DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Tablets and Chewables

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for veterinary prescription use of chewable ivermectin tablets in dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.

DATES: This rule is effective July 22, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed ANADA 200–297 that provides for veterinary prescription use of Ivermectin Chewable Tablets for Dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection. Phoenix Scientific, Inc.'s Ivermectin Chewable Tablets for Dogs are approved as a generic copy of Merial Ltd.'s HEARTGARD Chewables, approved under NADA 140–886. The ANADA is approved as of June 18, 2004, and the regulations are amended in 21 CFR 520.1193 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ 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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1193 [Amended]

■ 2. Section 520.1193 is amended in paragraph (b)(2) by removing ''No. 051311'' and by adding in its place ''Nos. 051311 and 059130''.

Dated: July 13, 2004.

Stephen Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–16627 Filed 7–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9142]

RIN 1545–BB58

Deemed IRAs in Qualified Retirement Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final regulations providing guidance under section 408(q) regarding accounts or annuities that are part of qualified employer plans but are to be treated as individual retirement plans. These regulations reflect changes made to the law by the Economic Growth and Tax Relief Reconciliation Act of 2001 and by the Job Creation and Worker Assistance Act of 2002. This document also contains temporary regulations under section 408(a) providing a special rule for governmental units seeking approval to serve as nonbank trustees of individual retirement accounts for purposes of section 408(q). These regulations affect administrators of, participants in, and beneficiaries of qualified employer plans.

DATES: *Effective Date:* These regulations are effective July 22, 2004.

Applicability Dates: For dates of applicability, see §§ 1.408(q)–1(i) and 1.408–2T(e)(8)(iv).

FOR FURTHER INFORMATION CONTACT: Linda Conway at (202) 622–6090 (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 1545–1841. Responses to this collection of information are required for taxpayers who want to include individual retirement plans as part of a qualified employer plan.

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

The estimated annual burden per respondent/recordkeeper is 50 hours.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, 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 a 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

This document contains amendments to the Income Tax Regulations (26 CFR Part 1) under section 408(q) of the Internal Revenue Code (Code). On May 20, 2003, a notice of proposed rulemaking (REG–157302–02) was published in the **Federal Register** (68

FR 27493) under section 408(q). No public hearing was requested or held. Written comments responding to the notice of proposed rulemaking were received. After consideration of all the comments, the proposed regulations are adopted as amended by this Treasury decision.

This document also contains an amendment to the regulations under section 408(a) regarding the approval of nonbank trustees of individual retirement accounts. Section 1.408–2(e)(5)(v)(A) of the regulations currently provides that a person seeking approval to serve as a nonbank trustee must demonstrate that, except for investments pooled in a common investment fund, the investments of each account will not be commingled with any other property. Because section 408(q)(1) expressly provides that deemed IRAs need not satisfy the requirements of section 408(a)(5) regarding the commingling of IRA and plan assets, § 1.408–2(e)(5)(v)(A) is modified to reflect the statutory rule.

In addition, this document contains a temporary amendment to the regulations under section 408(a) regarding the approval of nonbank trustees. This temporary amendment modifies the requirements for approval as a nonbank trustee for certain governmental units that intend to serve as the trustees of individual retirement accounts subject to section 408(q).

Explanation of Provisions and Summary of Comments

A. Overview

Section 408(q) provides that, if a qualified employer plan allows employees to make voluntary employee contributions to a separate account or annuity established under the plan and under the terms of the qualified employer plan the account or annuity meets the applicable requirements of section 408 or section 408A for an individual retirement account or annuity, then the account or annuity is treated for purposes of the Code in the same manner as an individual retirement plan rather than as a qualified employer plan. It further provides that contributions to such a ''deemed IRA'' are treated as contributions to the deemed IRA rather than to the qualified employer plan. Section 408(q) also expressly provides that the requirements of section 408(a)(5) regarding the commingling of IRA assets with other property shall not apply to deemed IRAs.

