomicroscope	78N-3207	II	Yes.
886.1860	Ophthalmic instrument stand	78N-3208	I	Yes.
(886.1860)	Ophthalmic instrument stand (AC-powered) [1]	78N-3208		Yes.
886.1870	Stereoscope	78N-3210	I	Yes.
(886.1870)	Stereoscope (AC-powered) [1]	78N-3210		Yes.
886.1880	Fusion and stereoscopic target	78N-3212	I	No.
886.1905	Nystagmus tape	78N-3213	I	No.
886.1910	Spectacle dissociation test system	78N-3214	I	Yes.
(886.1910)	Spectacle dissociation test system (AC-powered) [1]	78N-3214		Yes.
886.1930	Tonometer and accessories	78N-3218	II	Yes.
(886.1940)	Tonometer sterilizer [1]	78N-3220		Yes.
886.1945	Transilluminator	78N-3221	I	Yes.
(886.1945)	Transilluminator (AC-powered) [1]	78N-3221		Yes.
	Subpart D—Prosthetic Devices			
886.3100	Ophthalmic tantalum clip	78N-3224	II	Yes.
886.3130	Ophthalmic conformer	78N-3225	II	Yes.
886.3200	Artificial eye	78N-3226	II	Yes.
886.3300	Absorbable implant (scleral buckling method)	78N-3227	II	Yes.
886.3320	Eye sphere implant	78N-3228	II	Yes.
886.3340	Extraocular orbital implant	78N-3229	II	Yes.
886.3400	Keratoprosthesis	78N-3230	III	No.
886.3600	Intraocular lens [2]		III	
886.3800	Scleral shell	78N-3231	II	Yes.
886.3920	Eye valve implant	78N-3232	III	No.
	Subpart E—Surgical Devices			
886.4070	Powered corneal burr	78N-3233	I	Yes.
(886.4070)	Powered corneal burr (AC-powered) [1]	78N-3233		Yes.
881.4100	Radiofrequency electrosurgical cautery apparatus	78N-3235	II	Yes.
886.4115	Thermal cautery unit	78N-3237	II	Yes.
886.4150	Vitreous aspiration and cutting instrument*	78N-3239	II	Yes.
886.4170	Cryophthalmic unit	78N-3241	II	Yes.
886.4230	Ophthalmic knife test drum	78N-3243	I	No.
886.4250	Ophthalmic electrolysis unit	78N-3244	I	Yes.
(886.4250)	Ophthalmic electrolysis unit (AC-powered) [1]	78N-3244		Yes.
886.4300	Intraocular lens guide	78N-3250	I	No.
886.4270	Intraocular gas [2]		III	
886.4275	Intraocular fluid [2]		III	
886.4280	Intraocular pressure measuring device [2]		III	
886.4335	Operating headlamp	78N-3252	I	Yes.
(886.4335)	Operating headlamp (AC-powered) [1]	78N-3252		Yes.
886.4350	Manual ophthalmic surgical instrument	78N-3253	I	No.

SUBPART B—DIAGNOSTIC DEVICES—Continued

Section	Device name	Docket No.	Class	Comments
886.4360	Ocular surgery irrigation device	78N-3254	I	No.
886.4370	Keratome	78N-3255	I	Yes.
(886.4370)	Keratome (AC-powered) [1]	78N-3255		Yes.
886.4390	Ophthalmic laser	78N-3257	II	Yes.
886.4400	Electronic metal locator	78N-3258	II	Yes.
886.4440	AC-powered magnet	78N-3259	II	Yes.
886.4445	Permanent magnet	78N-3260	I	No.
886.4570	Ophthalmic surgical marker	78N-3261	I	No.
886.4610	Ocular pressure applicator	78N-3264	II	Yes.
(886.4650)	Eye pad [1]	78N-3265		Yes.
886.4670	Phacofragmentation system*	78N-3266	II	Yes.
886.4690	Ophthalmic photocoagulator	78N-3267	II	Yes.
886.4750	Ophthalmic eye shield	78N-3268	I	No.
886.4770	Ophthalmic operating spectacles (loupes)	78N-3269	I	No.
886.4790	Ophthalmic sponge	78N-3270	II	Yes.
886.4855	Ophthalmic instrument table	78N-3272	I	Yes.
(886.4855)	Ophthalmic instrument table (AC-powered) [1]	78N-3272		Yes.
	Subpart F—Therapeutic Devices			
886.5100	Ophthalmic beta radiation source	78N-3273	II	Yes.
886.5120	Low-power binocular loupe	78N-3274	I	No.
(886.5400)	Polymethylmethacrylate (PMMA) contact lens [1]	78N-3277		Yes.
886.5420	Contact lens inserter/remover	78N-3278	I	No.
886.5540	Low-vision magnifier	78N-3281	I	No.
886.5600	Ptosis crutch	78N-3282	I	No.
886.5800	Ophthalmic bar reader	78N-3283	I	No.
886.5810	Ophthalmic prism reader	78N-3284	I	No.
(886.5820)	Closed-circuit television reading system [1]	78N-3285		Yes.
886.5840	Magnifying spectacles*	78N-3286	I	Yes.
886.5842	Spectacle frame* (proposed as § 886.5270)	78N-3276	I	Yes.
886.5844	Prescription spectacle lens* (proposed as § 886.5450)	78N-3279	I	Yes.
886.5850	Sunglasses (nonprescription)*	78N-3287	II	Yes.
886.5870	Low-vision telescope	78N-3288	I	No.
886.5900	Electronic vision aid	78N-3290	I	Yes.
(886.5900)	Electronic vision aid (AC-powered) [1]	78N-3290		Yes.
886.5910	Image intensification vision aid	78N-3292	I	No.
886.5915	Optical vision aid	78N-3293	I	Yes.
(886.5915)	Optical vision aid (AC-powered) [1]	78N-3293		Yes.
886.5916	Rigid gas permeable contact lens [2]		III	
886.5918	Rigid gas permeable contact lens solution [2]		III	
886.5925	Soft (hydrophilic) contact lens [2]		III	
886.5928	Soft (hydrophilic) contact lens solution [2]		III	
886.5933	Contact lens heat disinfection unit [2]		III	

[1] Classification postponed.
[2] Not proposed; statutory classification.

H. Summaries of Comments on Classification and FDA's Responses to Comments

To clarify the final rule and save printing costs, FDA is responding once to comments that apply to more than one ophthalmic device.

1. FDA proposed that all AC-powered ophthalmic devices be classified into class II. Comments argued that manufacturers have complied with voluntary electrical design and construction standards for AC-powered ophthalmic devices. Comments said that compliance with such standards has provided reasonable assurance of the safety of these devices. Further, comments questioned whether the risks to health FDA identified in the proposed regulation for each of the devices–justified establishment of a performance standard for the device. The comments recommended that FDA classify AC-powered ophthalmic devices in class I instead of class II.

FDA agrees in part and disagrees in part with the comments. FDA now is considering classifying 34 AC-powered ophthalmic devices into class I where the only risk to health is electrical shock or leakage current. To allow time for FDA to review additional data on safety of AC-powered devices, FDA is postponing classification of these 34 AC-powered ophthalmic devices. The 34 devices are listed above under "D. Devices Not Being Classified at this Time."

However, where an AC-powered ophthalmic device presents risks to health in addition to the risk of electrical shock or leakage current, FDA believes that the general controls of class I alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA is classifying the AC-powered ophthalmic devices listed below into class II as proposed. FDA believes that performance standards are necessary for these AC-powered devices to control the risks to health identified below for each device, and that sufficient information is available to establish such standards.

Section 886.1220 *Corneal electrode.* The materials used in the device should be biocompatible to prevent adverse tissue reactions. Design and construction should be controlled to prevent surface roughness that may cause corneal abrasion. Electrical properties should be controlled to prevent burns.

