endolymphatic shunt tube with valve from class III (premarket approval) into class II (special controls) based on new information regarding this device. FDA also identified the document entitled ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve; Guidance for Industry and FDA'' as the special control capable of providing reasonable assurance of safety and effectiveness for this device.

Interested persons were invited to comment on the proposed rule by November 13, 2001. FDA received one comment. The comment, from the petitioner, Hood Laboratories, supported the proposed reclassification.

II. FDA's Conclusion

Based on a review of the available information referenced in the preamble to the proposed rule and placed on file in FDA's Dockets Management Branch, FDA concludes that the guidance document entitled ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve; Guidance for Industry and FDA,'' in conjunction with general controls, provides reasonable assurance of the safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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 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 (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.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the endolymphatic shunt tube with valve from class III will relieve all manufacturers of these devices of the cost of complying with the premarket approval requirements in section 515 of the act.

FDA believes that Hood Laboratories is the only manufacturer of the endolymphatic shunt tube with valve and Hood Laboratories states that they are in compliance with special controls proposed for this device. Therefore, the special controls will not impose significant new costs on the affected manufacturer. Because reclassification will reduce regulatory costs with respect to the endolymphatic shunt tube with valve, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. 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 Executive order and, consequently, a federalism summary impact statement is not 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 in 21 CFR Part 874

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 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR part 874 continues to read as follows:

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

2. Section 874.3850 is revised to read as follows:

§ 874.3850 Endolymphatic shunt tube with valve.

(a) *Identification.* An endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve; Guidance for Industry and FDA.''

Dated: April 15, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–10426 Filed 4–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 121

[Public Notice 3997]

Amendments to the United States Munitions List

AGENCY: Bureau of Political-Military Affairs, Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is revising Category I—Firearms—of the U.S. Munitions List (USML). The title of the revised category is being changed to include close assault weapons and combat shotguns. Certain interpretations (*e.g.,* definitions) of firearms and their components and parts previously found elsewhere in the International Traffic in Arms Regulations (ITAR) are being consolidated in the revised text for Category I. Reference to related

exemptions from export licensing requirements of the ITAR are also being added. Further, certain accessories, such as silencers, sound suppressors and flash suppressors are, henceforth, designated significant military equipment (''SME'').

EFFECTIVE DATE: April 29, 2002.

FOR FURTHER INFORMATION CONTACT: Mr. Peter Berry, Chief, Arms Licensing Division, Office of Defense Trade Controls, Department of State, Telephone (202) 663–2806 or FAX (202) 261–8199. ATTN: Regulatory Change, USML Part 121, Category I.

SUPPLEMENTARY INFORMATION: The Departments of State and Defense, in consultation with the Department of Commerce and other U.S. Government agencies, are reviewing items controlled on the U.S. Munitions List (USML) in order to ensure that the list of defense articles and defense services controlled pursuant to the International Traffic in Arms Regulations is up-to-date and appropriately reflects current U.S. security and foreign policy interests. Consistent with the policy announced by the United States at the May 2000 NATO Ministerial meeting, the Executive Branch initiated a procedure that involves a four-year review cycle, whereby one-quarter of the USML is reviewed each year. This policy and procedure is consistent with Section 38(f) of the Arms Export Control Act (AECA), which states that the President shall periodically review the items on the USML to determine what items, if any, no longer warrant export controls under Section 38. Five categories are currently under review: Categories I, V, VIII, XIV and XVI. This rulemaking concerns the results of the Category I review. The results pertaining to the remaining four categories will be published upon completion of inter-agency review. With regard to Category I, no substantive additions or deletions of the articles and services controlled under this heading by Category I are being made. But, there are substantial changes in the title and in the text that are designed to provide greater clarity and precision for defense industry exporters and closer scrutiny and reporting of certain items (*e.g.,* automatic weapons and accessories, such as silencers), and to consolidate various other provisions of the ITAR relating to firearms. Specifically, the new title of this category is ''Firearms, Close Assault Weapons and Combat Shotguns.'' Category I is being amended to move fully automatic firearms from paragraph (a) to paragraph (b) and combat shotguns from paragraph (a) to (d). The components, parts, accessories and attachments currently in paragraph (d) are moved to a new paragraph (h). The silencers and suppressors in paragraph (b) are re-designated as Significant Military Equipment (SME) and moved to paragraph (e), with the remainder of the items currently in paragraph (b) moving to a new paragraph (f). The barrels, cylinders, receivers (frames) and breech mechanisms in paragraph (d) are moved to a new paragraph (g). The technical data and defense services currently in (e) are moved to a new paragraph (i). The text from § 121.9 is moved to a new paragraph (j) and a Note at the end of the category. Section 121.9 is being reserved.