In general, the proposed regulations provided that a qualified employer plan and a deemed IRA would be treated as separate entities under the Code and that each entity would be subject to the rules generally applicable to that entity for purposes of the Code. Thus, a qualified employer plan (excluding the deemed IRA portion of the plan), whether it is a plan under section 401(a), 403(a), or 403(b), or a governmental plan under section 457(b), would be subject to the rules applicable to that type of plan rather than to the rules applicable to IRAs under section 408 or 408A. Similarly, the deemed IRA portion of the qualified employer plan would generally be subject to the rules applicable to traditional and Roth IRAs under sections 408 and 408A, respectively, and not to the rules applicable to plans under section 401(a), 403(a), 403(b), or 457.

B. Separate Trusts

Section 1.408(q)–1(f)(2) of the proposed regulations provided that any trust holding deemed individual retirement account assets must be separate from the trust holding the other assets of the qualified employer plan. The separate trust rule was intended to ensure better compliance with the IRA requirements and limit confusion of IRA and plan assets. The proposed regulations also provided a comparable rule for deemed IRAs that are individual retirement annuities.

Several commentators argued that a separate trust for deemed individual retirement accounts should not be required where the assets of the qualified employer plan are already held in a trust. They argued the plan's trust could satisfy the requirement of section 408 that the individual retirement account be held in a trust and that separate accounting would ensure compliance with the IRA requirements and avoid any confusion of IRA and plan assets. They also argued the requirement of a separate trust would unduly complicate the administration of the plan and lead to potentially higher costs for the plan sponsor. In response to these comments, the final regulations provide that a separate trust is not required in those cases in which the qualified employer plan maintains a trust but only if separate accounting is maintained for each deemed IRA. Revenue Procedure 2003–13 (2003–4 I.R.B. 317), which includes sample amendments providing for separate trusts for deemed IRAs, does not apply to the extent it provides to the contrary.

The regulations specify that if deemed IRAs are held in a single trust that includes the qualified employer plan, the trustee must maintain a separate account for each deemed IRA and the qualified employer plan.

Permitting deemed IRAs that are individual retirement accounts to be held in a single trust that includes the qualified employer plan raises the issue of whether, if the qualified employer plan portion of the trust invests in life insurance contracts, the deemed IRA would be considered to have violated section 408(a)(3), which provides that ''no part of the trust funds will be invested in life insurance contracts.'' The regulations clarify that, in that case, section 408(a)(3) is treated as satisfied if no part of the separate account of any of the deemed IRAs is invested in life insurance contracts,

Section 408A(b) and the regulations thereunder set forth rules under which a Roth IRA must be clearly designated as a Roth IRA. Pursuant to the regulations under § 1.408A–2, Roth IRAs that are individual retirement accounts must be trusts separate from traditional IRAs. These final regulations permit a departure from these rules for deemed Roth IRAs, allowing them to be held in a single trust with deemed traditional IRAs, provided that the trustee maintains separate accounts for the deemed Roth IRAs and deemed traditional IRAs of each participant, and each of those accounts is clearly designated as such. Thus, the rules under §§ 1.408A–2 and 1.408A–4 of the regulations, regarding designation and redesignation of IRAs as Roth IRAs, apply to deemed IRAs as if the separate accounts maintained for the deemed Roth IRAs and deemed traditional IRAs were separate trusts.

The requirements for separate accounts within a trust as described above are not meant to imply that a trust that includes deemed IRAs and a qualified employer plan (or Roth and traditional IRAs) can be segmented for other purposes. For example, where a qualified employer plan and deemed IRAs are included in the same trust, there cannot be separate trustees for each account, and the trustee for the trust must be either a bank or a nonbank trustee that satisfies the requirements of section 408(a)(2) and the regulations thereunder.

The proposed regulations included a rule for individual retirement annuities similar to that for individual retirement accounts. Under the proposed regulations, separate annuity contracts were to be maintained for individual retirement annuities when the qualified employer plan also maintains annuity contracts. However, unlike the rules applicable to deemed individual retirement accounts which provide for separate accounts and not separate

trusts, section 408(q)(1)(A) expressly provides that a separate annuity is to be established for a deemed individual retirement annuity. Accordingly, these final regulations retain the rule in the proposed regulations that a separate annuity is to be established under the plan with respect to deemed individual retirement annuities.