Section 886.1360 *Visual field laser.* The design and construction should be controlled to (1) ensure detection (diagnosis) of any defects in a patient's visual field to prevent inappropriate therapy and (2) prevent exposure to unnecessary laser radiation.

Section 886.1510 *Eye movement monitor.* The materials used in the device should be biocompatible to prevent adverse tissue reactions. Design and construction should be controlled to prevent surface roughness that may cause corneal abrasions. Electrical properties should be controlled to prevent burns.

Section 886.1570 *Ophthalmoscope.* The design and construction of the AC-powered and battery-powered ophthalmoscope should be controlled to regulate the intensity of light to prevent eye damage. See "E. Safety of Light Emitted from Certain Ophthalmic Devices" above for further information on this issue.

Section 886.1630 *AC-powered photostimulator.* The intensity of light emitted should be controlled to prevent retinal damage.

Section 886.1640 *Ophthalmic reamplifier.* The design and construction of the AC-powered and battery-powered ophthalmic preamplifier should be controlled to ensure accuracy of measurement functions (diagnosis) to prevent inappropriate therapy. Labeling should provide users with precise information regarding accuracy, reproducibility, and any limitations on performance.

Section 886.1670 *Ophthalmic isotope uptake probe.* The design and construction should be controlled to ensure (1) the accuracy of measurements (diagnosis) to prevent need for repeat examinations which may result in exposure of the patient to unnecessary radiation and (2) the device's capability of being sterilized to prevent infection.

Section 886.1760 *Ophthalmic refractometer.* The design and construction should be controlled to ensure accuracy of measurements of refraction (diagnosis) to prevent inappropriate therapy. Labeling should provide users with precise information regarding accuracy, reproducibility, and any limitations on performance.

Section 886.1850 *AC-powered slitlamp biomicroscope.* The design and construction should be controlled to (1) ensure accuracy of diagnosis to prevent inappropriate therapy and (2) regulate the intensity of light emitted to prevent eye damage. See "E. Safety of Light Emitted from Certain Ophthalmic Devices" above for further information on the latter issue.

Section 886.1930 *Tonometer and accessories.* The design and construction should be controlled to ensure (1) the accuracy of measurements (diagnosis) to prevent inappropriate therapy and (2) the device's capability of being sterilized to prevent infection. Labeling should provide users with precise information regarding accuracy, reproducibility, and any limitations on performance.

Section 886.4100 *Radiofrequency cautery apparatus.* The design and construction should be controlled to ensure that (1) the level of electrical current or heat delivered by the device provides precise, reproducible tissue coagulation or arrest of bleeding without unwanted effects, (2) the electrodes are capable of being sterilized to prevent infection, and (3) the electronic radiation is controlled to prevent interference with other nearby devices. There also is a risk of fire or explosion if the device is used in the presence of flammable anesthetic gases.

Section 886.4115 *Thermal cautery unit.* The risks are the same as for the radiofrequency cautery apparatus above, except that the risk that electronic radiation may interfere with other nearby devices does not apply.

Section 886.4170 *Cryophthalmic unit.* The design and construction should be controlled to ensure (1) that the operating tip can withstand appropriate levels of refrigerant gas pressure without bursting, (2) that the temperature provided at the tip is predictable and reproducible, and (3) that the device does not produce excessively cold temperatures that could injure the eye.

Section 886.4390 *Ophthalmic laser.* The design and construction should be controlled to prevent exposure of the patient to excessive intensity of laser radiation resulting in unnecessary tissue damage or prevent any unnecessary laser radiation exposure of the patient or user.

Section 886.4400 *Electronic metal locator.* The design and construction should be controlled to ensure that the device is capable of being sterilized to prevent infection. Labeling should provide users with precise information regarding accuracy, reproducibility, and any limitations on performance.

Section 886.4440 *AC-powered magnet.* The design and construction of the operating tip should be controlled to prevent burns to the eye.

Section 886.4690 *Ophthalmic photocoagulator.* The design and construction should be controlled to prevent (1) power surges that could cause unwanted tissue destruction in the eye, (2) malfunction of the filter that may result in burns to the eye of the operator, and (3) injury from explosion of the xenon tube.

Accordingly, FDA is adopting the 18 proposed regulations identified above with minor clarifying changes.

2. FDA proposed that each of the devices below in paragraphs a. through i. be classified into class II. Comments questioned whether the risks to health that FDA identified in the proposed regulation for each device are sufficient to justify promulgation of a performance standard for the device. Comments suggested that the devices be classified into class I instead of class II.

FDA disagrees with the comments. FDA believes that the general controls of class I are insufficient to provide reasonable assurance of the safety and effectiveness of these devices. FDA believes that performance standards are necessary for the devices to control the risks to health identified below for each device and that sufficient information is available to establish such standards.

a. Sections 886.3100 *Ophthalmic tantalum clip;* 886.3300 *Absorbable implant (scleral buckling method);* 886.3320 *Eye sphere implant;* and 886.3340 *Extraocular orbital implant.* The materials used in each of the devices should be biocompatible to prevent adverse tissue reactions. The design and construction of each of the devices should be controlled to prevent breakage or erosion and to ensure that the devices are capable of being sterilized to prevent infection. The design and construction of the eye sphere implant should be controlled to prevent extrusion. Further, the four devices above are intended to be implanted. Section 513(d)(2)(B) of the act (21 U.S.C. 360c(d)(2)(B) requires that FDA classify a device intended to be implanted into class III unless the agency determines that classification of the device in this class is unnecessary to provide reasonable assurance of its safety and effectiveness. Although FDA believes that the safety and effectiveness of the four implanted devices listed above can be assured by a performance standard, FDA believes that insufficient evidence of safety and effectiveness is available at this time for any of these devices to support its classification into class I.

b. Sections 886.1405 *Ophthalmic trial lens set* and 886.1750 *Skiascopic rack.* The design and construction should be controlled to ensure that each lens in the sets of lenses has the necessary performance characteristics, such as lens power, centration, front curve, thickness, additive sphere, cylindrical powers at a constant vertex distance, and axis alignment for cylindrical lenses, to prevent inaccurate measurements of refraction (misdiagnosis) and inappropriate therapy.

c. Section 886.1385 *Polymethylmethacrylate (PMMA) diagnostic contact lens.* The design and construction should be controlled to ensure that the device is capable of being sterilized to prevent infection and, for a vacuum diagnostic contact lens, prevent suction of the aqueous that could result in angle closure glaucoma.

d. Section 886.3130 *Ophthalmic conformer.* The material used in the device should be biocompatible and not leach components or ingredients into adjacent tissues to prevent adverse tissue reactions.

e. Section 886.3200 *Artificial eye.* The materials used in the device should be biocompatible, nonallergenic, noncarcinogenic, and nonantigenic to prevent adverse tissue reactions. The device should be capable of being sterilized to prevent infections.

f. Section 886.3800 *Scleral shell.* The material used in the device should be biocompatible to prevent adverse tissue reactions. The surface finish of the device should be controlled to prevent corneal abrasion.

g. Section 886.4610 *Ocular pressure applicator.* The design and construction should be controlled to prevent excessive pressure being applied to the eye to prevent injury to tissues.

h. Section 886.4790 *Ophthalmic sponge.* The design and construction should be controlled to ensure (1) that the device does not shed particles of device material into the eye that may become intraocular foreign bodies or cause adverse tissue reactions, (2) that the device is capable of being sterilized to prevent infections, and (3) that materials used in the device are biocompatible to prevent adverse tissue reactions. See also paragraph 6 below for further discussion of the ophthalmic sponge.

i. Section 886.5100 *Ophthalmic beta radiation source.* The materials used to make the device should be controlled to ensure biocompatibility to prevent adverse tissue reactions. Radiation properties should be controlled to prevent exposure of the patient or user to excessive or unnecessary radiation to prevent adverse effects.

