

part B of this part, unless exempt under subpart D of this part.

(b) Foreign device establishments that export devices into the United States, whether or not the establishment is registered, shall comply with the device listing requirements unless exempt from registration as stated in § 807.65. Those foreign owners or operators for which there exists joint ownership and control with a domestic establishment may have the domestic establishment submit listing information and maintain the historical file. A foreign owner or operator may authorize a domestic initial distributor to submit listing information when joint ownership and control does not exist, only if:

(1) The domestic distributor is the sole initial distributor for the foreign owner or operator's device; and

(2) The foreign owner or operator submits a letter to the Food and Drug Administration authorizing the initial distributor to list on its behalf and maintain the historical file.

(c) Except for a device imported or offered for import that has in effect an approved exemption for investigational use under section 520(g) of the act, a device may not be imported from a foreign device establishment into the United States unless it is listed at the interval specified for updating device listing information in § 807.30(b). The device listing information shall be in the English language.

(d) Foreign device establishments shall submit, as part of the device listing, the name and address of the establishment and the name of the individual responsible for submitting device listing information. Any changes in this information shall be reported to the Food and Drug Administration at the intervals specified for updating device listing information in § 807.30(b).

Effective date: This regulation shall be effective October 10, 1978.

(Secs. 301 (p) and (q)(2), 501, 502, 508, 510, 519, 701(a), 52 Stat. 1042-1043 as amended, 1049-1050 as amended, 1055, 76 Stat. 789, 794 as amended, 86 Stat. 562 as amended, 90 Stat. 564-580 (21 U.S.C. 331 (p) and (q)(2), 351, 352, 358, 360, 360i, 371(a)).)

Dated: August 16, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Regulatory Affairs.

[FR Doc. 78-23757 Filed 8-24-78; 8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 539—BULK ANTIBIOTIC DRUGS SUBJECT TO CERTIFICATION

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

Sterile Amoxicillin Trihydrate; Sterile Amoxicillin Trihydrate for Suspension

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The regulations are amended to reflect approval of a new animal drug application (NADA) filed by Beecham Laboratories. The NADA provides for safe and effective use of sterile amoxicillin trihydrate for suspension for treating certain bacterial infections in dogs and cats. In addition, the regulations are amended to provide for certification of the bulk sterile amoxicillin trihydrate used in the manufacture of sterile amoxicillin trihydrate for suspension.

EFFECTIVE DATE: August 25, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert A. Baldwin, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Beecham Laboratories, Division of Beecham, Inc., Bristol, Tenn. 37620, filed a NADA (55-091V) providing for use of sterile amoxicillin for suspension for treating dogs for certain bacterial infections of the respiratory tract, genitourinary tract, gastrointestinal tract, bacterial dermatitis, and soft tissues, and cats for certain infections of the upper respiratory tract, genitourinary tract, gastrointestinal tract, skin, and soft tissues. A companion application form 6, 62-015, provides for certification of the sterile amoxicillin trihydrate used in the manufacture of the drug.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of the safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512 (i),

(n), 82 Stat. 347, 350-351 (21 U.S.C. 360b (i), (n))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), parts 539 and 540 are amended as follows:

1. Part 539 is amended in subpart A by adding new § 539.3 to read as follows:

§ 539.3 Sterile amoxicillin trihydrate.

(a) *Requirements for certification—*
(1) *Standards of identity, strength, quality, and purity.* Amoxicillin trihydrate is the trihydrate form of D(-) α-amino-p-hydroxybenzyl penicillin. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms and not more than 1,050 micrograms of amoxicillin per milligram on an anhydrous basis.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv) It passes the safety test.

(v) Its moisture content is not less than 11.5 percent and not more than 14.5 percent.

(vi) Its pH in an aqueous solution containing 2 milligrams per milliliter is not less than 3.5 and not more than 6.0.

(vii) Its amoxicillin content is not less than 90 percent on an anhydrous basis.

(viii) The acid-base titration concordance is such that the difference between the percent amoxicillin content when determined by nonaqueous acid titration and by nonaqueous base titration is not more than 6. The potency acid titration concordance is such that the difference between potency value divided by 10 and the percent amoxicillin content of the sample determined by the nonaqueous acid titration is not more than 6. The potency-base titration concordance is such that the difference between the potency value divided by 10 and the percent amoxicillin content of the sample determined by the nonaqueous base titration is not more than 6.

(ix) It is crystalline.

(x) It gives a positive identity test for amoxicillin trihydrate.

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5(b) of this chapter, this drug shall be labeled "amoxicillin".

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, pyrogens, safety, moisture, pH, amoxicillin content, concordance, crystallinity, and identity.

(ii) Samples required:

(a) For all tests except sterility: 10 packages, each containing approximately 600 milligrams.

(b) For sterility testing: 20 packages, each containing approximately 600 milligrams.

(b) *Tests and methods of assay*—(1) *Potency*. Use any of the following methods; however, the results obtained from the iodometric assay shall be conclusive:

(i) *Microbiological agar diffusion assay*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed portion of the sample in sufficient sterile distilled water to give a stock solution containing 1.0 milligram of amoxicillin per milliliter (estimated). Further dilute an aliquot of the stock solution with 0.1 M potassium phosphate buffer, pH 8.0 (solution 3) to the reference concentration of 0.1 microgram of amoxicillin per milliliter (estimated).

(ii) *Iodometric assay*. Proceed as directed in § 436.204 of this chapter.

(iii) *Hydroxylamine colorimetric assay*. Proceed as directed in § 436.205 of this chapter.