C. Disqualification

Section 1.408(q)–1(g) of the proposed regulations provided that the failure of any of the deemed IRAs maintained by the plan to satisfy the applicable requirements of section 408 or 408A caused the plan as a whole to fail to satisfy the plan's qualification requirements. The proposed regulations further provided that, if the qualified employer plan failed to satisfy its qualification requirements, the deemed IRA portion would no longer be a deemed IRA because section 408(q) does not apply if the plan is not a qualified employer plan. The proposed regulations provided, however, that although the account or annuity that was intended to be a deemed IRA was no longer a deemed IRA, it could still be treated as a traditional or a Roth IRA if it satisfied the applicable requirements of section 408 or 408A (including the requirements regarding the commingling of assets under section 408(a)(5)).

Several commentators objected to this rule as inconsistent with the general rule that the qualified employer plan and the deemed IRA portion of the plan are separate entities and with the requirement that the deemed IRA assets and the other assets of the qualified employer plan must be maintained in separate trusts. Some commentators objected in particular to the rule that the failure of the qualification of a deemed IRA could result in the failure of the qualification of the plan as a whole. They stated that various aspects of the operation of deemed IRAs are not within the control of the employer.

The final regulations provide that the failure of either the qualified employer plan portion or the deemed IRA portion of the plan to satisfy the applicable qualification rules of each will not cause the other portion to be automatically disqualified. This rule applies, however, only if the deemed IRA portion and the qualified employer plan portion are maintained as separate trusts (or separate annuity contracts, as required in the case of individual retirement annuities). If both the deemed IRA portion and the qualified plan portion are included in separate trusts and the qualified employer plan is disqualified, the IRA portion cannot be a deemed IRA under section 408(q) but it will not fail to satisfy the applicable requirements of section 408 or 408A if it satisfies the applicable requirements of those sections, including, with respect to individual retirement accounts, the requirements of section 408(a)(5). However, if the IRA assets and the non-IRA assets have been commingled (except in a common trust fund or common investment fund as permitted by section 408(a)(5)), the IRA portion will fail to satisfy the requirements of section 408(a).[1] Likewise, if the IRA assets and the non-IRA assets are commingled (except as permitted by section 408(a)(5), and the IRA is disqualified, the plan will also be disqualified.

D. Governmental Units as Nonbank Trustees

As noted above, the proposed regulations provided that a qualified employer plan and a related deemed IRA are generally treated as separate entities under the Code and each is subject to the rules applicable to that entity. Thus, under the proposed regulations, an individual retirement account that is a deemed IRA would be required to satisfy the requirements of section 408(a) except for the commingling limitations of section 408(a)(5). Consistent with this general rule, § 1.408(q)–1(f)(1) of the proposed regulations provided that the trustee or custodian of an individual retirement account must be a bank or other person that receives approval from the Commissioner to serve as a nonbank trustee pursuant to § 1.408–2(e) of the regulations.

Several commentators noted that because the nonbank trustee criteria were designed to test private entities, it is difficult, if not impossible, for most state and local governments to satisfy them. They also argued that, although it may be possible for a state or local government to appoint a bank or an approved nonbank trustee for the deemed IRA portion of the plan, this would impose unnecessary costs and administrative hardships on these governments that would outweigh any corresponding benefit and that such an appointment may contravene state law.

Several commentators argued that governments should be exempt from the nonbank trustee requirements, but the IRS and Treasury continue to believe that governments, like private entities, must demonstrate to the satisfaction of the Commissioner that the manner in which the government will administer the deemed IRA will be consistent with the requirements of section 408(a). Accordingly, the final regulations adopt the rule of the proposed regulations that the trustee of the deemed IRA must be a bank or a nonbank trustee approved by the Commissioner. The IRS and Treasury acknowledge, however, that § 1.408–2(e) of the regulations sets forth several criteria that governments may have difficulty satisfying. Accordingly, this document temporarily amends § 1.408–2(e) to provide that a governmental unit may serve as the trustee of any deemed IRA established by that governmental unit as part of its qualified employer plan if that governmental unit establishes to the satisfaction of the Commissioner that the manner in which it will administer the deemed IRA will be consistent with the requirements of section 408. The temporary amendment also provides special rules regarding the application of § 1.408–2(e) to governmental units.