Accordingly, FDA is adopting the 13 proposed regulations identified above in paragraphs a. through i. with minor clarifying changes.

3. Sections 886.1150; Visual acuity chart; proposed class II and 886.5850; Sunglasses (nonprescription); proposed class II.

Comments argued that experience has shown that the visual acuity chart and sunglasses are safe and effective under current levels of regulatory control and that any additional performance standards that would be established following classification of the devices into class II are unnecessary. Comments questioned whether the risks to health identified in the proposed regulation for each device are sufficient to justify establishment of performance standards for the devices. Further, a comment suggested that FDA grant an exemption from the requirements of the current good manufacturing practice (CGMP) regulations for sunglasses (nonprescription).

a. *Visual acuity chart.* FDA agrees with the comments. FDA now believes that the device meets the criteria in section 513(a)(1)(A)(i) of the act (21 U.S.C. 360c(a)(1)(A)(i) for devices to be classified into class I. FDA believes that the general controls of class I would provide reasonable assurance of the safety and effectiveness of the visual acuity chart, and that establishment of a performance standard for the device is unnecessary. Accordingly, FDA is classifying the visual acuity chart into class I instead of class II as proposed and with minor clarifying changes.

The agency also recognizes that the Committee on Optics and Visual Physiology of the American Academy of Ophthalmology is currently working on a voluntary standard for the visual acuity chart.

b. *Sunglasses (nonprescription).* FDA believes that these devices meet the criteria in section 513(a)(1)(A)(i) of the act (21 U.S.C. 360c(a)(1)(A)(i)) for devices to be classified into class I. FDA agrees that the general controls of class I are sufficient to provide reasonable assurance of the safety and effectiveness of the device and that the establishment of performance standards is unnecessary. FDA believes that its present regulations requiring use of spectacle lenses that have successfully passed the impact resistance tests in 21 CFR 801.410 ensure that the devices are impact resistant to prevent trauma to the eye following lens breakage.

Concerning the risk of flammability, the Federal Hazardous Substances Act, enacted in 1960 (15 U.S.C. 1261, et seq.), and administered by the Consumer Product Safety Commission, provides that agency the authority to regulate nonprescription sunglasses that contain flammable materials that may cause substantial injury. Thus, performance standards under section 514 of the act are unnecessary to control the risk of flammability of the device.

Also, manufacturers generally follow the voluntary standards for spectacle lenses that have been developed by the American National Standards Institute (Z–80).

Accordingly, FDA is classifying sunglasses (nonprescription) in class I instead of class II as proposed.

4. Section 886.4150; Vitreous aspiration and cutting instrument; proposed class III and 886.4670; Phacofragmentation system; proposed class III.

Comments requested that FDA classify both devices into class II instead of class III as proposed. Comments argued that the experience with these two devices has shown that the general controls of class I with performance standards established following classification of the devices in class II would be sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

FDA agrees with the comments urging classification of these devices into class II. FDA has reconsidered the information available on both devices and concluded that sufficient information is available to establish performance standards for the vitreous aspiration and cutting instrument and the phacofragmentation system and that establishing such standards would provide reasonable assurance of their safety and effectiveness. FDA believes that both devices have been shown through experience to be safe and effective for their intended uses. FDA now believes that the two devices do not present any greater potential for illness or injury than similar devices classified into class II, e.g., the ophthalmic laser (§ 886.4390) used in eye surgery. Therefore, premarket approval is unnecessary for these devices.

Establishing performance standards for the design and construction of the vitreous aspiration and cutting instrument would (1) reduce the risk of any malfunction causing destruction of the retina, choroid, or iris, (2) prevent particles or shavings shedding from the operating tip into the eye causing adverse tissue reactions, (3) prevent emission of unwanted levels of ultrasonic energy causing tissue damage, (4) ensure that the device is capable of being sterilized to prevent

infection, and (5) ensure that electrical properties of the device are controlled to prevent electrical injury.

Establishing performance standards for the design and construction of the phacofragmentation system would (1) prevent emission of unwanted levels of ultrasonic energy causing tissue damage, (2) prevent a reduced flow rate of irrigation solution that could cause overheating of the device or burns to eye tissue, (3) ensure that the device is capable of being sterilized to prevent infection; and (4) ensure that the electrical properties of the device are controlled to prevent electrical injury.

FDA believes that the general controls of class I alone are insufficient to provide reasonable assurance of the safety and effectiveness of the vitreous aspiration and cutting instrument and the phacofragmentation system and that establishing performance standards for the devices is necessary to provide such assurance. FDA now believes that classification of these devices into class III is unnecessary. Accordingly, FDA is classifying the two devices into class II, with minor clarifying changes, instead of class III as proposed.

5. Section 886.4790; Ophthalmic sponge; proposed class II.

a. A comment suggested that the identification of the device should be changed to include use of materials other than cellulose to make the device.

FDA has changed the identification of the device to show that various materials can be used to make the device, subject, of course, to the requirements of section 510(k) of the act and implementing regulations (21 CFR Part 807, Subpart E).

b. A comment suggested that the labeling of the device include a warning against cutting or trimming the device, to reduce hazards from shedding of particulate matter.

FDA agrees with the comment. The labeling should warn against cutting or trimming the device and should identify the materials used in the device.

c. A comment agreed with FDA's proposed regulation classifying the device into class II and recommended that a standard be established to ensure the biocompatibility of the materials used in the device.

FDA agrees with the comment. Accordingly, FDA is adopting the proposed regulation for the ophthalmic sponge with minor clarifying changes. See also paragraph 2h. above for a further discussion of the ophthalmic sponge.

6. Section 886.5270; Spectacle frame; proposed class II.

a. A comment suggested that the spectacle frame be classified as an accessory to a prescription spectacle lens rather than as a separate generic type of device.

FDA disagrees with the comment. Because the spectacle frame is made of different materials using different manufacturing procedures and presents different risks to health, FDA believes that it should be classified as a generic type of device separate from the prescription spectacle lens.

b. Comments suggested that the spectacle frame be classified into class I because establishment of a performance standard for the device is unnecessary.

FDA believes that the device meets the criteria in section 513(a)(1)(A)(i) of the act (21 U.S.C. 360c(a)(1)(A)(i)) for devices to be classified into class I. FDA agrees that the general controls of class I are sufficient to provide reasonable assurance of the safety and effectiveness of the spectacle frame and that establishment of a performance standard for the device is unnecessary. Thus, FDA believes that the general controls of class I are sufficient to control the risks to health presented by the device: (1) That the materials used in the device do not cause dermatitis, (2) that the design of the device does not interfere with a patient's vision, and (3) that the design or construction of the device prevents breakage of the device or the lens used with the device. Concerning the risk of flammability, the Federal Hazardous Substances Act, enacted in 1960 (15 U.S.C. 1261, et seq.), and administered by the Consumer Product Safety Commission, provides that agency authority to ban spectacle frames intended for children, and to require precautionary labeling on spectacle frames intended for adults, where such spectacle frames contain flammable materials that may cause substantial injury. Thus, performance standards under section 514 of the act are unnecessary to control the risk of flammability of the device. Also, manufacturers generally follow the voluntary standards for the device that have been developed by the American National Standards Institute (Z-80).

Accordingly, FDA is classifying the spectacle frame in class I, with minor clarifying changes, instead of class II as proposed. Although FDA proposed to codify the spectacle frame at § 886.5270, in the final rule FDA is codifying the device at § 886.5842, to place the device next to the prescription spectacle lens (§ 886.5844).

7. Sections 886.5450; Prescription spectacle lens; proposed class II and 886.5840; Magnifying spectacles; proposed class II.

a. A comment suggested that the identification of the prescription spectacle lens be broadened to include the raw glass spectacle lens blanks as well as the finished prescription spectacle lens.