This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures required by 5 U.S.C. 533 and 554. It is exempt from review under Executive Order 12866 but has been reviewed internally by the Department to ensure consistency with the purposes thereof. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. It has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Act of 1966. It will not have substantial direct effects on the States, the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant application to Executive Orders 12372 and 13123. However, interested persons are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory Change, USML Part 121, 12th Floor, SA–1, Washington, D.C. 20522–0112. Such persons must be registered with the Department's Office of Defense Trade Controls (DTC) pursuant to the registration requirements of section 38 of the Arms Export Control Act.

List of Subjects in 22 CFR Part 121

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, Part 121, is amended as follows:

PART 121—THE UNITED STATES MUNITIONS LIST

1. The authority citation for part 121 is revised to read as follows:

Authority: Sec. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2278, 2797); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2658; Pub. L. 105–261, 112 Stat. 1920.

2. In § 121.1, Category I—Firearms is revised to read as follows:

§ 121.1 General. The United States Munitions List.

* * * * *

Category I—Firearms, Close Assault Weapons and Combat Shotguns

* (a) Nonautomatic and semi-automatic firearms to caliber .50 inclusive (12.7 mm).

* (b) Fully automatic firearms to .50 caliber inclusive (12.7 mm).

* (c) Firearms or other weapons (e.g. insurgency-counterinsurgency, close assault weapons systems) having a special military application regardless of caliber.

* (d) Combat shotguns. This includes any shotgun with a barrel length less than 18 inches.

* (e) Silencers, mufflers, sound and flash suppressors for the articles in (a) through (d) of this category and their specifically designed, modified or adapted components and parts.

(f) Riflescopes manufactured to military specifications (See category XII(c) for controls on night sighting devices.)

* (g) Barrels, cylinders, receivers (frames) or complete breech mechanisms for the articles in paragraphs (a) through (d) of this category.

(h) Components, parts, accessories and attachments for the articles in paragraphs (a) through (g) of this category.

(i) Technical data (as defined in § 120.10 of this subchapter) and defense services (as defined in § 120.9 of this subchapter) directly related to the defense articles enumerated in paragraphs (a) through (h) of this category. Technical data directly related to the manufacture or production of any defense articles enumerated elsewhere in this category that are designated as Significant Military Equipment (SME) shall itself be designated SME.

(j) The following interpretations explain and amplify the terms used in this category and throughout this subchapter:

(1) A firearm is a weapon not over .50 caliber (12.7 mm) which is designed to expel a projectile by the action of an explosive or which may be readily converted to do so.

(2) A rifle is a shoulder firearm which can discharge a bullet through a rifled barrel 16 inches or longer.

(3) A carbine is a lightweight shoulder firearm with a barrel under 16 inches in length.

(4) A pistol is a hand-operated firearm having a chamber integral with or permanently aligned with the bore.

(5) A revolver is a hand-operated firearm with a revolving cylinder containing chambers for individual cartridges.

(6) A submachine gun, ''machine pistol'' or ''machine gun'' is a firearm originally designed to fire, or capable of being fired, fully automatically by a single pull of the trigger.

Note: This coverage by the U.S. Munitions List in paragraphs (a) through (i) of this category excludes any non-combat shotgun with a barrel length of 18 inches or longer, BB, pellet, and muzzle loading (black powder) firearms. This category does not cover riflescopes and sighting devices that are not manufactured to military specifications. It also excludes accessories and attachments (e.g., belts, slings, after market rubber grips, cleaning kits) for firearms that do not enhance the usefulness, effectiveness, or capabilities of the firearm, components and parts. The Department of Commerce regulates the export of such items. See the Export Administration Regulations (15 CFR parts 730–799). In addition, license exemptions for the items in this category are available in various parts of this subchapter (e.g. §§ 123.17, 123.18 and 125.4).

* * * * *

§ 121.9 [Removed and Reserved]

3. Section 121.9 is removed and reserved.

Dated: April 5, 2002.