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter using the method described in paragraph (e)(2) of that section, except use medium C in lieu of medium A, medium F in lieu of medium E, and during the period of incubation shake the tubes at least once daily.

(3) *Pyrogens*. Proceed as directed in § 436.32(f) of this chapter, using a solution containing 20 milligrams of amoxicillin per milliliter.

(4) *Safety*. Proceed as directed in § 436.33 of this chapter.

(5) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(6) *pH*. Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 2 milligrams per milliliter.

(7) *Amoxicillin content*. Proceed as directed in § 436.213 of this chapter, using both the titration procedures described in paragraph (e) (1) and (2) of that section. Calculate the percent amoxicillin content as follows:

(i) *Acid titration*.

Percent amoxicillin content = $(A - B) \text{ (normality of lithium methoxide reagent)} \times (365.4) \times (100) / (\text{weight of sample in milligrams}) \times (100 - m)$

where:

A = Milliliters of lithium methoxide reagent used in titrating the sample.

B = Milliliters of lithium methoxide reagent used in titrating the blank.

m = Percent moisture content of the sample.

Difference = Potency in micrograms per milligram/10 - percent amoxicillin content.

(ii) *Base titration*.

Percent amoxicillin content = $(A - B) \text{ (normality of perchloric acid reagent)} \times (365.4)$

$(100) \times (100) / (\text{weight of sample in milligrams}) \times (100 - m)$

where:

A = Milliliters of perchloric acid reagent used in titrating the sample.

B = Milliliters of perchloric acid reagent used in titrating the blank.

m = Percent moisture content of the sample.

Difference = Potency in micrograms per milligram/10 - percent amoxicillin content.

(8) *Crystallinity*. Proceed as directed in § 436.203(a) of this chapter.

(9) *Identity*. Proceed as directed in § 436.211 of this chapter, using a 0.5 percent potassium bromide disc prepared as described in paragraph (b)(1) of that section.

2. Part 540 is amended in subpart B by adding new § 540.203 to read as follows:

§ 540.203 Sterile amoxicillin trihydrate for suspension.

(a) *Requirements for certification*—

(1) *Standards of identity, strength, quality, and purity*. Sterile amoxicillin trihydrate for suspension is a dry mixture of amoxicillin trihydrate and one or more suitable and harmless buffer substances, stabilizers, suspending agents, and preservatives. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the labeled amount of amoxicillin. It is sterile. It is nonpyrogenic. It passes the safety test. Its moisture content is not less than 11.0 percent and not more than 14.0 percent. When reconstituted as directed in the labeling, its pH is not less than 5.0 and not more than 7.0. The amoxicillin trihydrate used conforms to the requirements of § 539.3 of this chapter.

(2) *Labeling*. It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter, and in addition, this drug shall be labeled "sterile amoxicillin for suspension, veterinary".

(3) *Requests for certification; samples*. In addition to complying with the requirements of § 514.50 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The amoxicillin trihydrate used in making the batch for potency, moisture, pH, amoxicillin content, concordance, crystallinity, and identity.

(b) The batch for potency, sterility, pyrogens, safety, moisture, and pH.

(ii) Samples required:

(a) The amoxicillin trihydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of 12 immediate containers.

(2) For sterility testing: 20 immedi-

ate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation*. Reconstitute as directed in the labeling. Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if the container is represented as a single-dose container or, if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Dilute the resultant solution with 0.1 M potassium phosphate buffer, pH 8.0 (solution 3), for the microbiological agar diffusion, assay, or distilled water for the iodometric assay, to give a stock solution of convenient concentration.

(ii) *Assay procedure*. Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) *Microbiological agar diffusion assay*. Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of amoxicillin per milliliter (estimated).

(b) *Iodometric assay*. Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with distilled water to the prescribed concentration.

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use medium C in lieu of medium A, medium F in lieu of medium E, and during the period of incubation shake the tubes at least once daily.

(3) *Pyrogens*. Proceed as directed in § 436.32(f) of this chapter, using a solution containing 20 milligrams of amoxicillin per milliliter.

(4) *Safety*. Proceed as directed in § 436.33 of this chapter.

(5) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(6) *pH*. Proceed as directed in § 436.202 of this chapter, using the solution obtained when the product is reconstituted as directed in the labeling.

(c) *Conditions of marketing*—(1) *Specifications*. Each vial contains 3 grams of amoxicillin activity as the trihydrate. It is reconstituted with sterile water for injection USP to the concentration of 100 or 250 milligrams per milliliter.

(2) *Sponsor*. See 000029 in § 510.600(c) of this chapter.

(3) *Conditions of use in dogs and cats*—(i) *Amount*. 5 milligrams per pound of body weight daily.

[4830-01]

Title 26—Internal Revenue

CHAPTER I—INTERNAL REVENUE
SERVICE, DEPARTMENT OF THE
TREASURYSUBCHAPTER F—PROCEDURE AND
ADMINISTRATION

[T.D. 7561; LR-265-74]

PART 301—PROCEDURE AND
ADMINISTRATIONAnnual Registration for Employee
Retirement Benefit PlansAGENCY: Internal Revenue Service,
Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final regulations relating to the requirement that the plan administrator of an employee retirement benefit plan annually file information relating to plan participants who separate from service covered by the plan and are entitled to a retirement benefit under the plan, but are not paid this retirement benefit. This document also provides final regulations relating to the requirement that a plan administrator report certain changes in plan status, and to amounts imposed for failure to file with the Internal Revenue Service certain information required in connection with employee retirement benefit plans. Changes to the applicable tax law were made by the Employee Retirement Income Security Act of 1974 ("ERISA"). These regulations provide plan administrators and employers with the necessary guidance to comply with the law, and also affect plan participants who separate from service covered by an employee retirement benefit plan and are entitled to a retirement benefit under the plan.