FDA disagrees with the comment. FDA believes that it is unnecessary to broaden the identification of prescription spectacle lens to include raw glass spectacle lens blanks, which are simply components.

b. One comment agreed with FDA's proposed regulations classifying the prescription spectacle lens and the magnifying spectacle lens into class II. Other comments questioned whether the risks to health that FDA identified in the proposed regulations for these devices are sufficient to justify establishment of performance standards for the devices. These comments suggested that each of these devices be classified into class I instead of class II.

FDA now believes that the general controls of class I are sufficient to provide reasonable assurance of the safety and effectiveness of the two devices and that establishment of performance standards is unnecessary. FDA believes that its present regulations requiring use of spectacle lenses that have successfully passed the impact resistance tests in 21 CFR 801.410 ensure that the devices above are impact resistant to prevent trauma to the eye following lens breakage. FDA also believes that these devices meet the criteria in section 513(a)(1)(A)(i) of the act (21 U.S.C. 360c(a)(1)(A)(i)) for devices to be classified into class I. FDA now believes that performance standards are not necessary for these two devices. Also, manufacturers generally follow the voluntary standards for spectacle lenses that have been developed by the American National Standards Institute (Z-80).

Accordingly, FDA is classifying the prescription spectacle lens and magnifying spectacles into class I, with minor clarifying changes, instead of class II as proposed. Although FDA proposed to codify the prescription spectacle lens at § 886.5450, in the final rule FDA is codifying the device at § 886.5844, to place the device next to sunglasses (nonprescription) (§ 886.5850).

I. Exemptions for Class I Devices

8. FDA proposed to exempt 29 devices from most requirements of the current good manufacturing practice (CGMP) regulations in 21 CFR Part 820. Comments requested that exemptions from CGMP requirements be granted for all class I ophthalmic devices.

The agency is granting exemptions from most CGMP requirements for 49

generic types of class I ophthalmic devices. FDA is exempting manufacturers of these 49 devices from all of the CGMP requirements with the exception of §§ 820.180 and 820.198 relating to records and complaint files. As stated in the proposed regulations, the agency has determined that exemption of manufacturers of any device from requirements in §§ 820.180 and 820.198 of the CGMP regulations would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The complaint file requirements of § 820.198 ensure that device manufacturers have adequate systems for complaint investigation and followup. The general requirements concerning records in § 820.180 ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether an exemption from other sections of the CGMP regulations, if one has been granted, is still appropriate. Also, for reasons given in the proposed regulations, these exemptions do not apply to devices that are labeled or otherwise represented as sterile.

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device CGMP regulations. The agency announced the availability of these guidelines in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671). The guidelines assist petitioners in complying with the provisions of section 520(f)(2) of the act (21 U.S.C. 360j(f)(2)). Section 513(d)(2)(A) of the act allows FDA to approve an exemption for a device from a requirement if the agency determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with the act.

Exemptions from premarket notification procedures. Many comments requested that exemptions from premarket notification procedures in section 510(k) of the act and Subpart E of 21 CFR Part 807 be granted for all class I ophthalmic devices.

Elsewhere in this issue of the **Federal Register**, FDA is proposing to grant an exemption from the requirement of premarket notification for each of 55 class I ophthalmic devices. FDA is explaining in that proposed rule its recently developed policy on granting such exemptions.

J. Classification Regulations Published to Date

The following table shows the current structure of the advisory committees involved with the classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel name	Publication date in Federal Register
Circulatory Systems Devices Panel	March 9, 1979; 44 FR 13284–13434 (proposals); February 5, 1980; 45 FR 7904–7971 (final regulations).
Clinical Chemistry and Clinical Toxicology Devices Panel.	February 2, 1982; 47 FR 4802–4929 (proposals); May 1, 1987; 52 FR 16102–16138 (final regulations).
Hematology and Pathology Devices Panel	September 11, 1979; 44 FR 52950–53063 (proposals); September 12, 1980; 45 FR 60576–60651 (final regulations).
General Hospital and Personal Use Devices Panel.	August 24, 1979; 44 FR 49844–49954 (proposals); October 21, 1980; 45 FR 69678–69737 (final regulations).
Gastroenterology-Urology Devices Panel	January 23, 1981; 46 FR 7562–7641 (proposals); November 23, 1983; 48 FR 53012–53029 (final regulations).
Immunology Devices Panel	April 22, 1980; 45 FR 27204–27359 (proposals); November 9, 1982; 47 FR 50814–50840 (final regulations).
Microbiology Devices Panel	April 22, 1980; 45 FR 27204–27359 (proposals); November 9, 1982; 47 FR 50814–50840 (final regulations).
Obstetrics-Gynecology Devices Panel	April 3, 1979; 44 FR 19894–19971 (proposals); February 26, 1980; 45 FR 12682–12720 (final regulations).
Radiologic Devices Panel	January 29, 1982; 47 FR 4406–4451 (proposals).
Ophthalmic Devices Panel	January 26, 1982; 47 FR 3694–3749 (proposals); September 2, 1987 (final regulations).
Ear, Nose, and Throat Devices Panel	January 22, 1982; 47 FR 3280–3325 (proposals); November 6, 1986; 51 FR 40378 (final regulations).
Dental Devices Panel	December 30, 1980; 45 FR 85962–86168 (proposals); August 12, 1987; 52 FR 30082–30106 (final regulations).
Anesthesiology and Respiratory Therapy Devices Panel.	November 2, 1979; 44 FR 63292–63426 (proposals); July 16, 1982; 47 FR 31130–31150 (final regulations).
Neurological Devices Panel	November 23, 1978; 43 FR 54640–55732 (proposals); September 4, 1979; 44 FR 51726–51778 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Physical Medicine Devices).	August 28, 1979; 44 FR 50458–50537 (proposals); November 23, 1983; 48 FR 53032–53054 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Orthopedic Devices).	July 2, 1982; 47 FR 29052–29140 (proposals).
General and Plastic Surgery Devices Panel	January 19, 1982; 47 FR 2810–2853 (proposals).

K. Codification of Transitional Devices

The amendments include transitional provisions applicable to devices intended for human use that were declared to be new drugs before enactment of the amendments. (See section 520(1)(1)(E) of the act (21 U.S.C. 360j(1)(1)(E)).) The transitional provisions assure that devices formerly regarded as new drugs continue to be subject to needed regulatory controls as the amendments are being implemented. Thus, a device previously considered a new drug is classified into class III unless the agency in response to a petition has reclassified it into class I or class II. FDA is codifying the statutory classification into class III of the following nine commercially distributed transitional ophthalmic devices. Most of these devices were the subject of a **Federal Register** notice (see 42 FR 63472; December 16, 1977) on their former status as new drugs, and certain of these

devices were the subject of subsequent Federal Register documents concerning the classification of rigid gas permeable contact lenses (see 48 FR 56778; December 23, 1983) and soft (hydrophilic) contact lenses (see 49 FR 17523; April 24, 1984).

In this final rule, FDA is codifying the statutory classification of solutions that are accessories to contact lenses as three separate generic types of devices: rigid gas permeable contact lens solution (§ 886.5918), soft (hydrophilic) contact lens solution (§ 886.5928), and contact lens heat disinfection unit (§ 886.5933).

Section	Transitional device
886.3600	Intraocular lens.
886.4270	Intraocular gas.
886.4275	Intraocular fluid.
886.4280	Intraocular pressure measuring device.
886.5916	Rigid gas permeable contact lens.
886.5918	Rigid gas permeable contact lens solution.
886.5925	Soft (hydrophilic) contact lens.
886.5928	Soft (hydrophilic) contact lens solution.
886.5933	Contact lens heat disinfection unit.