E. Other Comments

Other comments included one noting that the proposed regulations require that the plan document of the qualified employer plan must contain the deemed IRA provisions and that Revenue Procedure 2003–13 provides that the deemed IRA provisions must address every applicable point in the IRA Listing of Required Modifications. The commentator suggested that plan sponsors be permitted to incorporate by reference the terms of separate IRA agreements or annuities. Although incorporation by reference may be possible in some circumstances, it is not possible where the IRA document is inconsistent with the provisions of the plan. For example, assuming the deemed IRA is to provide for commingling as allowed under section 408(q), it is not possible to incorporate an IRA document that prohibits such commingling.

Various comments were received relating to administrative issues such as

[1] The Department of Labor has advised the IRS and Treasury that consistent with section 4(c) of the Employee Retirement Income Security Act (ERISA), accounts and annuities (and contributions thereto) established in accordance with section 408(q) of the Code are not to be treated as part of the pension plan under which such accounts and annuities are allowed (or as a separate pension plan) ''for purposes of any provision of [title I of ERISA] other than § 403(c), 404, or 405 (relating to exclusive benefit, and fiduciary and co-fiduciary responsibilities) and part 5 (relating to administration and enforcement).'' Accordingly, fiduciaries need to take appropriate steps to ensure that they satisfy any fiduciary duties associated with implementation and operation of a deemed IRA feature that is related to a plan covered under title I of ERISA. These duties may include, but are not limited to, a duty to monitor the activities of holders of deemed IRAs in order to prevent disqualification of the deemed IRA feature and/or the qualified employer plan where the plan is intended to be maintained as a tax-qualified plan.

reporting and withholding rules and whether the separate rules applicable to qualified employer plans and IRAs were to be applied. As indicated in § 1.408(q)–1(c) of the proposed regulations, except as otherwise provided in the regulations, the qualified employer plan and the deemed IRA are treated as separate entities under the Code and they are subject to the separate rules applicable to qualified employer plans and IRAs, respectively. Accordingly, the reporting and withholding rules on plan and IRA distributions apply separately depending on whether the distributions are made from the deemed IRA or the qualified employer plan. Thus, for example, the reporting rules for required minimum distributions apply separately for the two portions of the plan. Similarly, a total distribution of amounts held in the qualified employer plan portion and the deemed IRA portion is reported on two Forms 1099–R, ''Distributions from Pensions, Annuities, Retirement or Profit-Sharing Plans, IRAs, Insurance Contracts, etc.'', one for the distribution from the deemed IRA portion and one for the rest of the distribution. Also, the 20% withholding rules of section 3405(c) do not apply to a distribution from the deemed IRA portion but would apply to a distribution from the qualified employer plan portion, and section 72(t) applies separately to the two portions.

Questions were also raised regarding who may participate in a deemed IRA. For example, one commentator, noting that the term *employee* is not defined by section 408(q) or by the proposed regulations, asked whether that term includes self-employed individuals. Although *employee* is not defined by section 408(q), section 408(q)(3)(B) defines a voluntary employee contribution, in part, as a contribution by an individual ''as an employee under a qualified employer plan which allows employees'' to elect to make contributions to a separate account under the plan. Thus, these regulations provide that to the extent a self-employed individual is an *employee* for purposes of the qualified employer plan, that individual will be treated as an employee for purposes of section 408(q). In the case of a qualified plan under section 401(a) and a qualified annuity plan under section 403(a), *employee* includes self-employed individuals as defined in section 401(c). The only circumstance under which a self-employed individual may participate in a section 403(b) plan is when a self-employed minister described in section 414(e)(5) participates in a retirement income account as described in section 403(b)(9). In contrast, section 457(e)(2) permits independent contractors as well as employees to participate in a section 457 plan. However, since section 408(q) permits only employees to make contributions to a deemed IRA, only employees (including self-employed individuals) may be permitted to participate in a deemed IRA maintained by a governmental section 457 plan.

Another commentator asked whether an employee can participate in a deemed IRA if he or she does not participate in the qualified employer plan, or even if the employee is not eligible to participate in the qualified employer plan. Again, as noted above, the deemed IRA and the qualified employer plan are generally treated as separate entities under the Code. Section 408(q) does not impose a requirement that an employee must participate in both portions of the plan or that an employee must be eligible to participate in both portions of the plan. Accordingly, the two portions of the plan may have different eligibility requirements.

