**List of Subjects**

*21 CFR Part 556*

Animal drugs, Foods.

*21 CFR Part 558*

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

## PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

2. Section 556.570 is added to subpart B to read as follows:

**§ 556.570 Ractopamine.**

(a) *Acceptable daily intake (ADI).* The ADI for total residues of ractopamine is 1.25 micrograms ractopamine hydrochloride per kilogram of body weight per day.

(b) *Tolerances.* Swine—Tolerances are established for residues of ractopamine hydrochloride parent (marker residue) in edible swine tissues of 0.05 part per million (ppm) in muscle, and 0.15 ppm in liver (target tissue). Residues of ractopamine in swine muscle are not indicative of the safety of residues in other edible tissue.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

4. Section 558.4 is amended in paragraph (d) in the ''Category I'' table by adding an entry alphabetically for ''Ractopamine'' to read as follows:

**§ 558.4 Medicated feed applications.**

* * * * *

(d) * * *

CATEGORY I

| Drug | Assay limits percent [1] type A | Type B maximum (200x) | Assay limits percent [1] type B/C [2] |
|---|---|---|---|
| * * | * | * * | * * |
| Ractopamine | 85–105 | 1.8 g/lb (0.4%) | 80–110 |
| * * | * | * * | * * |

[1] Percent of labeled amount.

[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

* * * * *

5. Section 558.500 is added to subpart B to read as follows:

**§ 558.500 Ractopamine.**

(a) *Approvals.* Type A medicated articles: 9 grams of ractopamine hydrochloride per pound to 000986 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) *Related tolerances.* See § 556.570 of this chapter.

(d) *Conditions of use.* (1) *Swine*—(i) *Amount.* 4.5 grams of ractopamine hydrochloride per ton of Type C feed for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; 4.5 to 18 grams per ton for improved feed efficiency and increased carcass leanness; fed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight.

(ii) *Limitations.* Feed continuously as sole ration. Not for use in breeding swine.

(2) [Reserved]

Dated: January 13, 2000.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 00–1789 Filed 1–25–00; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 803 and 804

**[Docket No. 98N–0170]**

## Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations governing reporting by manufacturers, importers, distributors and health care (user) facilities of adverse events related to medical devices. Amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**EFFECTIVE DATE:** March 27, 2000.

**FOR FURTHER INFORMATION CONTACT:** Susan E. Bounds, Center for Devices and Radiological Health (HFZ–500), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

**SUPPLEMENTARY INFORMATION:**

### I. General

In the **Federal Register** of September 14, 1984 (49 FR 36326), FDA issued medical device reporting regulations for manufacturers and importers under the act and the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295). To correct weaknesses noted in the 1976 amendments, and to better protect the public health by increasing reports of device-related adverse events, Congress enacted the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), which required medical device user facilities and distributors to report certain device-related adverse events.

Distributor reporting requirements became effective on May 28, 1992, following the November 26, 1991 (56 FR 60024), the publication of those provisions in a tentative final rule. In the **Federal Register** of September 1, 1993 (58 FR 46514), FDA published a notice announcing that the proposed distributor reporting regulations had become final by operation of law and were now codified in part 804 (21 CFR part 804).

On June 16, 1992, the President signed into law the Medical Device Amendments of 1992 (the 1992 amendments) (Public Law 102–112) amending certain provisions of section 519 of the act (21 U.S.C. 360i) relating to reporting of adverse device events. Among other things, the 1992 amendments amended section 519 of the act to modify the requirements for manufacturer and importer reporting. Under the regulations issued under the SMDA and the 1992 amendments, importers are required to report as manufacturers if they are engaged in manufacturing activities or to report as distributors if they are engaged solely in distribution activities.

On November 21, 1997, the President signed FDAMA (Public Law 105–115) into law. FDAMA made several changes regarding the reporting of adverse experiences related to devices. On May 12, 1998, FDA published a proposed rule (63 FR 26129) (hereinafter referred to as the May 1998 proposal) and a direct final rule (63 FR 26069) (hereinafter referred to as the May 1998 direct final rule) to implement the amendments to the Medical Device Reporting (MDR) provisions. FDA received at least one significant adverse comment on the direct final rule. Accordingly, consistent with FDA's procedures on direct final rulemaking, FDA is withdrawing the May 1998 direct final rule and is addressing the comments in this final rule based upon the May 1998 proposal.

The May 1998 proposal was intended to amend the medical device reporting requirements to implement the following changes made by FDAMA:

1. Section 213(a) of FDAMA revised section 519(a) of the act to eliminate distributors as an entity required to report adverse device events. Importers are still required to report under section 519(a) of the act.

2. Section 213(a) of FDAMA also amended section 519(a) of the act to clarify that existing requirements for distributors to keep records concerning adverse device events and make them available to FDA upon request continue to apply.

3. Section 213(a)(2) of FDAMA revoked section 519(d) of the act, which required manufacturers, importers, and distributors to submit to FDA an annual certification concerning the number of reports filed under section 519(a) in the preceding year. As a result, certification requirements are eliminated.

4. Section 213(c)(1)(A) of FDAMA revised section 519(b)(1)(C) of the act to require that device user facilities submit an annual rather than a semiannual summary of their reports to FDA.