L. Minor Changes or Clarifications

Occasionally, the agency has made minor changes in the name of a generic type of device or its identification to clarify the final regulation. The agency is adding new § 886.3 in Subpart A to explain the various effective dates for premarket approval requirements for devices classified into class III. FDA also is adding a new paragraph (c) in the classification regulation for each device classified into class III to declare, where applicable, the effective date for premarket approval requirements for the device.

M. References

The following information has been placed on file in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Pitts, D.G., L.L. Cameron, J. Jose, S. Lerman, E. Moss, S.D. Varma, S.D. Zigler, S. Zigman, and J. A. Zuclich, "Cataracts and Optical Radiation" in *Optical Radiation and Visual Health*, M. Waxler and V.M. Hitchins (Eds.), CRC Press, Inc., in press, 1986.

2. Ederer, F., "Epidemiologic Considerations," ibid.

3. Ham, W.T., Jr., R.G. Allen, L. Feeney-Burns, M.F. Marmor, L. Parver, P.H. Proctor, D.H. Sliney, and M.L. Wolbarsht, "Retinal Pigment Epithelial Damage Induced By Optical Radiation," ibid.

4. Massof, R.W., S.A. Sykes, L. Rapp, W.G. Robison, Jr., H. Zwick, and B. Hochheimer, "Photoreceptor Damage Induced By Optical Radiation," ibid.

5. Newsome, D.A., E. Berson, H.G. Sperling, M.O.M. Tso, T. Lawwill, M. LaVail, R. Bonner, L. Hyman, and M.A. Mainster, "Possible Role of Optical Radiation in Retinal Degenerations," ibid.

6. Sliney, D.H., "Sunglasses May Not Provide Best Protection for Retinas," *Ophthalmology Times*, 8(9):13, 1983.

7. Pike, A., "Protecting Your Human Camera, Your Eyes," *Let's LIVE*, July 1984, pp. 66–69.

8. *Proceedings of the Workshop on Long-Term Visual Health and Optical Radiation*, September 26, 1983, Rockville, MD, pp. 243–245.

9. Calkins, J.L., and B.F. Hochheimer, "Retinal Light Exposure from Ophthalmoscopes, Slit Lamps, and Overhead Surgical Lamps—An Analysis of Potential Hazards," *Association for Research in Vision and Ophthalmology, Inc.*, 19(9):1009–1015, 1980.

10. Hochheimer, B.F., S.A. D'Anna, and J.L. Calkins, "Retinal Damage from Light," *American Journal of Ophthalmology*, 88(6):1039–1044, 1979.

11. Delori, F.C., O. Pomerantzeff, and M.A. Mainster, "Light Levels in Ophthalmic Diagnostic Instruments," SPIE, 229 (Ocular Effects of Non-Ionizing Radiation) pp. 154–160, 1980.

12. American Conference of Governmental Industrial Hygienists: "Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment," ACGIH, 6500 Glenway Ave., Cincinnati, OH 45211, 1985–1986.

N. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) (April 26, 1985; 50 FR 16636) 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.

O. Economic Impact

The agency has carefully analyzed the economic effects of this final rule and has determined that the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the agency has carefully analyzed the impact of this final rule and has determined that the final rule does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules classifying devices into class I generally maintain the status quo: These devices are now subject only to the general controls provisions of the act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard was established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated under section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket approval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act, whichever occurs later. In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules.

List of Subjects in 21 CFR Part 886

Ophthalmic devices; Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 886, to read as follows:

PART 886—OPHTHALMIC DEVICES

Subpart A—General Provisions

Sec.

Subpart B—Diagnostic Devices

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

Subpart A—General Provisions

§ 886.1 Scope.

(a) This part sets forth the classification of ophthalmic devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an ophthalmic device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 886.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(l) of the act is automatically classified by statute into class III and must have an approval

under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

Subpart B—Diagnostic Devices

§ 886.1040 Ocular esthesiometer.

(a) *Identification.* An ocular esthesiometer is a device, such as a single-hair brush, intended to touch the cornea to assess corneal sensitivity.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1140 Ophthalmic chair.

(a) *Identification.* An ophthalmic chair is a manual device with adjustable positioning in which a patient is intended to sit or recline during ophthalmological examination or treatment.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1150 Visual acuity chart.

(a) *Identification.* A visual acuity chart is a device that is a chart, such as a Snellen chart with block letters or other symbols in graduated sizes, intended to test visual acuity.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1170 Color vision tester.

(a) *Identification.* A color vision tester is a device that consists of various colored materials, such as colored yarns or color vision plates (multicolored plates which patients with color vision deficiency would perceive as being of one color), intended to evaluate color vision.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1190 Distometer.

(a) *Identification.* A distometer is a device intended to measure the distance between the cornea and a corrective lens during refraction to help measure the change of the visual image when a lens is in place.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1200 Optokinetic drum.

(a) *Identification.* An optokinetic drum is a drum-like device covered with alternating white and dark stripes or pictures that can be rotated on its handle. The device is intended to elicit and evaluate nystagmus (involuntary rapid movement of the eyeball) in patients.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1220 Corneal electrode.

(a) *Identification.* A corneal electrode is an AC-powered device, usually part of a special contact lens, intended to be applied directly to the cornea to provide data showing the changes in electrical potential in the retina after electroretinography (stimulation by light).

(b) *Classification.* Class II.

§ 886.1250 Euthyscope.

(a) *Identification.* A euthyscope is a device that is a modified battery-powered ophthalmoscope (a perforated mirror device used to inspect the interior of the eye) that projects a bright light encompassing an arc of about thirty degrees on the fundus of the eye. The center of the light bundle is blocked by a black disk covering the fovea (the central depression of the macular retinae where only cones are present and blood vessels are lacking). The device is intended for use in the treatment of amblyopia (dimness of vision without apparent disease of the eye).

(b) *Classification.* Class I.

§ 886.1270 Exophthalmometer.

(a) *Identification.* An exophthalmometer is a device, such as a ruler, gauge, or caliper, intended to measure the degree of exophthalmos (abnormal protrusion of the eyeball).

(b) *Classification.* Class I.

§ 886.1320 Fornixscope.

(a) *Identification.* A fornixscope is a device intended to pull back and hold open the eyelid to aid examination of the conjunctiva.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1330 Amsler grid.

(a) *Identification.* An Amsler grid is a device that is a series of charts with grids of different sizes that are held at 30 centimeters distance from the patient and intended to rapidly detect central and paracentral irregularities in the visual field.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1350 Keratoscope.

(a) *Identification.* A keratoscope is a battery-powered device intended to measure and evaluate the corneal curvature of the eye. Lines and circles within the keratoscope are used to observe the corneal reflex. This generic type of device includes the photokeratoscope which records corneal curvature by taking photographs of the cornea.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1360 Visual field laser instrument.

(a) *Identification.* A visual field laser instrument is an AC-powered device intended to provide visible laser radiation that produces an interference pattern on the retina to evaluate retinal function.

(b) *Classification.* Class II.

§ 886.1375 Bagolini lens.

(a) *Identification.* A Bagolini lens is a device that consists of a plane lens containing almost imperceptible striations that do not obscure visualization of objects. The device is placed in a trial frame and intended to determine harmonious/anomalous retinal correspondence (a condition in which corresponding points on the retina have the same directional values).

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1380 Diagnostic condensing lens.

(a) *Identification.* A diagnostic condensing lens is a device used in binocular indirect ophthalmoscopy (a procedure that produces an inverted or reversed direct magnified image of the eye) intended to focus reflected light from the fundus of the eye.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1385 Polymethylmethacrylate (PMMA) diagnostic contact lens.

(a) *Identification.* A polymethylmethacrylate (PMMA) diagnostic contact lens is a device that is a curved shell of PMMA intended to be applied for a short period of time directly on the globe or cornea of the eye for diagnosis or therapy of intraocular abnormalities.

(b) *Classification.* Class II.

§ 886.1390 Flexible diagnostic Fresnel lens.