One commentator asked whether the automatic enrollment principles applicable to section 401(k), 403(b), and 457 plans under Revenue Rulings 2000–8 (2000–1 C.B. 617); 2000–35 (2000–2 C.B. 138); and 2000–33 (2000–2 C.B. 142), apply to deemed IRAs. These revenue rulings specify the criteria to be met in order for an employee's compensation to be automatically reduced by a certain amount where that amount is contributed as an elective deferral to these three types of plans. The IRS and Treasury agree that the automatic enrollment principles applicable to section 401(k), 403(b), and 457 plans in the cited revenue rulings may also be applied to deemed IRAs.

With respect to the requirements for approval as a nonbank trustee, one commentator noted that § 1.408–2(e)(5)(v) requires that an applicant must demonstrate that, except for investments pooled in a common investment fund, the investments of each account will not be commingled with any other property. The commentator noted that this requirement is inconsistent with the provisions of section 408(q)(1), which provide that the requirements of section 408(a)(5) regarding commingling do not apply to deemed IRAs. Accordingly, this document amends § 1.408–2(e)(5)(v) to provide that an applicant that intends to serve as a nonbank trustee need not satisfy this requirement with respect to any assets held in a deemed IRA.

Finally, these regulations provide that neither the assets held in the deemed IRA portion of the qualified employer plan, nor any benefits attributable thereto, shall be taken into account for purposes of determining the benefits of employees and their beneficiaries under the plan (within the meaning of section 401(a)(2)) or determining the plan's assets or liabilities for purposes of section 404 or 412. The Pension Benefit Guaranty Corporation (PBGC) has advised the IRS and Treasury that a deemed IRA feature that is related to a qualified employer plan is not covered by Title IV of ERISA. The PBGC has further advised that the deemed IRA feature is treated as a separate entity from the qualified employer plan for purposes of Title IV. For example, neither the assets in, nor the benefits attributable to, the deemed IRA are taken into account in determining the amount of the PBGC's variable-rate premium, and an individual who is a participant in the deemed IRA but who is not a participant in the qualified employer plan is not included in the PBGC's flat-rate participant count. In addition, for purposes of Title IV, the deemed IRA will be treated as separate from the qualified employer plan in the event of termination of the qualified employer plan, and the fiduciary of the deemed IRA would continue to be responsible for the continued operation, transfer, or termination of the deemed IRA. The PBGC would allocate the assets of the qualified employer plan to the priority categories under section 4044 of ERISA without regard to any assets in, or benefits attributable to, the deemed IRA, and the PBGC would not serve as trustee of the deemed IRA. Termination of a deemed IRA would not be subject to the rules governing plan termination under Title IV of ERISA.

Effective Date

The regulations apply to accounts or annuities established under section 408(q) on or after August 1, 2003.

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 is hereby certified that the collection of information in these final regulations will not have a significant economic impact on a substantial number of small entities. The collection of information in the regulations is in § 1.408(q)–1(f)(2) and consists of the optional requirement that deemed IRAs may be held in trusts or annuity contracts separate from the trust or annuity contract of the qualified employer plan. This certification is

based on the fact that the burden of reporting these separate trusts and annuity contracts is small, particularly for small entities. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For the applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6) to the temporary regulations, refer to the Special Analyses section of the preamble to the cross-referencing notice of proposed rulemaking published in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding the final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business. The temporary regulations will also be submitted to the Chief Counsel for Advocacy for such comment.

Drafting Information

The principal authors of these regulations are Robert Walsh of the Tax Exempt and Government Entities Division and Linda Conway, Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury participated in the development of these regulations

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements

26 CFR Part 602

Reporting and recordkeeping requirements.

Amendments to the Regulations

■ Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read in part as follows:

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

§ 1.408–2 also issued under 26 U.S.C. 408(a) and 26 U.S.C. 408(q). * * *

§ 1.408(q)–1 also issued under 26 U.S.C. 408(q). * * *

■ **Par. 2.** In § 1.408–2, paragraph (e)(5)(v)(A) is revised and (e)(8) is added to read as follows:

§ 1.408–2 Individual retirement accounts

* * * * *

(e) * * *

(5) * * *

(v) *Custody of investments.* (A) Except for investments pooled in a common investment fund in accordance with the provisions of paragraph (e)(5)(vi) of this section and for investments of accounts established under section 408(q) on or after August 1, 2003, the investments of each account will not be commingled with any other property.