DATES: The regulations relating to the reporting of the deferred vested retirement benefit of a separated plan participant are generally effective with respect to participants separating from service in plan years beginning after 1975. The regulations relating to the reporting of a change in plan status are also effective for plan years beginning after 1975. The regulations relating to amounts imposed for failure to file certain information with respect to employee benefit plans are generally effective for plan years beginning after September 2, 1974.

FOR FURTHER INFORMATION
CONTACT:

Richard L. Johnson of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224 (Attention: CC:LR:T:LR-265-74), 202-566-6358 (not a toll-free number).

(ii) *Indications for use*—(a) Dogs: Use for the treatment of infections caused by susceptible strains of organisms as follows: Respiratory infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli*, and *Proteus mirabilis*; genitourinary infections (cystitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli*, and *Proteus mirabilis*; gastrointestinal infections (bacterial gastroenteritis) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli*, and *Proteus mirabilis*; bacterial dermatitis due to *Staphylococcus aureus*, *Streptococcus* spp., and *Proteus mirabilis*; soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli*, and *Proteus mirabilis*.

(b) Cats: Use for the treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory infections due to *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* spp., *E. coli*, *Pasteurella* spp., and *Proteus mirabilis*; genitourinary infections (cystitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *E. coli*, *Proteus mirabilis*, and *Corynebacterium* spp.; gastrointestinal infections due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(iii) *Limitations*. Administer once daily for up to 5 days by intramuscular or subcutaneous injection. Treatment should be continued for 48 hours after the animal has become afebrile or asymptomatic. If no improvement is seen within 5 days, review the diagnosis and change therapy. As with all antibiotics, appropriate in vitro culturing and susceptibility testing of samples taken before treatment should be conducted. For use in dogs and cats only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date: This regulation is effective August 25, 1978.

(Sec. 512(i), (n), 82 Stat. 347, 350-351 (21 U.S.C. 360b(i), (n)).)

Dated: August 16, 1978.

LESTER M. CRAWFORD,
Director, Bureau of
Veterinary Medicine.

[FR Doc. 78-23572 Filed 8-24-78; 8:45 am]

SUPPLEMENTARY INFORMATION:

BACKGROUND

On January 20, 1978, the FEDERAL REGISTER published proposed amendments to the procedure and administration regulations (26 CFR Part 301) under sections 6057, 6652 (e) and (f), and 6690 of the Internal Revenue Code of 1954 (43 FR 2892). A correction notice was published in the FEDERAL REGISTER on February 16, 1978 (43 FR 6812). The amendments were proposed to conform the regulations to section 1031 of the Employee Retirement Income Security Act of 1974 (88 Stat. 943) ("ERISA"). A public hearing was held on April 13, 1978. After consideration of all comments regarding the proposed amendments, those amendments are adopted as revised by this Treasury decision.

IDENTIFICATION OF SEPARATED PARTICIPANTS WITH DEFERRED VESTED RETIREMENT BENEFIT

ERISA requires that the plan administrator of an employee retirement benefit plan file with the Internal Revenue Service information relating to each plan participant who separates from service covered by the plan, is entitled to a deferred vested retirement benefit under the plan and is not paid this retirement benefit. The information required describes the nature, amount, and form of the benefit to which the participant is entitled, and is to be filed on schedule SSA ("Identification of Separated Participants With Deferred Vested Benefits") as an attachment to the annual return/report of employee benefit plan (form 5500 series). The description of the retirement benefit is also to be provided the participant.

The final regulations provided by this document differ in part from the proposed regulations. First, the final regulations provide that a plan to which more than one employer contributes is required to file schedule SSA starting with the first plan year beginning after 1977. Accordingly, the earliest required filing date for a plan to which more than one employer contributes is July 31, 1979. This is 1 year later than the date provided in the proposed regulations.

Under the proposed regulations, no information relating to the retirement benefit of a plan participant was required to be filed on schedule SSA if the participant is paid some or all of the benefit, forfeits the benefit or returns to service covered by the plan before the end of the plan year for which the schedule SSA is filed. The final regulations provide that no filing is required if such an event occurs before the date the schedule SSA is required to be filed, normally 7 months after the end of the plan year.

The final regulations provide that a plan administrator may, at its option, request that information relating to a plan participant's retirement benefit be deleted from Social Security Administration records if, after the information is filed on schedule SSA, the participant is paid some or all of the benefit or forfeits the benefit under the plan.

As described above, information relating to a participant's retirement benefit is not required to be filed on schedule SSA if the participant is paid only some of the benefit, and information previously filed may be deleted upon payment of only some of the benefit. The final regulations provide that if the participant is not paid all of the benefit, information relating to the benefit to which the participant remains entitled is required to be filed on the schedule SSA filed for the plan year following the plan year in which a portion of the benefit is last paid to the participant.

The final regulations clarify that a church or governmental plan is not required to file schedule SSA. In addition, certain other clarifying changes have been made in the final regulations.

DRAFTING INFORMATION

The principal author of these proposed regulations was Richard L. Johnson of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both on matters of substance and style.

ADOPTION OF AMENDMENT TO THE REGULATIONS

Accordingly, the proposed amendments are adopted with the changes set forth below:

Paragraph 1. Section 301.6057-1(a)(3) is revised by adding at the end thereof a new sentence to read: "The filing requirements described in this section and § 301.6057-2 (relating to notification of change in plan status) do not apply to a governmental or church plan described in section 414 (d) or (e)."