John R. Bolton,

Under Secretary for Arms Control and International Security, Department of State.

[FR Doc. 02–10474 Filed 4–26–02; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8990]

RIN 1545–AX66

Equity Options With Flexible Terms; Qualified Covered Call Treatment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation.

SUMMARY: This document contains final regulations providing guidance on the application of the rules governing qualified covered calls. The new rules address concerns that were created by the introduction of new financial instruments several years after the enactment of the qualified covered call rules. The final regulations provide guidance to taxpayers writing equity call options.

DATES: *Effective Date:* These regulations are effective April 29, 2002.

Applicability Date: For dates of applicability, see §§ 1.1092(c)–1(c), 1.1092(c)–2(d), 1.1092(c)–3(c), and 1.1092(c)–4(g).

FOR FURTHER INFORMATION CONTACT: Pamela Lew, (202) 622–3950 or Viva Hammer, (202) 622–0869 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

On January 18, 2001, the IRS published in the **Federal Register** proposed regulations (REG–115560–99, 66 FR 4751) addressing various issues concerning qualified covered call (QCC) options under section 1092(c)(4). No requests to speak at a public hearing were received, and no public hearing was held.

The proposed regulations provide that equity options with flexible terms (FLEX options) may be QCC options as long as they satisfy the general rules for QCC treatment described in section 1092(c)(4), are not for a term of longer than one year, and meet other specified requirements. In addition, an equity option with standardized terms must be outstanding for the underlying equity. For purposes of applying the general rules, the bench marks will be the same as those for an equity option with standardized terms on the same stock having the same applicable stock price.

The proposed regulations also provide that certain over-the-counter (OTC) options may be QCC options so that OTC options that are economically similar to FLEX options may receive the same tax treatment as FLEX options. Specifically, the proposed regulations provide that an OTC option is eligible for QCC treatment if it is entered into with a person registered with the Securities and Exchange Commission (SEC) as a broker-dealer or alternative trading system and meets the same requirements for QCC treatment that apply to FLEX options.

The proposed regulations further provide that equity options with standardized terms with maturities of longer than one year cannot be QCC options.

Comments were requested about the proposed one-year limit for all QCCs, including a discussion of time limitations in general. If a commentator recommended a time limitation greater than one year or recommended that there be no time limitation, a detailed, comprehensive description of possible solutions to the problem of increased risk reduction caused by longer term options was requested. Commentators were also asked to address the administrability of any proposed solutions.

After revisions to take into account several of the comments submitted, the proposed regulations are adopted by this Treasury decision.

Summary of Principal Comments

Four commentators responded to the request for comments. Two of the commentators addressed only the proposed 1-year limitation applicable to all QCC options. A third commentator addressed the proposed 1-year limit as well as a number of other issues. The fourth commentator focused on issues other than the proposed 1-year limitation.

One-Year Term Limitation

A number of commentators object to the proposal to limit QCC treatment to options with a duration of one year or less. These commentators note that the statute does not contain any limitation on the maximum term for QCCs and argue that a one-year limitation would be overly harsh. Among other things, they note that a strict one-year rule would preclude QCC status for even out-of-the-money options. One commentator notes that section 1092(c)(4) does not remove a QCC option completely from the straddle rules. Paragraphs (c)(4)(E) and (f) of section 1092 provide special limitations on QCCs for recognition of loss and suspension of holding period.[1] This commentator suggests that these rules limit the extent to which longer-term QCCs would lead to results inconsistent with the purposes of section 1092.

In response to the request in the preamble to the proposed regulation for alternative regimes to address the increased risk reduction created by longer-term options, two commentators suggest an adjustment to the ''applicable stock price'' to reflect forward pricing concepts. These commentators suggest that the unadjusted applicable stock price, as determined on the date the option is granted, be multiplied by a simple adjusting factor to produce an

[1] Under section 1092(c)(4)(E), the exception for QCCs does not apply to a covered call that would otherwise qualify for the exception if one leg is disposed of at a loss in one year, gain on the other position is includible for a later year, and less than 30 days has elapsed between these transactions. Under section 1092(f), if a taxpayers grants an in-the-money QCC, then loss on the call is treated as long-term capital loss if gain on the underlying stock would be long-term capital gain. In addition, the holding period is suspended for the period during which the taxpayer is the grantor of the option.