5. Section 213(c)(1)(B) of FDAMA eliminated section 519(b)(2)(C) of the act. This section had required FDA to disclose, upon request, the identity of a device user facility making a report under section 519(b) of the act if the identity of the device user facility was included in a report required to be submitted by a manufacturer, distributor, or importer. As a result of this change by FDAMA, FDA now may disclose the identity of a device user facility only: in connection with an action concerning a failure to report or false or fraudulent reporting; in a communication to the manufacturer of the device; or to the employees of the Department of Health and Human Services, the Department of Justice, and duly authorized committees and subcommittees of Congress.

6. Section 422 of FDAMA states that FDA's regulatory authority under the act, relating to tobacco products, tobacco ingredients, and tobacco additives shall be exercised under the act as in effect on the day before the date of enactment of FDAMA. The proposal stated that, under this rule of construction, the reporting requirements for manufacturers and distributors (including distributors who are importers) of cigarettes or smokeless tobacco would remain unchanged.

Furthermore, along with the substantive changes to the MDR provisions required by FDAMA, the agency proposed certain nonsubstantive changes to the organization of the provisions contained in parts 803 (21 CFR part 803) and 804. These organizational changes did not affect any reporting burdens; rather, the changes were made for the sake of clarity and consistency within the CFR.

## II. Summary of Comments

The agency received nine comments submitted by medical device manufacturers, importers, distributors, and trade associations.

1. Four comments stated that the agency did not follow Congress' direction that FDA consider changing the distributor recordkeeping requirements. The Congressional Conference Committee (the Conference Committee) recommended that FDA consider limiting the length of time that distributors are required to retain records to a period of 6 years (the current requirement is a minimum of 2 years, or the expected life of the product). The Conference Committee also recommended that FDA consider providing for electronic retention of records.

The agency disagrees that it did not properly follow Congress' direction or intent. The Conference Committee recommended that the agency consider changes to the distributor recordkeeping requirements. However, FDAMA contained no provisions that required any specific changes to the requirements.

The agency carefully considered the recommendations of the conference committee. The agency determined that the protection of the public health would not be adequately served if distributor recordkeeping was limited to a period of 6 years. Under the new quality system regulations contained in part 820 (21 CFR part 820), manufacturers (including initial distributors of foreign manufacturers) must retain records for a period equal to the design and expected life of the device (but no less than 2 years). The agency believes it is appropriate to require distributors to retain records for the same time period. This is especially important because distributors are no longer required to report any adverse event information to the agency, and the agency's primary access to the distributor complaint information is through its periodic inspection and examination of the distributor records.

FDA also considered electronic retention of distributor records. Prior to FDAMA and the proposed rule, the agency had not prohibited the electronic retention of records, nor did it intend to prohibit electronic recordkeeping based upon the proposal. When the distributor recordkeeping requirements were shifted from part 804 to part 803, the language remained largely unchanged. However, in order to avoid further confusion regarding electronic retention of records, the agency is modifying proposed § 803.18(d)(1) to clarify that distributor records may be either written or electronic.

2. Three comments stated that in describing distributor recordkeeping, reference to the quality system regulations, specifically § 820.198 (Complaint files), is inappropriate because § 820.198 applies only to manufacturers.

The agency agrees with this comment in part. The section being revoked (804.35) references § 820.198 because many of the recordkeeping requirements in § 820.198 would apply to all distributors. However, for the sake of clarity, the agency is revising § 803.18(d) to remove the reference to § 820.198, and is substituting language to identify the relevant requirements from § 820.198 that apply to distributors who are not importers.

3. Two comments suggested that the requirement that importers submit

adverse event reports within 10 days be changed to allow 30 days for reporting.

The agency agrees and is modifying the regulation accordingly. Prior to the SMDA, importers were subject to the same reporting timeframes as manufacturers under the 1984 MDR regulation. Consistent with the requirements of the SMDA, the 10-day reporting requirement was imposed on distributors and, because part 804 defined distributors to include importers, the 10-day reporting requirement was imposed on importers as well. Under FDAMA, distributors are no longer required to submit adverse event reports, but the reporting requirements continue to apply to importers. Because importers are subject to many of the same requirements as manufacturers under the new quality system regulations contained in part 820, the agency will allow importers the same 30 days it provides manufacturers to gather information and submit reports.

4. One comment stated that the fields to be filled out on FDA Form 3500A (MEDWATCH reporting form) should be specifically identified for importers. The comment also requested clarification regarding whether the agency's definition of ''importer'' for the purpose of MDR includes firms who sell directly to the ultimate user.

The agency agrees that the fields to be filled out by importers on FDA Form 3500A should be specified within the regulation. Because the requirements and burdens would not be affected by revising the style and format of § 803.43, the agency is modifying the section to be consistent with §§ 803.32 and 803.52, which describe the information to be submitted on the MEDWATCH form. Furthermore, proposed § 803.43 was inadvertently misnumbered. For the sake of consistency in numbering, the final rule will renumber this section as § 803.42.

The agency notes that, because ''distributors'' had previously been defined to include ''importers,'' FDA Form 3500A does not specifically address importer information and does not use the term ''importers.'' However, block F of the MEDWATCH form is identified for use by device user facilities and distributors. An importer should continue to complete blocks A, B, D, E, and F until the form is revised to remove references to ''distributor'' and replace them with ''importer.''

The agency clarifies that firms who purchase products from a foreign manufacturer and sell directly to the ultimate user are considered retailers and not importers under part 803 and are not required to report.

5. One comment stated that distributor reporting is important for the protection of the public health. The comment recommended, as an alternative to distributor reporting, a modification to the medical device labeling requirements to require that manufacturer contact information be included in the labeling for all devices in order to ensure proper adverse event reporting.