Par. 2. Section 301.6057-1(a)(5)(ii) is revised to read as follows:

§ 301.6057-1 *Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.*

(a) *Annual registration statement* * * *

(5) *Time for reporting deferred vested retirement benefit* * * *

(ii) *Exception.* Notwithstanding subdivision (i), no information relating to the deferred vested retirement benefit of a separated participant is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pur-

suant to section 6081), the participant (A) is paid some or all of the deferred vested retirement benefit under the plan, (B) returns to service covered by the plan, or (C) forfeits all of the deferred vested retirement benefit under the plan.

Par. 3. Section 301.6057-1(b)(2) is revised to read as follows:

§ 301.6057-1 *Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.*

(b) *Plans to which more than one employer contributes* * * *

(2) *Time for reporting deferred vested retirement benefit—(i) In general.* In the case of a plan to which more than one employer contributes, information relating to the deferred vested retirement benefit of a plan participant must be filed no later than on the schedule SSA filed for the plan year within which the participant completes the second of two consecutive 1-year breaks in service (as defined in the plan for vesting percentage purposes) in service computation periods (as defined in the plan for vesting percentage purposes) which begin after December 31, 1974. At the option of the plan administrator, information relating to a participant's deferred vested retirement benefit may be filed earlier (that is, on the schedule SSA filed for the plan year in which the participant incurs the first 1-year break in service or, in the case of a separated participant, on the schedule SSA filed for the plan year in which the participant separates from service).

(ii) *Special rules.* For purposes of this subparagraph (1)—

(A) For the definition of the term "1-year break in service" in the case of a plan which uses the elapsed time method described in Department of Labor regulations for crediting service for vesting percentage purposes, see § 1.411(a)-6(c)(2).

(B) In the case of a plan which does not define the term "1-year break in service" for vesting percentage purposes, a plan participant shall be deemed to incur a 1-year break in service under the plan in any plan year within which the participant does not complete more than 500 hours of service covered by the plan.

(iii) *Transitional rule.* Notwithstanding subdivision (i), if the second consecutive 1-year break in service described in subdivision (i) is incurred in a plan year beginning before January 1, 1978, information relating to the participant's deferred vested retirement benefit is not required to be filed earlier than on the schedule SSA filed for the first plan year beginning after December 31, 1977.

(iv) *Exception.* Notwithstanding subdivision (i) or (iii) of this subparagraph, no information relating to a participant's deferred vested retirement benefit is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (A) is paid some or all of the deferred vested retirement benefit under the plan, (B) accrues additional retirement benefits under the plan, or (C) forfeits all of

the deferred vested retirement benefit under the plan.

Par. 4. Section 301.6057-1(b)(3)(iii) is revised by deleting the second and third sentences and inserting in lieu thereof "If, in view of information provided either by the incomplete records or the plan participant, there is a significant likelihood that the plan participant is vested in a deferred retirement benefit under the plan, information relating to the participant must be filed on schedule SSA with the notation that the participant may be entitled to a deferred vested retirement benefit under the plan, but information relating to the amount of the benefit may be omitted".

Par. 5. Section 301.6057-1(c) is revised to read as follows:

§ 301.6057-1 *Employee retirement benefits plans; identification of participant with deferred vested retirement benefit.*

(c) *Voluntary filing—(1) In general.* The plan administrator of an employee retirement benefit plan described in paragraph (a)(3) of this section, or any other employee retirement benefit plan (including a governmental or church plan), may at its option, file on schedule SSA information relating to the deferred vested retirement benefit of any plan participant who separates at any time from service covered by the plan, including plan participants who separate from service in plan years beginning before 1976.

(2) *Deleting previously filed information.* If, after information relating to the deferred vested retirement benefit of a plan participant is filed on schedule SSA, the plan participant—

(i) Is paid some or all of the deferred vested retirement benefit under the plan, or

(ii) Forfeits all of the deferred vested retirement benefit under the plan,

the plan administrator may, at its option, file on schedule SSA (or such other form as may be provided for this purpose) the name and social security number of the participant with the notation that information previously filed relating to the participant's deferred vested retirement benefit should be deleted.

Par. 6. Paragraphs (d), (e) and (f) of § 301.6057-1 are redesignated (e), (f), and (g), respectively, and a new paragraph (d) is added to read as follows:

§ 301.6057-1 *Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.*

(d) *Filing incident to cessation of payment of benefits—(1) In general.* As described in this section, no information relating to the deferred vested retirement benefit of a plan participant is required to be filed on schedule SSA if before the date such schedule SSA is required to be filed, some of the deferred vested retirement benefit is paid to the participant, and infor-

mation relating to a participant's deferred vested retirement benefit which was previously filed on schedule SSA may be deleted if the participant is paid some of the deferred vested retirement benefit. If payment of the deferred vested retirement benefit ceases before all of the benefit to which the participant is entitled is paid to the participant, information relating to the deferred vested retirement benefit to which the participant remains entitled shall be filed on the schedule SSA filed for the plan year following the last plan year within which a portion of the benefit is paid to the participant.

(2) *Exception.* Notwithstanding subparagraph (1) of this paragraph, no information relating to the deferred vested retirement benefit to which the participant remains entitled is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (i) returns to service covered by the plan, (ii) accrues additional retirement benefits under the plan, or (iii) forfeits the benefit under the plan.

