J–25 [Revised]

From the INT of the United States/Mexican Border and the Brownsville, TX, INT 221° radial via Brownsville; INT of the Brownsville 358° and the Corpus Christi, TX, 178° radials; Corpus Christi; INT of the Corpus Christi 311° and the San Antonio, TX, 174° radials; San Antonio; Centex, TX; Waco, TX; Ranger, TX; Tulsa, OK; Kansas City, MO; Des Moines, IA; Mason City, IA; Gopher, MN; Brainerd, MN; to Winnipeg, MB, Canada. The airspace within Canada is excluded. The airspace within Mexico is excluded.

* * * * *

Issued in Washington, DC, on June 27, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division

[FR Doc. 00–16915 Filed 7–3–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–ASO–18]

RIN 2120–AA66

Realignment and Establishment of VOR Federal Airways; KY and TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published in the **Federal Register** on June 2, 2000. The legal description of Federal Airway V–384 inadvertently listed incorrect radials. This action corrects that error.

EFFECTIVE DATE: July 5, 2000.

FOR FURTHER INFORMATION CONTACT: Terry Brown, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION: On June 2, 2000, Airspace Docket No. 97–ASO–18, FR Doc. 00–13750, was published establishing V–384 between Livingston, TN, and Volunteer, TN. This rule included a legal description for V–384, which inadvertently listed incorrect radials. This action corrects this situation by omitting the radials in the legal description for V–384, thereby eliminating the error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the legal description for V–384 as published in the **Federal Register** on June 2, 2000 (65 FR 35272); FR Doc. 00–13750, and incorporated by reference in 14 CFR 71.1, is corrected as follows:

§ 71.1 [Corrected]

On page 35273, the legal description for V–384 is corrected as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

* * * * *

V–384—[Revised]

From Livingston, TN; to Volunteer, TN.

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Issued in Washington, DC, on June 27, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 00–16914 Filed 7–3–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 95N–0084]

Medical Devices; Effective Date of Requirement for Premarket Approval for a Class III Preamendments Obstetrical and Gynecological Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for a Group 1 preamendments class III device, the obstetric data analyzer intended to analyze data from fetal and maternal monitors during labor and to warn of possible fetal distress. The agency has summarized its findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's approval requirements and the benefits to the public from the use of the devices.

DATES: This rule is effective July 5, 2000.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA issued a notice of availability of a preamendments class III devices strategy document. The strategy document set forth FDA's plans for implementing the provisions of section 515(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(i)) for preamendments class III devices for which FDA had not yet required premarket approval. FDA divided this universe of devices into three groups as referenced in the May 6, 1994, notice.

In the **Federal Register** of September 7, 1995 (60 FR 46718), FDA published a proposed rule to require the filing under section 515(b) of the act of a PMA or a notice of completion of a PDP for 43 preamendment class III devices, including the obstetric data analyzer. In accordance with section 515(b)(A)(2) of the act, FDA included in the preamble to the proposal the agency's tentative findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and the benefits to the public from use of the device. The September 7, 1995, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's findings. Under section 515(b)(2)(B) of the act, FDA provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the devices was required to be submitted by September 22, 1995. The comment period closed January 5, 1996.

FDA received one citizen petition requesting a change in the classification of the obstetrical data analyzer. FDA reviewed the petition, identified a deficiency in the petition, and issued a deficiency letter on March 7, 1996, to the petitioner. From the petitioner's response to the deficiency letter, it was apparent that the petitioner had misinterpreted the September 7, 1995, proposed rule because he believed that it was about another device and not the obstetrical data analyzer. In light of this petition, FDA has amended the identification of the device in § 884.2050(a) by changing the first two sentences to read as follows: ''An obstetric data analyzer (fetal status data analyzer) is a device used during labor to analyze electronic signal data obtained from fetal and maternal monitors. The obstetric data analyzer provides clinical diagnosis of fetal

status and recommendations for labor management and clinical interventions.'' With this clarifying change, FDA is proceeding to issue a final rule to require the filing of a PMA or a PDP for the obstetric data analyzer.

II. Findings With Respect to Risks and Benefits

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the proposed rule of September 7, 1995. As required by section by section 515(b) of the act, FDA published its findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP; and (2) the benefits to the public from the use of the device.

These findings are based on the reports and recommendations of the Obstetrical and Gynecological Devices Panel, an FDA advisory committee for the classification of the devices, along with any additional information FDA discovered. Additional information can be found in the proposed and final rules classifying the devices in the **Federal Register** of April 3, 1979 (44 FR 19894) and February 26, 1980 (45 FR 12682), respectively.

III. The Final Rule

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the preamble to the proposed rule and issuing this final rule to require premarket approval of the generic type of device, the obstetric data analyzer, by revising 21 CFR part 884.