The agency agrees that consumers are likely to contact medical device distributors with their device complaints. Without distributor reporting, it is possible that the agency will not receive information regarding some complaints. However, under FDAMA, the agency no longer has the authority to require distributor reporting.

Although distributors are no longer under an obligation to report adverse device events, the agency continues to encourage distributors to provide manufacturers with adverse event information so that consumer complaints may be appropriately investigated and reported.

The alternative suggestion that manufacturer contact information be included in device labeling would be likely to increase the amount of information the manufacturer and the agency receives from the consumer. However, implementing this type of change to the medical device labeling regulation is beyond the scope of this rule. The agency is currently reviewing its medical device labeling regulation and considering certain modifications. The question of manufacturer contact information appearing on device labeling will be considered as part of that regulatory effort.

6. One comment stated that the agency erroneously interpreted section 422 of FDAMA, regarding the regulation of tobacco products, tobacco ingredients, or tobacco additives. The comment stated that section 422 simply provides that nothing in FDAMA shall affect the question of whether or not FDA has authority to regulate such products. The comment suggests that, if FDA has the authority to regulate such products, they should be regulated in the same manner as other medical devices.

The agency disagrees with this comment. Section 422 of FDAMA states that ''Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive.'' Although this language may suggest that FDAMA is simply silent regarding the agency's authority to regulate tobacco, section 422 goes on to state that ''Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this act.'' Beyond the question of whether the agency has authority to regulate tobacco, this language directs the agency as to how it should exercise any such authority once pending litigation is resolved.

Under section 422 of FDAMA, therefore, Congress neither affirms nor denies the agency's authority to regulate tobacco, but it does direct the agency to continue regulating tobacco as it had been doing prior to FDAMA (if authority to regulate tobacco exists). Prior to FDAMA, distributor reporting and manufacturer and distributor certification were required under the act. If the agency were to exercise its authority under the act ''as in effect on the day before the date of the enactment of [FDAMA],'' distributor reporting and manufacturer and distributor certification requirements would continue to apply to manufacturers and distributors of cigarettes and smokeless tobacco products.

However, while the agency disagrees with the comment's interpretation of section 422 of FDAMA, FDA finds persuasive the comment's arguments that tobacco manufacturers and distributors should be exempt from the requirement of annual certification of MDR's and that distributors should be exempt from MDR reporting requirements under the residual authority of the act. The agency has authority under section 519(c) of the act to exempt, by regulation, any class of persons from the medical device reporting requirements upon a finding that such reporting by that class is not necessary to ''assure that a device is not adulterated or misbranded or * * * otherwise to assure its safety and effectiveness'' (21 U.S.C. 360i(c)). The agency finds that the statutory criteria for exemption are met because reasonable assurances will be provided by the remaining medical device reporting requirements, that is, reporting and recordkeeping required by manufacturers and importers and recordkeeping required by distributors.

7. On its own initiative, FDA has revised § 803.22(b)(2) to make clear that importers who receive reportable information about a device not imported by them need not submit a report to FDA but, instead, must forward the information to FDA along with a cover letter explaining that they do not import the device in question.

8. On its own initiative, FDA has determined that it is not necessary for importers to submit supplemental reports under § 803.56 as proposed. Instead, FDA will require importers to submit additional information only when requested by FDA under § 803.15. No change to § 803.15 is necessary.

9. Also on its own initiative, FDA has made some nonsubstantive changes to the definitions in § 803.3 in order to integrate the requirements for importer reporting into part 803.

**III. Environmental Impact**

The agency has determined under 21 CFR 25.30(h) 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.

**IV. Analysis of Impacts**

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The Office of Management and Budget (OMB) has determined that this final rule is a significant regulatory action subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The rule codifies the elimination of reporting by distributors, continues reporting by importers as they have been doing to date with an extension of the time for reporting, increases protection from disclosure of the identity of device user facilities that have submitted reports, reduces summary reporting by device user facilities from semiannual to annual, eliminates annual certification for manufacturers and distributors (including importers) of medical devices, and makes other nonsubstantive changes. The agency certifies that this final rule will not have a significant negative economic impact on a substantial number of small entities. This final rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year.

**V. Paperwork Reduction Act of 1995**

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title:* Reporting and recordkeeping requirements for manufacturers, importers, user facilities, and distributors of medical devices under the FDA Modernization Act (FDAMA)—General Requirements.

*Description:* FDAMA contained provisions that affect medical device reporting in a variety of ways. Section 213 of FDAMA eliminated the reporting requirements for medical device distributors (but not for importers), as well as the certification requirements for medical device manufacturers and distributors. This section of FDAMA also modified the summary reporting requirements for user facilities to require annual, rather than semiannual, reporting, and increased confidentiality of user facility identities.

This final rule amends FDA's regulations in part 803 and revokes part 804 to reflect the changes to medical device reporting made by FDAMA. The final rule has also been amended to implement the exemptions for manufacturers and distributors of cigarettes and smokeless tobacco products discussed below.

In accordance with 5 CFR 1320.8(d), on May 12, 1998, requests for public comment were published in the **Federal Register** (see 63 FR 26069 and 63 FR 26129). Several comments were received in response to the proposed rule and are discussed in detail previously in this final rule.

Four comments objected that FDA did not follow the congressional recommendation in the conference report on FDAMA that FDA limit the time that distributors be required to keep records to a maximum of 6 years. The direct final rule required that distributors keep records for 2 years or the expected life of the device, whichever is greater.