Par. 7. Section 301.6057-1(d), redesignated as § 301.6057-1(e), is revised to read as follows:

§ 301.6057-1 *Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.*

(e) *Individual statement to participant.* The plan administrator of an employee retirement benefit plan defined in paragraph (a)(3) of this section must provide each participant with respect to whom information is required to be filed on schedule SSA a statement describing the deferred vested retirement benefit to which the participant is entitled. The description provided the participant must include the information filed with respect to the participant on schedule SSA. The statement is to be delivered to the participant or forwarded to the participant's last known address no later than the date on which any schedule SSA reporting information with respect to the participant is required to be filed (including any extension of time for filing granted pursuant to section 6081).

Par. 8. Section 301.6057-1(e), redesignated as § 301.6057-1(f), is revised by deleting "paragraph (d)" where it appears therein and inserting in lieu thereof "paragraph (e)".

Par. 9. Section 301.6057-1(f)(2), redesignated as § 301.6057-1(g)(2), is revised to read as follows:

§ 301.6057-1 *Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.*

(g) *Effective dates.* * * *

(2) *Plans to which more than one employer contributes.* In the case of a plan to which more than one employer contributes, this section is effective for plan years beginning after December 31, 1977, and with respect to a participant who completes two consecutive one-year breaks in service under the plan in service computation periods beginning after December 31, 1974.

Par. 10. Section 301.6652-3(a) is revised by deleting "(determined with regard to any extension of time for filing)" where it appears in subparagraphs (4) and (5), and inserting in lieu thereof "(determined with regard to any extension of time for filing)".

Par. 11. Section 301.6652-3(e)(1)(ii) is revised as follows:

§ 301.6652-3 *Failure to file information with respect to employee retirement benefit plan.*

(e) *Effective dates—(1) Annual registration statement.* * * *

(ii) In the case of a plan to which more than one employer contributes, for plan years beginning after December 31, 1977, and with respect to participants who complete two consecutive 1-year breaks in service under the plan in service computation periods beginning after December 31, 1974.

Par. 12. Section 301.6690-1 is revised by deleting "§ 301.6057-1(d)" each place it appears therein and inserting in lieu thereof "§ 301.6057-1(e)".

This Treasury decision is issued under the authority contained in sections 6057 and 7805 of the Internal Revenue Code of 1954 (88 Stat. 943 and 68A Stat. 917; 26 U.S.C. 6057 and 7805).

JEROME KURTZ,
Commissioner of
Internal Revenue.

Approved: August 17, 1978.

DONALD C. LUBICK,
Assistant Secretary
of the Treasury.

PARAGRAPH 1. There is inserted in the appropriate place the following new sections:

§ 301.6057-1 *Employee retirement benefit plans; identification of participant with deferred vested retirement benefit.*

(a) *Annual registration statement—*
(1) *In general.* Under section 6057(a), the plan administrator (within the meaning of section 414(g)) of an employee retirement benefit plan must file with the Internal Revenue Service information relating to each plan participant who separates from service covered by the plan and is entitled to a deferred vested retirement benefit under the plan, but is not paid this retirement benefit. Plans subject to this filing requirement are described in subparagraph (3) of this paragraph. Subparagraph (4) describes how the information is to be filed with the Internal Revenue Service. In the case of a plan to which only one employer contributes, the time for filing the information with respect to each separated participant is described in subparagraph (5). In the case of a plan to

which more than one employer contributes the time for filing the information with respect to a participant is described in paragraph (b)(2). Paragraph (b) also provides other rules applicable only to plans to which more than one employer contributes.

(2) *Deferred vested retirement benefit.* For purposes of this section, a plan participant's deferred retirement benefit is considered a vested benefit if it is vested under the terms of the plan at the close of the plan year described in paragraph (a)(5) or (b)(4) (whichever is applicable) for which information relating to any deferred vested retirement benefit of the participant must be filed. A participant's deferred retirement benefit need not be a nonforfeitable benefit within the meaning of section 411(a) for the filing requirements described in this section to apply. Accordingly, information relating to a participant's deferred vested retirement benefit must be filed as required by this section notwithstanding that the benefit is subject to forfeiture by reason of an event or condition occurring subsequent to the close of the plan year described in paragraph (a)(5) or (b)(4) (whichever is applicable) for which information relating to any deferred vested retirement benefit of the participant must be filed.

(3) *Plans subject to filing requirement.* The term "employee retirement benefit plan" means a plan to which the vesting standards of section 203 of part 2 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (88 Stat. 854) apply for any day in the plan year. (For purposes of this section, "plan year" means the plan year as determined for purposes of the annual return required by section 6058(a)). Accordingly, a plan need not be a qualified plan within the meaning of section 401(a) to be subject to these filing requirements. A plan to which more than one employer contributes must file the report of deferred vested retirement benefits described in this section, but see paragraph (b) for special rules applicable to such a plan. The filing requirements described in this section and § 301.6057-2 (relating to notification of change in plan status) do not apply to a governmental or church plan described in section 414 (d) or (e).

(4) *Filing requirements.* Information relating to the deferred vested retirement benefit of a plan participant must be filed on schedule SSA as an attachment to the Annual Return/Report of Employee Benefit Plan (form 5500 series). Schedule SSA shall be filed on behalf of an employee retirement benefit plan for each plan year for which information relating to the deferred vested retirement benefit of a plan participant is filed under paragraph (a)(5) or (b)(2) of this sec-

tion. There shall be filed on schedule SSA the name and social security number of the participant, a description of the nature, form, and amount of the deferred vested retirement benefit to which the participant is entitled, and such other information as is required by section 6057(a) or schedule SSA and the accompanying instructions. The form of the benefit reported on schedule SSA shall be the normal form of benefit under the plan, or, if the plan administrator (within the meaning of section 414(g)) considers it more appropriate, any other form of benefit.