* * * * *

(8) [Reserved]. For further guidance, see § 1.408–2T(e)(8).

■ **Par. 3.** Section 1.408–2T is added to read as follows:

§ 1.408–2T Individual retirement accounts (temporary).

(a) through (e)(7) [Reserved]. For further guidance, see § 1.408–2(a) through (e)(7).

(8) *Special rules for governmental units.* (i) A governmental unit that seeks to qualify as a nonbank trustee of a deemed IRA that is part of its qualified employer plan must demonstrate to the satisfaction of the Commissioner that it is able to administer the trust in a manner that is consistent with the requirements of section 408. The demonstration must be made by written application to the Commissioner. Notwithstanding the requirement of § 1.408–2(e)(1) that a person must demonstrate by written application that the requirements of paragraphs (e)(2) to (e)(6) of that section will be met in order to qualify as a nonbank trustee, a governmental unit that maintains a plan qualified under section 401(a), 403(a), 403(b) or 457 need not demonstrate that all of these requirements will be met with respect to any individual retirement accounts maintained by that governmental unit pursuant to section 408(q). For example, a governmental unit need not demonstrate that it satisfies the net worth requirements of § 1.408–2(e)(3)(ii) if it demonstrates instead that it possesses taxing authority under applicable law. The Commissioner, in his discretion, may exempt a governmental unit from certain other requirements upon a showing that the governmental unit is able to administer the deemed IRAs in the best interest of the participants. Moreover, in determining whether a governmental unit satisfies the other requirements of §1.408–2 (e)(2) to (e)(6), the Commissioner may apply the requirements in a manner that is consistent with the applicant's status as a governmental unit.

(ii) *Governmental unit.* For purposes of this special rule, the term *governmental unit* means a State, political subdivision of a State, and any agency or instrumentality of a State or political subdivision of a State.

(iii) *Additional rules.* The Commissioner may in revenue rulings, notices, or other guidance of general applicability provide additional rules for governmental units seeking approval as nonbank trustees.

(iv) *Effective date.* This special rule is applicable for written applications made on or after August 1, 2003, or such earlier application as the Commissioner deems appropriate.

■ **Par. 4.** Section 1.408(q)–1 is added to read as follows:

§ 1.408(q)–1 Deemed IRAs in qualified employer plans.

(a) *In general.* Under section 408(q), a qualified employer plan may permit employees to make voluntary employee contributions to a separate account or annuity established under the plan. If the requirements of section 408(q) and this section are met, such account or annuity is treated in the same manner as an individual retirement plan under section 408 or 408A (and contributions to such an account or annuity are treated as contributions to an individual retirement plan and not to the qualified employer plan). The account or annuity is referred to as a deemed IRA.

(b) *Types of IRAs.* If the account or annuity meets the requirements applicable to traditional IRAs under section 408, the account or annuity is deemed to be a traditional IRA, and if the account or annuity meets the requirements applicable to Roth IRAs under section 408A, the account or annuity is deemed to be a Roth IRA. Simplified employee pensions (SEPs) under section 408(k) and SIMPLE IRAs under section 408(p) may not be used as deemed IRAs.

(c) *Separate entities.* Except as provided in paragraphs (d) and (g) of this section, the qualified employer plan and the deemed IRA are treated as separate entities under the Internal Revenue Code and are subject to the separate rules applicable to qualified employer plans and IRAs, respectively. Issues regarding eligibility, participation, disclosure, nondiscrimination, contributions, distributions, investments, and plan administration are generally to be resolved under the separate rules (if

any) applicable to each entity under the Internal Revenue Code.

(d) *Exceptions.* The following exceptions to treatment of a deemed IRA and the qualified employer plan as separate entities apply:

(1) The plan document of the qualified employer plan must contain the deemed IRA provisions and a deemed IRA must be in effect at the time the deemed IRA contributions are accepted. Notwithstanding the preceding sentence, employers that provided deemed IRAs for plan years beginning before January 1, 2004, (but after December 31, 2002) are not required to have such provisions in their plan documents before the end of such plan years.