FDA carefully considered the recommendations of the conference committee. The agency determined that the protection of the public health would not be adequately served if distributor recordkeeping was limited to a period of 6 years. Under the new quality system regulations contained in part 820, manufacturers (including initial distributors of foreign manufacturers) must retain records for a period equal to the design and expected life of the device (but no less than 2 years). The agency believes it is appropriate to require distributors to retain records for the same time period. This is especially important because distributors are no longer required to report any adverse event information to the agency, and the agency's primary access to the distributor complaint information is its periodic inspection and examination of the distributor records.

FDA considered electronic retention of distributor records. Prior to FDAMA and the May 1998 proposal, the agency had not prohibited the electronic retention of records, nor did it intend to prohibit electronic recordkeeping based upon the May 1998 proposal. When the distributor recordkeeping requirements were shifted from part 804 to part 803, the language remained largely unchanged. However, in order to avoid further confusion regarding electronic retention of records, the agency is modifying proposed § 803.18(d)(1) to clarify that distributor records may be either written or electronic.

Three comments stated that it is inappropriate to refer to the quality systems regulations (§ 820.198) in describing distributor recordkeeping because § 820.198 does not apply to distributors.

FDA agrees and has revised § 803.18(d) accordingly to remove the reference to § 820.198. FDA is substituting language to identify the relevant requirements from § 820.198 that apply to distributors who are not importers. FDA notes, however, that § 820.198 does apply to importers of devices.

Two comments suggested that the reporting timeframe for importers should be changed to 30 days from 10 days.

FDA agrees with these comments and has revised the final rule. Previously,

importers were included in part 804 with the reporting requirements for distributors. Because distributors are no longer required to report, part 804 is eliminated and importers are included in part 803 with manufacturers. The 30-day timeframe is consistent with the timeframe for manufacturers.

One comment suggested that the form for reporting adverse events (FDA Form 3500A) should be revised to refer specifically to importers. Another comment asked for clarification as to whether a person who sells directly to the ultimate user may be considered an ''importer''.

The agency agrees that the fields to be filled out by importers on FDA Form 3500A should be specified within the regulation. Because the requirements and burdens would not be affected by revising the style and format of § 803.43, the agency is modifying the section to be consistent with §§ 803.32 and 803.52, which describe the information to be submitted on the MEDWATCH form. Furthermore, proposed § 803.43 was inadvertently misnumbered. For the sake of consistancy in numbering, the final rule will renumber this section as § 803.42.

The agency notes that, because ''distributors'' had previously been defined to include ''importers,'' FDA Form 3500A does not specifically address importer information and does not use the term, ''importers.'' However, block F of the MEDWATCH form is identified for use by device user facilities and distributors. An importer should continue to complete blocks A, B, D, E, and F until the form is revised to remove references to ''distributor'' and replace them with ''importer.'' The agency clarifies that firms who purchase products from a foreign manufacturer and sell directly to the ultimate user are considered retailers and not importers under part 803 and are not required to report.

One comment suggested that distributor reporting is important for the protection of the public health and recommended that, as an alternative to distributor reporting, FDA should require manufacturer contact information on the labeling to assure proper adverse event reporting.

The agency agrees that consumers are likely to contact medical device distributors with their device complaints. Without distributor reporting, it is possible that the agency will not receive information regarding some complaints. However, under FDAMA, the agency no longer has the authority to require distributor reporting. Although FDA cannot require distributor reporting, FDA encourages distributors to report adverse event information to manufacturers so that they may investigate and report it as appropriate. The suggestion that FDA require manufacturer contact information on the labeling is beyond the scope of this rule and FDA will consider it separately.

One comment objected that FDA incorrectly interpreted section 422 of FDAMA regarding the regulation of tobacco products, tobacco ingredients and tobacco additives. The comment stated that section 422 only means that nothing in FDAMA shall affect whether FDA has the authority to regulate tobacco products. The comment further said that section 422 of FDAMA does not mean, as FDA believes, that the requirements, such as MDR reporting, for manufacturers and distributors of tobacco products are unchanged by FDAMA.

The agency disagrees with this comment. Section 422 of FDAMA states that ''Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive.'' Although this language may suggest that FDAMA is simply silent regarding the agency's authority to regulate tobacco, section 422 of FDAMA goes on to state that ''Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this act.'' Beyond the question of whether the agency has authority to regulate tobacco, this language directs the agency as to how it should exercise such authority once pending litigation is resolved.

Under section 422 of FDAMA, therefore, Congress neither affirms nor denies the agency's authority to regulate tobacco, but it does direct the agency to continue regulating tobacco as it had been doing prior to FDAMA (if authority to regulate tobacco exists). Prior to FDAMA, distributor reporting and manufacturer and distributor certification were required under the act. If the agency were to exercise its authority under the act ''as in effect on the day before the date of the enactment of [FDAMA],'' distributor reporting and manufacturer and distributor certification requirements would continue to apply to manufacturers and distributors of cigarettes and smokeless tobacco products.