(5) *Time for reporting deferred vested retirement benefit*—(i) *In general*. In the case of a plan to which only one employer contributes, information relating to the deferred vested retirement benefit of a plan participant must be filed no later than on the schedule SSA filed for the plan year following the plan year within which the participant separates from service covered by the plan. Information relating to a separated participant may, at the option of the plan administrator, be reported earlier (that is, on the schedule SSA filed for the plan year in which the participant separates from service covered by the plan). For purposes of this paragraph a participant is not considered to separate from service covered by the plan solely because the participant incurs a break in service under the plan. In addition, for purposes of this paragraph, in the case of a plan which uses the elapsed time method described in Department of Labor regulations for crediting service for benefit accrual purposes, a participant is considered to separate from service covered by the plan on the date the participant severs from service covered by the plan.

(ii) *Exception*. Notwithstanding subdivision (i), no information relating to the deferred vested retirement benefit of a separated participant is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (A) is paid some or all of the deferred vested retirement benefit under the plan, (B) returns to service covered by the plan, or (C) forfeits all of the deferred vested retirement benefit under the plan.

(b) *Plans to which more than one employer contributes*—(1) *Application*. Section 6057 and this section apply to a plan to which more than one employer contributes with the modifications set forth in this paragraph. For purposes of section 6057 and this section, whether or not more than one employer contributes to a plan shall be determined by the number of employers who are required to contribute

to the plan. Thus, for example, this paragraph applies to plans maintained by more than one employer which are collectively bargained as described in section 413(a), multiple-employer plans described in section 413(c) and the regulations thereunder, multiemployer plans described in section 414(f), and plans adopted by more than one employer of certain controlled and common control groups described in section 414 (b) and (c).

(2) *Time for reporting deferred vested retirement benefit*—(i) *In general*. In the case of a plan to which more than one employer contributes, information relating to the deferred vested retirement benefit of a plan participant must be filed no later than on the schedule SSA filed for the plan year within which the participant completes the second of two consecutive one-year breaks in service (as defined in the plan for vesting percentage purposes) in service computation periods (as defined in the plan for vesting percentage purposes) which begin after December 31, 1974. At the option of the plan administrator, information relating to a participant's deferred vested retirement benefit may be filed earlier (that is, on the schedule SSA filed for the plan year in which the participant incurs the first one-year break in service or, in the case of a separated participant, on the schedule SSA filed for the plan year in which the participant separates from service).

(ii) *Special rules*—For purposes of this subparagraph (1)—

(A) For the definition of the term "1-year break in service" in the case of a plan which uses the elapsed time method described in Department of Labor Regulations for crediting service for vesting percentage purposes, see § 1.411(a)-6(c)(2).

(B) In the case of a plan which does not define the term "1-year break in service" for vesting percentage purposes, a plan participant shall be deemed to incur a 1-year break in service under the plan in any plan year within which the participant does not complete more than 500 hours of service covered by the plan.

(iii) *Transitional rule*. Notwithstanding subdivision (i), if the second consecutive 1-year break in service described in subdivision (i) is incurred in a plan year beginning before January 1, 1978, information relating to the participant's deferred vested retirement benefit is not required to be filed earlier than on the schedule SSA filed for the first plan year beginning after December 31, 1977.

(iv) *Exception*. Notwithstanding subdivision (i) or (iii) of this subparagraph, no information relating to a participant's deferred vested retirement benefit is required to be filed on

schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (A) is paid some or all of the deferred vested retirement benefit under the plan, (B) accrues additional retirement benefits under the plan, or (C) forfeits all of the deferred vested retirement benefit under the plan.

(3) *Information relating to deferred vested retirement benefit*—(i) *Incomplete records*. Section 6057(a) and paragraph (a)(4) of this section require the filing on schedule SSA of a description of the deferred vested retirement benefit to which the participant is entitled. If the plan administrator of a plan to which more than one employer contributes maintains records of a participant's service covered by the plan which are incomplete as of the close of the plan year with respect to which the plan administrator files information relating to the participant on schedule SSA, the plan administrator may elect to file the information required by schedule SSA based only upon these incomplete records. The plan administrator is not required, for purposes of completing schedule SSA, to compile from sources other than such records a complete record of a participant's years of service covered by the plan. Similarly, if retirement benefits under the plan are determined by taking into account a participant's service with an employer which is not service covered by the plan, but the plan administrator maintains records only with respect to periods of service covered by the plan, the plan administrator may complete schedule SSA taking into account only the participant's period of service covered by the plan.

(ii) *Inability to determine correct amount of participant's deferred vested retirement benefit*. If the amount of a participant's deferred vested retirement benefit which is filed on schedule SSA is computed on the basis of plan records maintained by the plan administrator which—

(A) Are incomplete with respect to the participant's service covered by the plan (as described in subdivision (i)), or

(B) Fail to account for the participant's service not covered by the plan which is relevant to a determination of the participant's deferred vested retirement benefit under the plan (as described in subdivision (i)),

then the plan administrator must indicate on schedule SSA that the amount of the deferred vested retirement benefit shown therein may be other than that to which the participant is actually entitled because the amount is based upon incomplete records.

(iii) *Inability to determine whether participant vested in deferred retirement benefit.* Where, as described in subdivision (i), information to be reported on schedule SSA is to be based upon records which are incomplete with respect to a participant's service covered by the plan or which fail to take into account relevant service not covered by the plan, the plan administrator may be unable to determine whether or not the participant is vested in any deferred retirement benefit. If, in view of information provided either by the incomplete records or the plan participant, there is a significant likelihood that the plan participant is vested in a deferred retirement benefit under the plan, information relating to the participant must be filed on schedule SSA with the notation that the participant may be entitled to a deferred vested retirement benefit under the plan, but information relating to the amount of the benefit may be omitted. This subdivision (iii) does not apply in a case in which it can be determined from plan records maintained by the plan administrator that the participant is vested in a deferred retirement benefit. Subdivision (ii), however, may apply in such a case.