(a) *Identification.* A flexible diagnostic Fresnel lens is a device that is a very thin lens which has its surface a concentric series of increasingly refractive zones. The device is intended to be applied to the back of the spectacle lenses of patients with aphakia (absence of the lens of the eye).

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1395 Diagnostic Hruby fundus lens.

(a) *Identification.* A diagnostic Hruby fundus lens is a device that is a 55 diopter lens intended for use in the examination of the vitreous body and the fundus of the eye under slitlamp illumination and magnification.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1400 Maddox lens.

(a) *Identification.* A Maddox lens is a device that is a series of red cylinders that change the size, shape, and color of an image. The device is intended to be handheld or placed in a trial frame to evaluate eye muscle dysfunction.

(b) *Classification.* Class I. The device is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1405 Ophthalmic trial lens set.

(a) *Identification.* An ophthalmic trial lens set is a device that is a set of lenses of various dioptric powers intended to be handheld or inserted in a trial frame for vision testing to determine refraction.

(b) *Classification.* Class II.

§ 886.1410 Ophthalmic trial lens clip.

(a) *Identification.* An ophthalmic trial lens clip is a device intended to hold prisms, spheres, cylinders, or occluders on a trial frame or spectacles for vision testing.

(b) *Classification.* Class I. The device is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1415 Ophthalmic trial lens frame.

(a) *Identification.* An opthalmic trial lens frame is a mechanical device intended to hold trial lenses for vision testing.

(b) *Classification.* Class I. The device is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1420 Ophthalmic lens gauge.

(a) *Identification.* An ophthalmic lens gauge is a calibrated device intended to manually measure the curvature of a spectacle lens.

(b) *Classification.* Class I.

§ 886.1460 Stereopsis measuring instrument.

(a) *Identification.* A stereopsis measuring instrument is a device intended to measure depth perception by illumination of objects placed on different planes.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1500 Headband mirror.

(a) *Identification.* A headband mirror is a device intended to be strapped to the head of the user to reflect light for use in examination of the eye.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1510 Eye movement monitor.

(a) *Identification.* An eye movement monitor is an AC-powered device with an electrode intended to measure and record ocular movements.

(b) *Classification.* Class II.

§ 886.1570 Ophthalmoscope.

(a) *Identification.* An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye.

(b) *Classification.* Class II.

§ 886.1605 Perimeter.

(a) *Identification.* A perimeter is a manual device intended to determine the extent of the peripheral visual field of a patient. The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1630 AC-powered photostimulator.

(a) *Identification.* An AC-powered photostimulator is an AC-powered device intended to provide light stimulus which allows measurement of retinal or visual function by perceptual or electrical methods (e.g., stroboscope).

(b) *Classification.* Class II.

§ 886.1640 Ophthalmic preamplifier.

(a) *Identification.* An ophthalmic preamplifier is an AC-powered or battery-powered device intended to amplify electrical signals from the eye in electroretinography (recording retinal action currents from the surface of the eyeball after stimulation by light), electrooculography (testing for retinal dysfunction by comparing the standing potential in the front and the back of the eyeball), and electromyography

(recording electrical currents generated in active muscle).

(b) *Classification.* Class II.

§ 886.1650 Ophthalmic bar prism.

(a) *Identification.* An ophthalmic bar prism is a device that is a bar composed of fused prisms of gradually increasing strengths intended to measure latent and manifest strabismus (eye muscle deviation) or the power of fusion of a patient's eyes.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1655 Ophthalmic Fresnel prism.

(a) *Identification.* An ophthalmic Fresnel prism is a device that is a thin plastic sheet with embossed rulings which provides the optical effect of a prism. The device is intended to be applied to spectacle lenses to give a prismatic effect.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1660 Gonioscopic prism.

(a) *Identification.* A gonioscopic prism is a device that is a prism intended to be placed on the eye to study the anterior chamber. The device may have angled mirrors to facilitate visualization of anatomical features.

(b) *Classification.* Class I.

§ 886.1665 Ophthalmic rotary prism.

(a) *Identification.* An ophthalmic rotary prism is a device with various prismatic powers intended to be handheld and used to measure ocular deviation in patients with latent or manifest strabismus (eye muscle deviation).

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1670 Ophthalmic isotope uptake probe.

(a) *Identification.* An ophthalmic isotope uptake probe is an AC-powered device intended to measure, by a probe which is placed in close proximity to the eye, the uptake of a radioisotope (phosphorus 32) by tumors to detect tumor masses on, around, or within the eye.

(b) *Classification.* Class II.

§ 886.1700 Pupillometer.

(a) *Identification.* A pupillometer is a manual device intended to measure by reflected light the width or diameter of the pupil of the eye.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180 with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1750 Skiascopic rack.

(a) *Identification.* A skiascopic rack is a device that is a rack and a set of attached ophthalmic lenses of various dioptric strengths intended as an aid in refraction.

(b) *Classification.* Class II.

§ 886.1760 Ophthalmic refractometer.

(a) *Identification.* An ophthalmic refractometer is an automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from the retina.

(b) *Classification.* Class II.

§ 886.1770 Manual refractor.

(a) *Identification.* A manual refractor is a device that is a set of lenses of varous dioptric powers intended to measure the refractive error of the eye.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1780 Retinoscope.

(a) *Identification.* A retinoscope is a battery-powered device intended to measure the refraction of the eye by illuminating the retina and noting the direction of movement of the light on the retinal surface and of the refraction by the eye of the emergent rays.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1790 Nearpoint ruler.

(a) *Identification.* A nearpoint ruler is a device calibrated in centimeters intended to measure the nearpoint of convergence (the point to which the visual lines are directed when convergence is at its maximum).

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1800 Schirmer strip.

(a) *Identification.* A Schirmer strip is a device made of filter paper or similar material intended to be inserted under a patient's lower eyelid to stimulate and evaluate formation of tears.

(b) *Classification.* Class I.

§ 886.1810 Tangent screen (campimeter).

(a) *Identification.* A tangent screen (campimeter) is a battery-powered device that is a large square cloth chart with a central mark of fixation intended to map on a flat surface the central thirty degrees of a patient's visual field. This generic type of device includes projection tangent screens, target tangent screens and targets, felt tangent screens, and battery-powered stereo campimeters.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1840 Simulatan (including crossed cylinder).

(a) *Identification.* A simulatan (including crossed cylinder) is a device that is a set of pairs of cylinder lenses that provides various equal plus and minus refractive strengths. The lenses are arranged so that the user can exchange the positions of plus and minus cylinder lenses of equal strengths. The device is intended for subjective refraction (refraction in which the patient judges whether a given object is clearly in focus, as the examiner uses different lenses).

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1850 AC-powered slitlamp biomicroscope.

(a) *Identification.* An AC-powered slitlamp biomicroscope is an AC-powered device that is a microscope intended for use in eye examination that projects into a patient's eye through a

control diaphragm a thin, intense beam of light.

(b) *Classification.* Class II.

§ 886.1860 Ophthalmic instrument stand.

(a) *Identification.* An ophthalmic instrument stand is a nonpowered device intended to store ophthalmic instruments in a readily accessible position.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1870 Stereoscope.

(a) *Identification.* A stereoscope is a battery-powered device that combines the images of two similar objects to produce a three-dimensional appearance of solidity and relief. It is intended to measure the angle of strabismus (eye muscle deviation), evaluate binocular vision (usage of both eyes to see), and guide a patient's corrective exercises of eye muscles.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1880 Fusion and stereoscopic target.

(a) *Identification.* A fusion and stereoscopic target is a device intended for use as a viewing object with a stereoscope (§ 886.1870).

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1905 Nystagmus tape.