However, while the agency disagrees with the comment's interpretation of section 422 of FDAMA, FDA finds persuasive the comment's arguments that tobacco manufacturers should be exempt from the requirement of annual certification of MDR's and that distributors should be exempt from MDR reporting requirements under the residual authority of the act. The agency has authority under section 519(c) of the act to exempt, by regulation, any person from the medical device reporting requirements upon a finding that such reporting is not necessary to ''assure that a device is not adulterated or misbranded or * * * otherwise to assure its safety and effectiveness'' (21 U.S.C. 360i(c)). The agency finds that the statutory criteria for exemption are met in light of the fact that Congress has repealed the requirements for manufacturer and distributor annual certification and distributor reporting. A reasonable assurance of the safety and effectiveness of tobacco products will be provided by the remaining medical device reporting requirements, that is, reporting and recordkeeping required of manufacturers and importers and recordkeeping required of distributors.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR Section/FDA Form | No. of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|---|---|---|---|---|---|
| 803.15 | 50 | 1 | 50 | 4 | 200 |
| 803.19 | 150 | 1 | 150 | 3 | 450 |
| 803.22(b)(2) | 100 | 1 | 100 | .25 | 25 |
| 803.33 (FDA Form 3419) | 1,800 | 1 | 1,800 | 1 | 1,800 |
| 803.40 | 195 | 1 | 195 | 3 | 585 |
| 803.55 (FDA Form 3417) | 1,000 | 20 | 20,000 | 1.1 | 22,000 |
| Total | | | | | 25,060 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR Section | No. of recordkeepers | Annual frequency per recordkeeping | Total annual records | Hours per recordkeeper | Total hours |
|---|---|---|---|---|---|
| 803.17 | 2,000 | 1 | 2,000 | 3.3 | 6,600 |
| 803.18 | 39,764 | 1 | 39,764 | 1.5 | 59,646 |
| Total | | | | | 66,246 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burdens under this direct final rule are explained as follows:

*A. Reporting Requirements*

Prior to the program change reflected in this rule, distributors (including importers) were required to submit supplemental information under § 804.32. Distributors (who are not importers) are no longer required to submit MDR reports (including supplemental reports), and FDA has determined that it will not be necessary for importers to submit supplemental information except when FDA requests additional information under § 803.15. FDA has revised the final rule accordingly. Section 803.15 provides that FDA may request a reporter to submit additional or clarifying information concerning an MDR report when FDA determines that additional information is necessary for the protection of the public health. The burden estimate for this section includes only the burden for importers.

Prior to the program change reflected in this rule, § 803.19 allowed manufacturers or user facilities to request an exemption or variance from the reporting requirements. The agency had estimated that it would receive approximately 100 such requests annually. Distributors (including importers) were able to request an exemption or variance from the reporting requirements under § 804.33. Under this rule, § 803.19 is modified to transfer the exemption provisions for importers of medical devices from § 804.33 to § 803.19. Furthermore, distributors (who are not importers) of medical devices are no longer required to submit MDR reports under this rule. The estimated burden for § 803.19 is further adjusted to reflect the agency's actual experience with this type of submission.

Prior to the program change reflected in this rule, § 803.22(b)(2) provided that, if a manufacturer erroneously receives information about an adverse event concerning a device that they had not manufactured, the manufacturer must submit the report to FDA along with a cover letter explaining that the device in question was not manufactured by that firm. This final rule amends § 803.22(b)(2) to apply the same requirement to importers. The requirements of § 803.22(b)(2) were not previously reviewed by OMB under the PRA. Thus, the estimated burden reflects FDA's experience with this provision with regard to manufacturers and includes the estimated burden for both manufacturers and importers.

Prior to the program change reflected in this rule, § 803.33 required medical device user facilities to submit summary reports semiannually. Under this rule, user facilities are required to submit summary reports annually, thereby significantly decreasing the reporting burden on user facilities. The estimated burden for this section is also adjusted to reflect the agency's actual experience with this type of submission. FDA Form 3419 is being revised to reflect this change.

Under this rule the reporting requirement for importers of medical devices previously codified under § 804.25 is being transferred to § 803.40. The estimated burden for importer reporting is based upon the agency's actual experience with this type of submission. Section 803.40 requires importers to submit reports within 30 days after learning of the reportable event rather than 10 days as provided in § 804.25; this change does not affect the burden.

This rule does not amend § 803.55 but FDA is seeking approval for FDA Form 3417 on which baseline reports are to be submitted. The agency's estimate is based on FDA's actual experience with this type of submission.

Prior to the program change reflected in this rule, § 803.57 required medical device manufacturers to annually certify as to the number of reports submitted during the previous year, or that no such reports had been submitted. Distributors (including importers) were required to certify under § 804.30. As stated above, FDA is also exempting manufacturers and distributors of cigarettes and smokeless tobacco products from the requirement of annual certification. Therefore, under this rule, §§ 803.57 and 804.30 are being eliminated.

Because distributors, including distributors of cigarettes and smokeless tobacco products, will no longer be required to report, the final rule also removes §§ 804.25 (Reports by distributors), 804.32 (Supplemental information), and 804.33 (Alternative reporting requirements).

*B. Recordkeeping Requirements*

Prior to the program change reflected in this rule, § 803.17 required manufacturers and user facilities to establish written procedures for employee education, complaint

processing, and documentation of information related to MDR's. Under this rule, the requirements for establishing written MDR procedures for importers of medical devices have been transferred to § 803.17. The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information related to MDR reporting as part of their internal quality control system. The agency has estimated that no more than 2,000 such entities would be required to establish new procedures, or revise existing procedures, in order to comply with this provision. For those entities, a one-time burden of 10 hours, annualized over a period of 5 years, is estimated for establishing written MDR procedures. The remainder of manufacturers, user facilities, and importers not required to revise their written procedures to comply with this provision are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

Prior to the program change reflected in this rule, § 803.18 required manufacturers and user facilities to establish and maintain MDR event files. Distributors (including importers) were required to establish and maintain MDR event files under § 804.35. Under this rule, § 803.18 is modified to transfer the recordkeeping requirements for importers and other distributors of medical devices including cigarettes and smokeless tobacco products from § 804.35 and § 804.35 is removed. As discussed above, this recordkeeping may be done in an electronic format.