(c) *Voluntary filing*—(1) *In general.* The plan administrator of an employee retirement benefit plan described in paragraph (a)(3) of this section, or any other employee retirement benefit plan (including a governmental or church plan), may at its option, file on schedule SSA information relating to the deferred vested retirement benefit of any plan participant who separates at any time from service covered by the plan, including plan participants who separate from service in plan years beginning before 1976.

(2) *Deleting previously filed information.* If, after information relating to the deferred vested retirement benefit of a plan participant is filed on schedule SSA, the plan participant—

(i) Is paid some or all of the deferred vested retirement benefit under the plan, or

(ii) Forfeits all of the deferred vested retirement benefit under the plan, the plan administrator may, at its option, file on schedule SSA (or such other form as may be provided for this purpose) the name and social security number of the participant with the notation that information previously filed relating to the participant's deferred vested retirement benefit should be deleted.

(d) *Filing incident to cessation of payment of benefits*—(1) *In general.* As described in this section, no information relating to the deferred vested retirement benefit of a plan participant is required to be filed on schedule SSA if before the date such schedule SSA

is required to be filed, some of the deferred vested retirement benefit is paid to the participant, and information relating to a participant's deferred vested retirement benefit which was previously filed on schedule SSA may be deleted if the participant is paid some of the deferred vested retirement benefit. If payment of the deferred vested retirement benefit ceases before all of the benefit to which the participant is entitled is paid to the participant, information relating to the deferred vested retirement benefit to which the participant remains entitled shall be filed on the schedule SSA filed for the plan year following the last plan year within which a portion of the benefit is paid to the participant.

(2) *Exception.* Notwithstanding subparagraph (1) of this paragraph, no information relating to the deferred vested retirement benefit to which the participant remains entitled is required to be filed on schedule SSA if, before the date such schedule SSA is required to be filed (including any extension of time for filing granted pursuant to section 6081), the participant (i) returns to service covered by the plan, (ii) accrues additional retirement benefits under the plan, or (iii) forfeits the benefit under the plan.

(e) *Individual statement to participant.* The plan administrator of an employee retirement benefit plan defined in paragraph (a)(3) of this section must provide each participant with respect to whom information is required to be filed on schedule SSA a statement describing the deferred vested retirement benefit to which the participant is entitled. The description provided the participant must include the information filed with respect to the participant on schedule SSA. The statement is to be delivered to the participant or forwarded to the participant's last known address no later than the date on which any schedule SSA reporting information with respect to the participant is required to be filed (including any extension of time for filing granted pursuant to section 6081).

(f) *Penalties.* For amounts imposed in the case of failure to file the report of deferred vested retirement benefits required by section 6057 (a) and paragraph (a) or (b) of this section, see section 6652(e)(1). For the penalty relating to a failure to provide the participant the individual statement of deferred vested retirement benefit required by section 6057(e) and paragraph (e) of this section, see section 6690.

(g) *Effective dates.*—(1) *Plans to which only one employer contributes.* In the case of a plan to which only one employer contributes, this section is effective for plan years beginning

after December 31, 1975, and with respect to a participant who separates from service covered by the plan in plan years beginning after that date.

(2) *Plans to which more than one employer contributes.* In the case of a plan to which more than one employer contributes, this section is effective for plan years beginning after December 31, 1977, and with respect to a participant who completes two consecutive 1-year breaks in service under the plan in service computation periods beginning after December 31, 1974.

§ 301.6057-2 Employee retirement benefit plans; notification of change in plan status.

(a) *Change in plan status.* The plan administrator (within the meaning of section 414(g)) of an employee retirement benefit plan defined in § 301.6057-1(a)(3) (including a plan to which more than one employer contributes, as described in § 301.6057-1(b)(1)) must notify the Internal Revenue Service of the following changes in plan status—

(1) A change in the name of the plan.

(2) A change in the name or address of the plan administrator,

(3) The termination of the plan, or

(4) The merger or consolidation of the plan with another plan or the division of the plan into two or more plans.

(b) *Notification.* A notification of a change in status described in paragraph (a) must be filed on the Annual Return/Report of Employee Benefit Plan (form 5500 series) for the plan year in which the change in status occurred. The notification must be filed at the time and place and in the manner prescribed in the form and any accompanying instructions.

(c) *Penalty.* For amounts imposed in the case of failure to file a notification of a change in plan status required by section 6057(b) and this section, see section 6652(e)(2).

(d) *Effective date.* This section is effective for changes in plan status occurring within plan years beginning after December 31, 1975.

§ 301.6652 [Deleted]

PAR. 2. Section 301.6652 is deleted.

PAR. 3. There is added immediately after § 301.6652-2 the following new section:

§ 301.6652-3 Failure to file information with respect to employee retirement benefit plan.

(a) *Amount imposed*—(1) *Annual registration statement.* The plan administrator (within the meaning of section 414(g)) of an employee retirement benefit plan defined in § 301.6057-1(a)(3) is liable for the amount imposed by section 6652(e)(1) in each

case in which there is a failure to file information relating to the deferred vested retirement benefit of a plan participant, as required by section 6057(a) and § 301.6057-1, at the time and place and in the manner prescribed therefor (determined without regard to any extension of time for filing). The amount imposed by section 6652(e)(1) on the plan administrator is \$1 for each participant with respect to whom there is a failure to file the required information, multiplied by the number of days during which the failure continues. However, the total amount imposed by section 6652(e)(1) on the plan administrator with respect to a failure to file on behalf of a plan for a plan year shall not exceed \$5,000.