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before October 3, 2000, for any obstetric data analyzer that was in commercial distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device on or before October 3, 2000. An approved PMA or a declared completed PDP is required to be in effect for any such devices on or before 180 days after FDA files the application. Any other obstetric data analyzer that was not in commercial distribution before May 28, 1976, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for an obstetric data analyzer is not filed on or before the 90th day past the effective date of this regulation, that device will be deemed adulterated under section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)), and commercial distribution of the device will be required to cease immediately. The device may, however, be distributed for investigational use, if the requirements of the investigational device exemption (IDE) regulations (21 CFR part 812) are met.

Under § 812.2(d) of the IDE regulations, FDA hereby stipulates that the exemptions from the IDE requirements in § 812.2(c)(1) and (c)(2) will no longer apply to clinical investigations of the obstetric data analyzer. Further, FDA concludes that investigational obstetric data analyzers are significant risk devices as defined in § 812.3(m) and advises that, as of the effective date of § 878.3530(c), the requirements of the IDE regulations regarding significant risk devices will apply to any clinical investigation of an obstetric data analyzer. For any obstetric data analyzer that is not subject to a timely filed PMA or PDP, an IDE must be in effect under § 812.20 on or before 90 days after the effective date of this regulation or distribution of the device must cease. FDA advises all persons presently sponsoring a clinical investigation involving the obstetric data analyzer to submit an IDE application to FDA no later than 60 days after the effective date of this final rule to avoid the interruption of ongoing investigations.

IV. 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Public Law 96–354), 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. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because FDA believes that there is little or no interest in marketing these devices, the agency certifies that the final rule, if issued, will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no new collections of information. The premarket approval program information collection is approved by the Office of Management and Budget (OMB) under OMB Control No. 0910–0231. Therefore, clearance by under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 884.2050 is revised to read as follows:

§ 884.2050 Obstetric data analyzer.

(a) *Identification.* An obstetric data analyzer (fetal status data analyzer) is a device used during labor to analyze electronic signal data obtained from fetal and maternal monitors. The obstetric data analyzer provides clinical diagnosis of fetal status and recommendations for labor management and clinical interventions. This generic type of device may include signal analysis and display equipment, electronic interfaces for other equipment, and power supplies and component parts.

(b) *Classification:* Class III (premarket approval).

(c) *Date PMA or notice of completion of PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before October 3, 2000, for any obstetric data analyzer described in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has been found, on or before October 3, 2000, to be substantially equivalent to an obstetric data analyzer described in paragraph (a) of this section that was in commercial distribution before May 28, 1976. Any other obstetric data analyzer described in paragraph (a) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: June 22, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–16808 Filed 7–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8890]

RIN 1545–AX25

Definition of Grantor

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final regulations defining the term *grantor* for purposes of part I of subchapter J, chapter 1 of the Internal Revenue Code. These regulations provide necessary guidance in determining who is the grantor of a trust in applying those Code sections. These regulations affect trusts and any person creating or funding a trust.

DATES: *Effective Date:* These regulations are effective July 5, 2000.

Applicability Dates: For dates of applicability of § 1.671–2(e), see § 1.671–2(e)(7).

FOR FURTHER INFORMATION CONTACT: James A. Quinn at (202) 622–3060 (not a toll-free number).

SUPPLEMENTARY INFORMATION

Background

On June 5, 1997, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–252487–96) under section 671 of the Internal Revenue Code (Code) in the **Federal Register** (62 FR 30785). Comments responding to the notice were received and a public hearing was held on August 27, 1997. After consideration of the comments, the proposed regulations under section 671 were re-issued as proposed (64 FR 43323) and temporary regulations (64 FR 43267) on August 10, 1999.

The proposed and temporary regulations provide a definition of grantor for purposes of part I of subchapter J, chapter 1 of the Code. No comments were received in response to the Notice of Proposed Rulemaking published on August 10, 1999, in the **Federal Register**, and no one requested to speak at the public hearing scheduled for November 2, 1999. Accordingly, the public hearing was canceled on October 28, 1999 (64 FR 58006). This document finalizes the proposed regulations and removes the temporary regulations.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on the regulations' impact on small business.

Drafting Information

The principal author of these regulations is James A. Quinn of the Office of the Assistant Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by removing the entry for section 1.671–2T and adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.671–2 also issued under 26 U.S.C. 643(a)(7) and 672(f)(6). * * *

§ 1.643(h)–1 [Amended]

Par. 2. Section 1.643(h)–1 is amended as follows:

1. In paragraph (a)(2)(i) the language ''§ 1.671–2T(e)(2)'' is removed, and ''§ 1.671–2(e)(2)'' is added in its place.

2. In paragraph (b)(1) the language ''§ 1.671–2T(e)(2)'' is removed, and ''§ 1.671–2(e)(2)'' is added in its place.

3. In paragraph (b)(2) the language ''§ 1.671–2T(e)'' is removed, and ''§ 1.671–2(e)'' is added in its place.

4. In paragraph (g) *Example 1* the language ''§ 1.671–2T(e)(2)'' is removed, and ''§ 1.671–2(e)(2)'' is added in its place.

Par. 3. Section 1.671–2(e) is revised to read as follows:

§ 1.671–2 Applicable principles.

* * * * *

(e)(1) For purposes of part I of subchapter J, chapter 1 of the Internal