Under the proposed rule, distributors of cigarettes and smokeless tobacco products would have been required to establish written internal procedures for evaluating and reporting events. Because distributors of cigarettes and smokeless tobacco products will not be required to report under the final rule, § 804.34 is deleted from the final rule.

The information collections of this final rule have been submitted to OMB for review. Prior to the effective date of the final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions of this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

**List of Subjects in 21 CFR Parts 803 and 804**

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

## PART 803—MEDICAL DEVICE REPORTING

1. The authority citation for 21 CFR part 803 continues to read as follows:

**Authority:** 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

2. Section 803.1 is amended by revising paragraph (a) to read as follows:

**§ 803.1 Scope.**

(a) This part establishes requirements for medical device reporting. Under this part, device user facilities, importers, and manufacturers, as defined in § 803.3, must report deaths and serious injuries to which a device has or may have caused or contributed, must establish and maintain adverse event files, and must submit to FDA specified followup and summary reports. Medical device distributors, as defined in § 803.3, are also required to maintain records of incidents (files). Furthermore, manufacturers and importers are also required to report certain device malfunctions. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

* * * * *

3. Section 803.3 is amended by redesignating paragraphs (m) through (ee) as paragraphs (n) through (ff), respectively; by revising paragraph (c), the first sentence of paragraph (f), newly redesignated paragraphs (p) introductory text and (p)(1), paragraph (r) introductory text and paragraph (r)(2), and by adding paragraphs (g) and (m) to read as follows:

**§ 803.3 Definitions.**

* * * * *

(c) *Become aware* means that an employee of the entity required to report has acquired information reasonably suggesting a reportable adverse event has occurred.

(1) Device user facilities are considered to have ''become aware'' when medical personnel, as defined in paragraph (s) of this section, who are employed by or otherwise formally affiliated with the facility, acquire such information about a reportable event.

(2) Manufacturers are considered to have become aware of an event when:

(i) Any employee becomes aware of a reportable event that is required to be reported within 30 days or that is required to be reported within 5 days under a written request from FDA under § 803.53(b); and

(ii) Any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becomes aware that a reportable MDR event or events, from any information, including any trend analysis, necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

(3) Importers are considered to have become aware of an event when any employee becomes aware of a reportable event that is required to be reported by an importer within 30 days.

* * * * *

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in paragraphs (l), (b), (t), (u), and (v), respectively, of this section, which is not a ''physician's office,'' as defined in paragraph (w) of this section.

* * *

(g) *Distributor* means, for the purposes of this part, any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under paragraph (o) of this section.

* * * * *

(m) *Importer* means, for the purposes of this part, any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under paragraph (o) of this section.

* * * * *

(p) *Manufacturer or importer report number* means the number that uniquely identifies each individual adverse event report submitted by a

manufacturer or importer. This number consists of three parts as follows:

(1) The FDA registration number for the manufacturing site of the reported device, or the registration number for the importer. (If the manufacturing site or the importer does not have a registration number, FDA will assign a temporary MDR reporting number until the site is officially registered. The manufacturer or importer will be informed of the temporary number.);

* * * * *

(r) *MDR reportable event (or reportable event)* means:

(1) * * *

(2) An event about which manufacturers or importers have received or become aware of information that reasonably suggests that one of their marketed devices:

(i) May have caused or contributed to a death or serious injury; or

(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause a death or serious injury if the malfunction were to recur.

* * * * *

**§ 803.9 [Amended]**

4. Section 803.9 *Public availability of reports* is amended by adding ''or'' after the semicolon at the end of paragraph (c)(2), by removing paragraph (c)(3), and by redesignating paragraph (c)(4) as paragraph (c)(3).

5. Section 803.10 is amended by revising the heading and paragraph (a)(2), and by adding paragraph (b) to read as follows:

**§ 803.10 General description of reports required from user facilities, importers, and manufacturers.**

(a) * * *

(2) User facilities must submit annual reports as described in § 803.33.

(b) Importers must submit MDR reports of individual adverse events within 30 days after the importer becomes aware of an MDR reportable event as described in § 803.3. Importers must submit reports of device-related deaths or serious injuries to FDA and to the manufacturer and reports of malfunctions to the manufacturer.

* * * * *

**§ 803.11 [Amended]**

6. Section 803.11 *Obtaining the forms* is amended in the first sentence by adding the word '', importers,'' after the phrase ''User facilities''.

7. Section 803.12 is amended by revising paragraph (b) to read as follows:

**§ 803.12 Where to submit reports.**

* * * * *

(b) Each report and its envelope shall be specifically identified, e.g., ''User Facility Report,'' ''Annual Report,'' ''Importer Report,'' ''Manufacturer Report,'' ''5–Day Report,'' ''Baseline Report,'' etc.

* * * * *

**§ 803.17 [Amended]**

8. Section 803.17 *Written MDR procedures* is amended in the introductory text by adding the word '', importers,'' after the phrase ''User facilities''.