(2) *Notification of change in status.* The plan administrator (within the meaning of section 414(g)) of an employee retirement benefit plan defined in § 301.6057-1(a)(3) is liable for the amount imposed by section 6652(e)(2) in each case in which there is a failure to file a notification of a change in plan status, as described in section 6057(b) and § 301.6057-2, at the time and place and in the manner prescribed therefor (determined without regard to any extension of time for filing). The amount imposed by section 6652(e)(2) on the plan administrator is \$1 for each day during which the failure to so file a notification of a change in plan status continues. However, the total amount imposed by section 6652(e)(2) on the plan administrator with respect to a failure to file a notification of a change in plan status shall not exceed \$1,000.

(3) *Annual return of employee benefit plan.* [Reserved.]

(4) *Actuarial statement in case of mergers.* The plan administrator (within the meaning of section 414(g)) is liable for an amount imposed by section 6652(f) in each case in which there is a failure to file the actuarial statement described in section 6058(b) at the time and in the manner prescribed therefor (determined with regard to any extension of time for filing). The amount imposed by section 6652(f) on the plan administrator is \$10 for each day during which the failure to file the statement with respect to a merger, consolidation or transfer of assets or liabilities continues. However, the amount imposed by section 6652(f) on the plan administrator with respect to a failure to file the statement with respect to a merger, consolidation or transfer shall not exceed \$5,000.

(5) *Information relating to certain trusts and annuity and bond purchase plans.* Under section 6652(f) the amount described in this subparagraph is imposed in each case in which there is a failure to file a return or

statement required by section 6047 at the time and in the manner prescribed therefor in § 1.6047-1 (determined with regard to any extension of time for filing). The amount is imposed upon the trustee of a trust described in section 401(a), custodian of a custodial account or issuer of an annuity contract, as the case may be (see § 1.6047-1(a)(1) (i) and (ii)). The amount imposed by section 6652(f) is \$10 for each day during which the failure to file with respect to a payee for a calendar year continues. However, the amount imposed with respect to a failure to file with respect to a payee for a calendar year shall not exceed \$5,000.

(b) *Showing of reasonable cause.* (1) No amount imposed by section 6652(e) shall apply with respect to a failure to file information relating to the deferred vested retirement benefit of a plan participant under section 6057(a), or a failure to give notice of a change in plan status under section 6057(b), if it is established to the satisfaction of the director of the internal revenue service center at which the information or notice is required to be filed that the failure was due to reasonable cause.

(2) No amount imposed by section 6652(f) shall apply with respect to a failure to file a return or statement required by section 6058 or 6047, or a failure to provide material items of information called for on such a return or statement, if it is established to the satisfaction of the appropriate district director or the director of the internal revenue service center at which the return or statement is required to be filed that the failure was due to reasonable cause.

(3) An affirmative showing of reasonable cause must be made in the form of a written statement setting forth all the facts alleged as reasonable cause. The statement must contain a declaration by the appropriate individual that the statement is made under the penalties of perjury.

(c) *Joint liability.* If more than one person is responsible for a failure to comply with sections 6057 (a) or (b) or section 6058 (a) or (b) or section 6047, all such persons shall be jointly and severally liable with respect to the failure.

(d) *Manner of payment.* An amount imposed under section 6652 (e) or (f) and this section shall be paid in the same manner as a tax upon the issuance of notice and demand therefor.

(e) *Effective dates.*—(1) *Annual registration statement.* With respect to the annual registration statement described in section 6057(a), this section is effective—

(i) In the case of a plan to which only one employer contributes, for plan years beginning after December 31, 1975, with respect to participants

who separate from service covered by the plan in plan years beginning after that date, and

(ii) In the case of a plan to which more than one employer contributes, for plan years beginning after December 31, 1977, and with respect to participants who complete two consecutive 1-year breaks in service under the plan in service computation periods beginning after December 31, 1974.

(2) *Notification of change in status.* With respect to the notification of change in plan status required by section 6057(b), this section is effective with respect to a change in status occurring within plan years beginning after December 31, 1975.

(3) *Annual return of employee benefit plan.* With respect to the annual return of employee benefit plan required by section 6058(a), this section is effective for plan years beginning after September 2, 1974.

(4) *Actuarial statement in case of mergers.* With respect to the actuarial statement required by section 6058(b), this section is effective with respect to mergers, consolidations or transfers of assets or liabilities occurring after September 2, 1974.

(5) *Information relating to certain trusts and annuity and bond purchase plans.* With respect to reports or statements required to be filed by section 6047 and the regulations thereunder, this section is effective with respect to calendar years ending after September 2, 1974.

PAR. 4. There is added in the appropriate place the following new section:

§ 301.6690-1 *Penalty for fraudulent statement or failure to furnish statement to plan participant.*

(a) *Penalty.* Any plan administrator required by section 6057(e) and § 301.6057-1(e) to furnish a statement of deferred vested retirement benefit to a plan participant is subject to a penalty of \$50 in each case in which the administrator (1) willfully fails to furnish the statement to the participant in the manner, at the time, and showing the information required by section 6057(e) and § 301.6057-1(e), or (2) willfully furnishes a false or fraudulent statement to the participant. The penalty shall be assessed and collected in the same manner as the tax imposed on employers under the Federal Insurance Contributions Act.

(b) *Effective date.* This section shall take effect on September 2, 1974.

[FR Doc. 78-24010 Filed 8-24-78; 8:45 am]