Background

Section 596(c)(1) of the Tariff Act of 1930 (19 U.S.C. 1595a(c)(1)) sets forth a list of merchandise which, if introduced or attempted to be introduced into the United States contrary to law, are required to be seized and forfeited.

Section 162.23(a), Customs Regulations (19 CFR 162.23(a)), reflects the list of merchandise that must be mandatorily seized if introduced or attempted to be introduced into the United States contrary to law as set forth in 19 U.S.C. 1595a(c).

Title VI, section 606 of Pub. L. 104–132, the ''Antiterrorism and Effective Death Penalty Act of 1996,'' amended 19 U.S.C. 1595a(c)(1), effective April 24, 1997, to add to the list of merchandise required to be seized, merchandise that ''is a plastic explosive, as defined in section 841(q) of Title 18, United States Code, which does not contain a detection agent, as defined in section 841(p) of such title.'' This amendment was made to implement the Convention on the Marking of Plastic Explosives for the Purpose of Detection, which the United States entered into at Montreal, Canada, in 1991.

This document amends § 162.23(a), Customs Regulations, to reflect that amendment to 19 U.S.C. 1595a(c)(1).

Inapplicability of Public Notice and Comment Requirements and Delayed Effective Date Requirements

Inasmuch as this amendment merely conforms the Customs Regulations to existing law, pursuant to 5 U.S.C. 553(b)(3)(B), good cause exists for dispensing with notice and public procedure for this amendment as they are unnecessary. For the same reason, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

Regulatory Flexibility Act and Executive Order 12866

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

This document does not meet the criteria for a significant regulatory action under Executive Order 12866.

Drafting Information: The principal author of this document was Janet Johnson, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 162

Customs duties and inspection, Imports, Inspection, Law enforcement, Prohibited merchandise, Restricted merchandise, Seizures and forfeitures.

Amendment to the Regulations

For the reasons set forth in the preamble, part 162 of the Customs Regulations (19 CFR part 162) is amended as set forth below.

PART 162—INSPECTION, SEARCH AND SEIZURE

1. The general authority citation for part 162 and the specific authority citation for § 162.23 continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1624.

* * * * *

Section 162.23 also issued under 19 U.S.C. 1595a(c).

* * * * *

2. Section 162.23(a) is amended by removing the word ''or'' at the end of paragraph (a)(2); by removing the period at the end of paragraph (a)(3) and adding ''; or'' in its place; and by adding a new paragraph (a)(4) to read as follows:

§ 162.23 Seizure under section 596(c) Tariff Act of 1930, as amended (19 U.S.C. 1595a(c)).

(a) *Mandatory seizures.* * * *

* * * * *

(4) A plastic explosive, as defined in section 841(q) of title 18, United States Code, which does not contain a detection agent, as defined in section 841(p) of that title.

* * * * *

Approved: December 1, 1998.

Raymond W. Kelly,

Commissioner of Customs.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 99–376 Filed 1–7–99; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862 and 892

[Docket Nos. 98P–0506 and 98P–0621]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting petitions requesting exemption from the premarket notification requirements for certain class II devices. FDA is publishing this order in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: January 8, 1999.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Pub. L. 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Pub. L. 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part

807, require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the World Wide Web on the CDRH home page at ''http://www.fda.gov/cdrh'' or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Petitions

FDA has received the following petitions requesting an exemption from premarket notification for class II devices:

1. Abbott Laboratories, 21 CFR 862.1715, triiodothyronin uptake test system devices.

2. Radiological Imaging Technology, 21 CFR 892.5050, film dosimetry system, a.k.a. film scanning system.

In the **Federal Register** of September 30, 1998 (63 FR 52275), FDA published a notice announcing that these petitions had been received and providing an opportunity for interested persons to submit comments on the petitions by October 30, 1998. FDA received no comments. FDA has reviewed these petitions and has determined that these devices meet the criteria for exemption described previously and is, therefore, issuing this order exempting these devices from the requirements of premarket notification and is codifying this order in the Code of Federal Regulations (CFR). The film dosimetry system is an accessory to the medical charged-particle radiation therapy system classified in 21 CFR 892.5050. The exemption for the film dosimetry system is limited only to film dosimetry systems intended for use as a quality control system. (See 21 CFR 892.9 for further information on limitations on exemptions for radiological devices.)

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 (5 U.S.C. 601–612), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121) and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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 this rule will relieve a burden and simplify the marketing of these devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Part 862

Medical devices.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 862 and 892 are amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

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

2. Section 862.1715 is amended by revising paragraph (b) to read as follows:

§ 862.1715 Triiodothyronine uptake test system.

* * * * *

(b) *Classification*. Class II. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

PART 892—RADIOLOGY DEVICES

3. The authority citation for 21 CFR part 892 continues to read as follows:

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

4. Section 892.5050 is amended by revising paragraph (b) to read as follows:

§ 892.5050 Medical charged-particle radiation therapy system.