(a) *Identification.* Nystagmus tape is a device that is a long, narrow strip of fabric or other flexible material on which a series of objects are printed. The device is intended to be moved across a patient's field of vision to elicit optokinetic nystagmus (abnormal and irregular eye movements) and to test for blindness.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1910 Spectacle dissociation test system.

(a) *Identification.* A spectacle dissocation test system is a battery-powered device, such as a Lancaster test system, that consists of a light source and various filters, usually red or green filters, intended to subjectively measure imbalance of ocular muscles.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.1930 Tonometer and accessories.

(a) *Identification.* A tonometer and accessories is a manual device intended to measure intraocular pressure by applying a known force on the globe of the eye and measuring the amount of indentation produced (Schiotz type) or to measure intraocular tension by applanation (applying a small flat disk to the cornea). Accessories for the device may include a tonometer calibrator or a tonograph recording system. The device is intended for use in the diagnosis of glaucoma.

(b) *Classification.* Class II.

§ 886.1945 Transilluminator.

(a) *Identification.* A transilluminator is a battery-powered device that is a light source intended to transmit light through tissues to aid examination of patients.

(b) *Classification.* Class I.

Subpart C—[Reserved]

Subpart D—Prosthetic Devices

§ 886.3100 Ophthalmic tantalum clip.

(a) *Identification.* An ophthalmic tantalum clip is a malleable metallic device intended to be implanted permanently or temporarily to bring together the edges of a wound to aid healing or prevent bleeding from small blood vessels in the eye.

(b) *Classification.* Class II.

§ 886.3130 Ophthalmic conformer.

(a) *Identification.* An ophthalmic conformer is a device usually made of molded plastic intended to be inserted temporarily between the eyeball and eyelid to maintain space in the orbital cavity and prevent closure or adhesions during the healing process following surgery.

(b) *Classification.* Class II.

§ 886.3200 Artificial eye.

(a) *Identification.* An artificial eye is a device resembling an eyeball, usually made of glass or plastic, intended to be inserted in a patient's eye socket for cosmetic purposes to replace an eye. The device is not intended to be implanted.

(b) *Classification.* Class II.

§ 886.3300 Absorbable implant (scleral buckling method).

(a) *Identification.* An absorbable implant (scleral buckling method) is a device intended to be implanted on the sclera to aid retinal reattachment.

(b) *Classification.* Class II.

§ 886.3320 Eye sphere implant.

(a) *Identification.* An eye sphere implant is a device intended to be implanted in the eyeball to occupy space following the removal of the contents of the eyeball with the sclera left intact.

(b) *Classification.* Class II.

§ 886.3340 Extraocular orbital implant.

(a) *Identification.* An extraocular orbital implant is a nonabsorbable device intended to be implanted during scleral surgery for buckling or building up the floor of the eye, usually in conjunction with retinal reattachment. Injectable substances are excluded.

(b) *Classification.* Class II.

§ 886.3400 Keratoprosthesis.

(a) *Identification.* A keratoprosthesis is a device made of plastic intended to be implanted to replace the central area of an opacified natural cornea of the eye to maintain or restore sight.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 886.3.

§ 886.3600 Intraocular lens.

(a) *Identification.* An intraocular lens is a device made of materials such as glass or plastic intended to be implanted to replace the natural lens of an eye.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.3800 Scleral shell.

(a) *Identification.* A scleral shell is a device made of glass or plastic that is intended to be inserted for short time periods over the cornea and proximal-cornea sclera for cosmetic or reconstructive purposes. An artificial eye is usually painted on the device. The device is not intended to be implanted.

(b) *Classification.* Class II.

§ 886.3920 Eye valve implant.

(a) *Identification.* An eye valve implant is a one-way, pressure-sensitive, valve-like device intended to be implanted to normalize intraocular pressure. The device may be used in the treatment of glaucoma.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 886.3.

Subpart E—Surgical Devices

§ 886.4070 Powered corneal burr.

(a) *Identification.* A powered corneal burr is a battery-powered device that is a motor and drilling tool intended to remove rust rings from the cornea of the eye.

(b) *Classification.* Class I.

§ 886.4100 Radiofrequency electrosurgical cautery apparatus.

(a) *Identification.* A radiofrequency electrosurgical cautery apparatus is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by a high frequency electric current.

(b) *Classification.* Class II.

§ 886.4115 Thermal cautery unit.

(a) *Identification.* A thermal cautery unit is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by heat conducted through a wire tip.

(b) *Classification.* Class II.

§ 886.4150 Vitreous aspiration and cutting instrument.

(a) *Identification.* A vitreous aspiration and cutting instrument is an electrically powered device, which may use ultrasound, intended to remove vitreous matter from the vitreous cavity or remove a crystalline lens.

(b) *Classification.* Class II.

§ 886.4170 Cryophthalmic unit.

(a) *Identification.* A cryophthalmic unit is a device that is a probe with a small tip that becomes extremely cold through the controlled use of a refrigerant or gas. The device may be AC-powered. The device is intended to remove cataracts by the formation of an adherent ice ball in the lens, to freeze the eye and adjunct parts for surgical removal of scars, and to freeze tumors.

(b) *Classification.* Class II.

§ 886.4230 Ophthalmic knife test drum.

(a) *Identification.* An ophthalmic knife test drum is a device intended to test the keenness of ophthalmic surgical knives to determine whether resharpening is needed.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.4250 Ophthalmic electrolysis unit.

(a) *Identification.* An ophthalmic electrolysis unit is a battery-powered device intended to destroy ocular hair follicles by applying a galvanic electrical current.

(b) *Classification.* Class I.

§ 886.4270 Intraocular gas.

(a) *Identification.* An intraocular gas is a device consisting of a gaseous fluid intended to be introduced into the eye to place pressure on a detached retina.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4275 Intraocular fluid.

(a) *Identification.* An intraocular fluid is a device consisting of a nongaseous fluid intended to be introduced into the eye to aid performance of surgery, such as to maintain anterior chamber depth, preserve tissue integrity, protect tissue from surgical trauma, or function as a tamponade during retinal reattachment.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4280 Intraocular pressure measuring device.

(a) *Identification.* An intraocular pressure measuring device is a manual or AC-powered device intended to measure intraocular pressure. Also included are any devices found by FDA to be substantially equivalent to such devices. Accessories for the device may include calibrators or recorders. The device is intended for use in the diagnosis of glaucoma.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4300 Intraocular lens guide.

(a) *Identification.* An intraocular lens guide is a device intended to be inserted into the eye during surgery to direct the insertion of an intraocular lens and be removed after insertion is completed.

(b) *Classification.* Class I.

§ 886.4335 Operating headlamp.

(a) *Identification.* An operating headlamp is a battery-powered device intended to be worn on the user's head to provide a light source to aid visualization during surgical, diagnostic, or therapeutic procedures.

(b) *Classification.* Class I.

§ 886.4350 Manual ophthalmic surgical instrument.

(a) *Identification.* A manual ophthalmic surgical instrument is a nonpowered, handheld device intended to aid or perform ophthalmic surgical procedures. This generic type of device includes the manual corneal burr, ophthalmic caliper, ophthalmic cannula, eyelid clamp, ophthalmic muscle clamp, iris retractor clip, orbital compressor, ophthalmic curette, cystotome, orbital depressor, lachrymal dilator, erisophake, expressor, ophthalmic forcep, ophthalmic hook, sphere introducer, ophthalmic knife, ophthalmic suturing needle, lachrymal probe, trabeculotomy probe, cornea-sclera punch, ophthalmic retractor, ophthalmic ring (Flieringa), lachrymal sac rongeur, ophthalmic scissors, enucleating snare, ophthalmic spatula, ophthalmic specula, ophthalmic spoon, ophthalmic spud, trabeculotome or ophthalmic manual trephine.

(b) *Classification.* Class I.

§ 886.4360 Ocular surgery irrigation device.