9. Section 803.18 is amended by revising the heading, the first sentence of paragraphs (a) and (b)(1) introductory text, paragraphs (b)(1)(ii) and (b)(2), and the second sentence of paragraph (c), and by adding paragraph (d) to read as follows:

**§ 803.18 Files and distributor records.**

(a) User facilities, importers, and manufacturers shall establish and maintain MDR event files. * * *

(b)(1) For purposes of this part, ''MDR event files'' are written or electronic files maintained by user facilities, importers, and manufacturers. * * *

* * * * *

(ii) Copies of all MDR forms, as required by this part, and other information related to the event that was submitted to FDA and other entities (*e.g.,* an importer, distributor, or manufacturer).

(2) User facilities, importers, and manufacturers shall permit any authorized FDA employee during all reasonable times to access, to copy, and to verify the records required by this part.

(c) * * * Manufacturers and importers shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. * * *

(d)(1) A device distributor shall establish and maintain device complaint records containing any incident information, including any written, electronic, or oral communication, either received by or generated by the firm, that alleges deficiencies related to the identity (*e.g.,* labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. Information regarding the evaluation of the allegations, if any, shall also be maintained in the incident record. Device incident records shall be prominently identified as such and shall be filed by device, and may be maintained in written or electronic form. Files maintained in electronic form must be backed up.

(2) A device distributor shall retain copies of the records required to be maintained under this section for a period of 2 years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the record.

(3) A device distributor shall maintain the device complaint files established under this section at the distributor's principal business establishment. A distributor that is also a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§ 820.180 and 820.198 of this chapter. A device distributor shall permit any authorized FDA employee, during all reasonable times, to have access to, and to copy and verify, the records required by this part.

* * * * *

**§ 803.19 [Amended]**

10. Section 803.19 *Exemptions, variances, and alternative reporting requirements* is amended by adding in paragraphs (b) and (c) the word '', importers,'' before the phrase ''or user facility'', and by adding in paragraph (c) a comma after the word ''variance''.

11. Section 803.20 is amended by revising the last sentence of the introductory text of paragraph (a), paragraph (a)(1), and the first sentence of paragraph (a)(2), and by adding paragraph (b)(2) to read as follows:

**§ 803.20 How to report.**

(a) * * * The form has sections that must be completed by all reporters and other sections that must be completed only by the user facility, importer, or manufacturer.

(1) The front of FDA Form 3500A is to be filled out by all reporters. The front of the form requests information regarding the patient, the event, the device, and the ''initial reporter'' (*i.e.,* the first person or entity that submitted the information to the user facility, manufacturer, or importer).

(2) The back part of the form contains sections to be completed by user facilities, importers, and manufacturers.

* * *

(b) * * *

(2) Importers are required to submit death and serious injury reports to FDA and the device manufacturer and submit malfunction reports to the manufacturer only:

(i) Within 30 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury.

(ii) Within 30 days of receiving information that a device marketed by the importer has malfunctioned and that such a device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

* * * * *

**§ 803.22 [Amended]**

12. Section 803.22 *When not to file* is amended by adding in paragraphs (a) and (b)(1) the word '', importer,'' after the word ''facility'' and in paragraph (b)(2) by adding the phrase ''or importer'' after the word ''manufacturer'' each time it appears and by adding the phrase ''or imported'' after the word ''manufactured'' each time it appears.

**§ 803.33 [Amended]**

13. Section 803.33 *Semiannual reports* is amended by revising the heading to read ''Annual reports''; in the introductory text of paragraph (a) by removing the phrase ''(for reports made July through December) and by July 1 (for reports made January through June)''; in the introductory text of paragraph (a) and paragraphs (a)(5), (a)(7) introductory text, and (c) by removing the word ''semiannual'' wherever it appears and adding in its place the word ''annual''; in paragraph (a)(1) by revising the reference ''§ 803.3(dd)'' to ''§ 803.3(ee)''; in paragraph (a)(2) by removing the phrase ''and period, *e.g.,* January through June or July through December'' and in paragraph (a)(7)(vi) by adding the word ''importer,'' after the word ''distributor,''.

14. Subpart D, consisting of §§ 803.40 and 803.42, is added to read as follows:

## Subpart D—Importer Reporting Requirements

Sec.



**§ 803.40 Individual adverse event reporting requirements; importers.**

(a) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 803.42 on FDA form 3500A as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

(b) An importer shall submit to the manufacturer a report containing information required by § 803.42 on FDA form 3500A, as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the importer's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

**§ 803.42 Individual adverse event report data elements.**

Individual medical device importer reports shall contain the following information, in so far as the information is known or should be known to the importer, as described in § 803.40, which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Adverse event or product problem;

(2) Outcomes attributed to the adverse event, that is:

(i) Death;

(ii) Life threatening injury or illness;

(iii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iv) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of the event or problem to include a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Other relevant patient history including preexisting medical conditions.

(c) Device information (Block D) shall contain the following:

(1) Brand name;

(2) Type of device;

(3) Manufacturer name and address;

(4) Operator of the device (health professional, patient, lay user, other);

(5) Expiration date;

(6) Model number, catalog number, serial number, lot number or other identifying number;

(7) Date of device implantation (month, day, year);

(8) Date of device explantation (month, day, year);

(9) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and

(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)

(d) Initial reporter information (Block E) shall contain the following:

(1) Name, address, and phone number of the reporter who initially provided information to the user facility, manufacturer, or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to FDA, if known.