* * * * *

(b) *Classification*. Class II. When intended for use as a quality control system, the film dosimetry system (film scanning system) included as an accessory to the device described in paragraph (a) of this section, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

Dated: December 22, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 99–380 Filed 1–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8806]

RIN 1545–AV94

Employee Stock Ownership Plans; Section 411(d)(6) Protected Benefits (Taxpayer Relief Act of 1997); Qualified Retirement Plan Benefits

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations providing for changes to the rules regarding qualified retirement plan benefits that are protected from reduction by plan amendment, that have been made necessary by the Taxpayer Relief Act of 1997 (TRA '97). The final regulations change the existing final regulations to conform with the TRA '97 rules regarding in-kind distribution requirements for certain employee stock ownership plans, and specify the time period during which certain plan amendments for which relief has been granted by TRA '97 may be made without violating the prohibition against plan amendments that reduce accrued benefits. These final regulations affect sponsors of qualified retirement plans, employers that maintain qualified retirement plans, and qualified retirement plan participants. The amendments to the temporary regulations remove previously issued temporary regulations on the same subject.

DATES: These regulations are effective January 8, 1999.

FOR FURTHER INFORMATION CONTACT: Linda S. F. Marshall, (202) 622–6030 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under section 411(d)(6). These regulations change the rules under section 411(d)(6) regarding qualified retirement plan benefits that are protected from reduction by plan amendment, to take into account amendments made by the Taxpayer Relief Act of 1997 (TRA '97), Public Law 105–34, 111 Stat. 788 (1997). On September 4, 1998, temporary regulations (TD 8781) under section 411(d)(6) were published in the **Federal Register** (63 FR 47172). A notice of proposed rulemaking (REG–101363–98), cross-referencing the temporary regulations, was published in the **Federal Register** (63 FR 47214) on the same day. The temporary regulations conform the regulations to the TRA '97 amendments to section 409 regarding the general requirement that employee stock ownership plans offer distributions in the form of employer securities. In addition, the temporary regulations specify the time period during which certain plan amendments for which relief has been granted by TRA '97 may be made without violating section 411(d)(6).

One written comment responding to the notice of proposed rulemaking was received. No public hearing was requested or held. The proposed regulations under section 411(d)(6) are adopted by this Treasury decision, and the corresponding temporary regulations are removed.

Explanation of Provisions

Section 411(d)(6) provides that a plan is not treated as satisfying the requirements of section 411 if the accrued benefit of a participant is decreased by a plan amendment. Under section 411(d)(6)(B), a plan amendment that eliminates an optional form of benefit is treated as reducing accrued benefits to the extent that the amendment applies to benefits accrued as of the later of the adoption date or the effective date of the amendment. Sections 1.411(d)–4, Q&A–1(b)(1) and 1.401(a)(4)–4(e) specify that different optional forms of benefit within the meaning of section 411(d)(6)(B) result from differences in the medium of a distribution (e.g., cash or in-kind) from a plan. Section 411(d)(6)(C) provides that any tax credit employee stock ownership plan or any employee stock ownership plan is not treated as failing to meet the requirements of section 411(d)(6) merely because it modifies distribution options in a nondiscriminatory manner.

Special Rules Regarding Medium of Distribution From ESOPs

Section 409(h) contains requirements relating to distributions from tax credit employee stock ownership plans. Section 4975(e)(7) extends the requirements of section 409(h) to other employee stock ownership plans as well, and section 401(a)(23) extends the requirements of section 409(h) to qualified plans that are stock bonus plans. Under section 409(h)(1)(A), an employee stock ownership plan or other stock bonus plan generally is required to make distributions available in the form of employer securities. Prior to its amendment by TRA '97, section 409(h)(2) provided an exception to this rule in the case of an employer whose charter or bylaws restrict the ownership of substantially all outstanding employer securities to employees or to a trust described in section 401(a).

Under section 1361, certain small business corporations that do not have more than 75 shareholders are eligible to elect treatment as S corporations whose tax attributes generally flow through to shareholders in accordance with the rules of subchapter S of chapter 1 of subtitle A of the Internal Revenue Code. Prior to the Small Business Job Protection Act of 1996 (SBJPA), Public Law 104–188, 110 Stat. 1755 (1996), an S corporation could not maintain an employee stock ownership plan because an S corporation could not have a qualified trust described in section 401(a) as a shareholder. SBJPA amended the requirements for S corporations, effective for tax years beginning after December 31, 1996, to permit certain tax-exempt organizations, including qualified trusts described in section 401(a), to be S corporation shareholders.

TRA '97 made an additional change to the rules governing qualified plans holding securities of an S corporation employer, to make it easier for S corporation employers to facilitate employee ownership of employer securities through qualified plans. Section 1506 of TRA '97 extends the exception of section 409(h)(2) to cover S corporations, effective for taxable years beginning after December 31, 1997. Pursuant to this change, tax credit employee stock ownership plans, employee stock ownership plans, and other stock bonus plans established and maintained by S corporation employers are not required to offer distributions in the form of employer securities.