(a) *Identification.* An ocular surgery irrigation device is a device intended to be suspended over the ocular area during ophthalmic surgery to deliver continuous, controlled irrigation to the surgical field.

(b) *Classification.* Class I.

§ 886.4370 Keratome.

(a) *Identification.* A keratome is battery-powered device intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.

(b) *Classification.* Class I.

§ 886.4390 Ophthalmic laser.

(a) *Identification.* An ophthalmic laser is an AC-powered device intended to coagulate or cut tissue of the eye, orbit, or surrounding skin by a laser beam.

(b) *Classification.* Class II.

§ 886.4400 Electronic metal locator.

(a) *Identification.* An electronic metal locator is an AC-powered device with

probes intended to locate metallic foreign bodies in the eye or eye socket.

(b) *Classification.* Class II.

§ 886.4440 AC-powered magnet.

(a) *Identification.* An AC-powered magnet is an AC-powered device that generates a magnetic field intended to find and remove metallic foreign bodies from eye tissue.

(b) *Classification.* Class II.

§ 886.4445 Permanent magnet.

(a) *Identification.* A permanent magnet is a nonelectric device that generates a magnetic field intended to find and remove metallic foreign bodies from eye tissue.

(b) *Classification.* Class I.

§ 886.4570 Ophthalmic surgical marker.

(a) *Identification.* An ophthalmic surgical marker is a device intended to mark by use of ink, dye, or indentation the location of ocular or scleral surgical manipulation.

(b) *Classification.* Class I.

§ 886.4610 Ocular pressure applicator.

(a) *Identification.* An ocular pressure applicator is a manual device that consists of a sphygmomanometer-type squeeze bulb, a dial indicator, a band, and bellows, intended to apply pressure on the eye in preparation for ophthalmic surgery.

(b) *Classification.* Class II.

§ 886.4670 Phacofragmentation system.

(a) *Identification.* A phacofragmentation system is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

(b) *Classification.* Class II.

§ 886.4690 Ophthalmic photocoagulator.

(a) *Identification.* An ophthalmic photocoagulator is an AC-powered device intended to use the energy from an extended noncoherent light source to occlude blood vessels of the retina, choroid, or iris.

(b) *Classification.* Class II.

§ 886.4750 Ophthalmic eye shield.

(a) *Identification.* An ophthalmic eye shield is a device that consists of a plastic or aluminum eye covering intended to protect the eye or retain dressing materials in place.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.4770 Ophthalmic operating spectacles (loupes).

(a) *Identification.* Ophthalmic operating spectacles (loupes) are devices that consist of convex lenses or lens systems intended to be worn by a surgeon to magnify the surgical site during ophthalmic surgery.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files.

§ 886.4790 Ophthalmic sponge.

(a) *Identification.* An ophthalmic sponge is a device that is an absorbant sponge, pad, or spear made of folded gauze, cotton, cellulose, or other material intended to absorb fluids from the operative field in ophthalmic surgery.

(b) *Classification.* Class II.

§ 886.4855 Ophthalmic instrument table.

(a) *Identification.* An ophthalmic instrument table is a manual device on which ophthalmic instruments are placed.

(b) *Classification.* Class I. This device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Subpart F—Therapeutic Devices

§ 886.5100 Ophthalmic beta radiation source.

(a) *Identification.* An ophthalmic beta radiation source is a device intended to apply superficial radiation to benign and malignant ocular growths.

(b) *Classification.* Class II.

§ 886.5120 Low-power binocular loupe.

(a) *Identification.* A low-power binocular loupe is a device that consists of two eyepieces, each with a lens or lens system, intended for medical purposes to magnify the appearance of objects.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5420 Contact lens inserter/remover.

(a) *Identification.* A contact lens inserter/remover is a handheld device intended to insert or remove contact lenses by surface adhesion or suction.

(b) *Classification.* Class I.

§ 886.5540 Low-vision magnifier.

(a) *Identification.* A low-vision magnifier is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device may be held in the hand or attached to spectacles.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5600 Ptosis crutch.

(a) *Identification.* A ptosis crutch is a device intended to be mounted on the spectacles of a patient who has ptosis (drooping of the upper eyelid as a result of faulty development or paralysis) to hold the upper eyelid open.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5800 Ophthalmic bar reader.

(a) *Identification.* An ophthalmic bar reader is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device is placed directly onto reading material to magnify print.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5810 Ophthalmic prism reader.

(a) *Identification.* An ophthalmic prism reader is a device intended for use by a patient who is in a supine position to change the angle of print to aid reading.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5840 Magnifying spectacles.

(a) *Identification.* Magnifying spectacles are devices that consist of spectacle frames with convex lenses intended to be worn by a patient who has impaired vision to enlarge images.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in

Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5842 Spectacle frame.

(a) *Identification.* A spectacle frame is a device made of metal or plastic intended to hold prescription spectacle lenses worn by a patient to correct refractive errors.

(b) *Classification.* Class I.

§ 886.5844 Prescription spectacle lens.

(a) *Identification.* A prescription spectacle lens is a glass or plastic device that is a lens intended to be worn by a patient in a spectacle frame to provide refractive corrections in accordance with a prescription for the patient. The device may be modified to protect the eyes from bright sunlight (i.e., prescription sunglasses). Prescription sunglass lenses may be reflective, tinted, polarizing, or photosensitized.

(b) *Classification.* Class I.

§ 886.5850 Sunglasses (nonprescription).

(a) *Identification.* Sunglasses (nonprescription) are devices that consist of spectacle frames or clips with absorbing, reflective, tinted, polarizing, or photosensitized lenses intended to be worn by a person to protect the eyes from bright sunlight but not to provide refractive corrections. This device is usually available over-the-counter.

(b) *Classification.* Class I.

§ 886.5870 Low-vision telescope.

(a) *Identification.* A low-vision telescope is a device that consists of an arrangement of lenses or mirrors intended for use by a patient who has impaired vision to increase the apparent size of objects. This generic type of device includes handheld or spectacle telescopes.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5900 Electronic vision aid.

(a) *Identification.* An electronic vision aid is a battery-powered device that consists of an electronic sensor/transducer intended for use by a patient who has impaired vision or blindness, to translate visual images of objects into tactile or auditory signals.

(b) *Classification.* Class I.

§ 886.5910 Image intensification vision aid.

(a) *Identification.* An image intensification vision aid is a battery-powered device intended for use by a patient who has limited dark adaptation or impaired vision to amplify ambient light.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5915 Optical vision aid.

(a) *Identification.* An optical vision aid is a device that consists of a magnifying lens with accompanying battery-powered light source intended for use by a patient who has impaired vision to increase the apparent size of object detail.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 886.5916 Rigid gas permeable contact lens.

(a) *Identification.* A rigid gas permeable contact lens is a device intended to be worn directly against the cornea of the eye to correct vision conditions. The device is made of various materials, such as cellulose acetate butyrate, polyacrylate-silicone, or silicone elastomers, whose main polymer molecules generally do not absorb or attract water.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.5918 Rigid gas permeable contact lens solution.

(a) *Identification.* A rigid gas permeable contact lens solution is a device intended to clean, disinfect, wet, or store a rigid gas permeable contact lens (§ 886.5916).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.5925 Soft (hydrophilic) contact lens.

(a) *Identification.* A soft (hydrophilic) contact lens is a device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions or act as a therapeutic bandage. The device is made of various polymer materials the main polymer molecules of which absorb or attract a certain volume (percentage) of water.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.5928 Soft (hydrophilic) contact lens solution.

(a) *Identification.* A soft (hydrophilic) contact lens solution is a device intended to clean, disinfect, wet, or store a soft (hydrophilic) contact lens (§ 886.5925).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.5933 Contact lens heat disinfection unit.

(a) *Identification.* A contact lens heat disinfection unit is a device intended to disinfect a contact lens by means of heat.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

Dated: June 15, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

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