(e) Importer information (Block F) shall contain the following:

(1) Whether reporter is an importer;

(2) Importer report number;

(3) Importer address;

(4) Contact person;

(5) Contact person's telephone number;

(6) Date the importer became aware of the event (month, day, year);

(7) Type of report (initial or followup (if followup, include report number of initial report));

(8) Date of the importer report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to FDA ''Coding Manual For Form 3500A'');

(11) Whether a report was sent to FDA and the date it was sent (month, day, year);

(12) Location, where event occurred;

(13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and

(14) Manufacturer name and address; if available.

**§ 803.57 [Removed]**

15. Section 803.57 *Annual certification* is removed.

## PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

16. Part 804 is removed.

Dated: August 6, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00–1785 Filed 1–25–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF THE TREASURY

## Internal Revenue Service

## 26 CFR Parts 1 and 602

**[TD 8864]**

**RIN 1545–AV87; 1545–AT97**

## Substantiation of Business Expenses

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final and temporary regulations.

**SUMMARY:** This document contains final and temporary Income Tax Regulations that provide rules for the substantiation of certain business expenses under sections 62 and 274 of the Internal Revenue Code (Code). Individuals and other taxpayers who claim or reimburse certain business expenses will be affected by these regulations.

**DATES:** *Effective date.* These regulations are effective January 26, 2000.

*Date of Applicability.* For date of applicability, see §§ 1.62–2(m) and 1.274–5(m).

**FOR FURTHER INFORMATION CONTACT:** Edwin B. Cleverdon, (202) 622–4920 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under control number 1545–0771. Responses to this collection of information are required in order to deduct certain business expenses or exclude from income certain reimbursed business expenses of employees.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The estimated annual burden per respondent or recordkeeper varies from 10 minutes to 20 hours, depending on individual circumstances, with an estimated average of 1.3 hours.

Comments concerning the accuracy of this burden estimate and suggestions or reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, OP:FS:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to this collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

### Background

On November 6, 1985, the IRS published in the **Federal Register** (50 FR 46006) temporary regulations (TD 8061) adding § 1.274–5T regarding substantiation of expenses with documentary evidence under section 274(d) of the Code. A notice of proposed rulemaking (LR–145–84, 1985–2 C.B. 809) cross-referencing the temporary regulations was published in the **Federal Register** (50 FR 46087) for the same day. The notice of proposed rulemaking invited comments on only those portions of the temporary regulations under § 1.274–5T that amended § 1.274–5 (now designated § 1.274–5A) to reflect contemporaneous legislation.

On March 25, 1997, the IRS published in the **Federal Register** (62 FR 13988) temporary regulations (TD 8715) amending paragraphs (c)(2)(iii)(B) and (f)(4) of § 1.274–5T. The amendments raised the receipt threshold from $25 to $75 and authorized the Commissioner to prescribe rules modifying the substantiation requirements for an adequate accounting by an employee to an employer. Under the amendment, the Commissioner could publish rules defining the circumstances (including the use of specified internal controls) under which an employee may make an adequate accounting to his employer by submitting an expense account alone, without the necessity of submitting documentary evidence (such as receipts). A notice of proposed rulemaking (REG–209785–95, 1997–1 C.B. 753) cross-referencing the temporary regulations was published in the **Federal Register** (62 FR 14051) for the same day.

On October 1, 1998, the IRS published a notice of proposed rulemaking (REG–122488–97, 1998–42 I.R.B. 19) in the **Federal Register** (63 FR 52660), proposing amendments to the Income Tax Regulations (26 CFR part 1) under sections 62(c) and 274(d) of the Code regarding substantiation of expenses using mileage and per diem rates. Specifically, the amendments removed the limitation in § 1.274(d)–1(a)(3) that provides that mileage allowances prescribed in rules by the Commissioner are available only to the owner of a vehicle. On that date the IRS also published temporary Income Tax Regulations (TD 8784, 1998–42 I.R.B. 4) under section 62(c) and 274(d) of the Code in the **Federal Register** (63 FR 52600), relating to the substantiation of expenses under a reimbursement or other expense allowance arrangement.

Comments were received in response to the 1985 proposed regulations, and a public hearing was held on March 3, 1986. Few of the written comments, and none of the comments at the hearing, relate to the provisions in this Treasury Decision. Written comments were also received with respect to the 1997 proposed regulations, but no public hearing was requested or held. No comments were received, and no hearings were requested or held, with respect to the 1998 proposed regulations.

### Summary and Discussion of Comments

This Treasury Decision incorporates the suggestions made in the written comments with some exceptions. With respect to the 1985 regulations, one commentator suggested that the definition of an adequate accounting in § 1.274–5T(f)(4), in the case of automobile expense reimbursements, should be satisfied by a reimbursement based on data on the type of automobile and local operating and fixed costs. Although this suggestion has not been specifically adopted in the final regulations, the standard mileage rate revenue procedure provides for this type of substantiation. See, e.g., section 8 of Rev. Proc. 98–63, 1998–52 I.R.B. 25.

Another commentator suggested, inter alia, (1) adding exceptions to the documentary evidence requirements under § 1.274–5T(c)(2)(iii) and (2) providing that the Commissioner, in establishing a meal allowance under § 1.274–5T(j), may allow a specific dollar allowance per meal. These suggestions are not adopted because the intent of the regulations is to give the Commissioner the discretion to make these practical decisions.

Similarly, with respect to the 1997 regulations, commentators made suggestions regarding the specific content of the guidance to be issued under the proposed regulations at § 1.274–5(f)(4). We did not incorporate these suggestions because the regulations are designed to describe appropriate published guidance of general applicability, not the specific