(2) The requirements of section 408(a)(5) regarding commingling of assets do not apply to deemed IRAs. Accordingly, the assets of a deemed IRA may be commingled for investment purposes with those of the qualified employer plan. However, the restrictions on the commingling of plan and IRA assets with other assets apply to the assets of the qualified employer plan and the deemed IRA.

(e) *Application of distribution rules.* (1) Rules applicable to distributions from qualified employer plans under the Internal Revenue Code and regulations do not apply to distributions from deemed IRAs. Instead, the rules applicable to distributions from IRAs apply to distributions from deemed IRAs. Also, any restrictions that a trustee, custodian, or insurance company is permitted to impose on distributions from traditional and Roth IRAs may be imposed on distributions from deemed IRAs (for example, early withdrawal penalties on annuities).

(2) The required minimum distribution rules of section 401(a)(9) must be met separately with respect to the qualified employer plan and the deemed IRA. The determination of whether a qualified employer plan satisfies the required minimum distribution rules of section 401(a)(9) is made without regard to whether a participant satisfies the required minimum distribution requirements with respect to the deemed IRA that is established under such plan.

(f) *Additional rules*—(1) *Trustee.* The trustee or custodian of an individual retirement account must be a bank, as required by section 408(a)(2), or, if the trustee is not a bank, as defined in section 408(n), the trustee must have received approval from the Commissioner to serve as a nonbank trustee or nonbank custodian pursuant to § 1.408–2(e). For further guidance regarding governmental units serving as nonbank trustees of deemed IRAs established under section 408(q), see § 1.408–2T(e)(8).

(2) *Trusts.* (i) General rule. Deemed IRAs that are individual retirement accounts may be held in separate individual trusts, a single trust separate from a trust maintained by the qualified employer plan, or in a single trust that includes the qualified employer plan. A deemed IRA trust must be created or organized in the United States for the exclusive benefit of the participants. If deemed IRAs are held in a single trust that includes the qualified employer plan, the trustee must maintain a separate account for each deemed IRA. In addition, the written governing instrument creating the trust must satisfy the requirements of section 408(a) (1), (2), (3), (4), and (6).

(ii) *Application of section 408(a)(3).* If deemed IRAs are held in a single trust that includes the qualified employer plan, section 408(a)(3) is treated as satisfied if no part of the separate accounts of any of the deemed IRAs is invested in life insurance contracts, regardless of whether the separate account for the qualified employer plan invests in life insurance contracts.

(iii) *Separate accounts for traditional and Roth deemed IRAs.* The rules of section 408A(b) and the regulations thereunder, requiring each Roth IRA to be clearly designated as a Roth IRA, will not fail to be satisfied solely because Roth deemed IRAs and traditional deemed IRAs are held in a single trust, provided that the trustee maintains separate accounts for the Roth deemed IRAs and traditional deemed IRAs of each participant, and each of those accounts is clearly designated as such.

(3) *Annuity contracts.* Deemed IRAs that are individual retirement annuities may be held under a single annuity contract or under separate annuity contracts. However, the contract must be separate from any annuity contract or annuity contracts of the qualified employer plan. In addition, the contract must satisfy the requirements of section 408(b) and there must be separate accounting for the interest of each participant in those cases where the individual retirement annuities are held under a single annuity contract.

(4) *Deductibility.* The deductibility of voluntary employee contributions to a traditional deemed IRA is determined in the same manner as if they were made to any other traditional IRA. Thus, for example, taxpayers with compensation that exceeds the limits imposed by section 219(g) may not be able to make contributions to deemed IRAs, or the deductibility of such contributions may be limited in accordance with sections 408 and 219(g). However, section 219(f)(5), regarding the taxable year in which amounts paid by an employer to an individual retirement plan are includible in the employee's income, is not applicable to deemed IRAs.

(5) *Rollovers and transfers.* The same rules apply to rollovers and transfers to and from deemed IRAs as apply to rollovers and transfers to and from other IRAs. Thus, for example, the plan may provide that an employee may request and receive a distribution of his or her deemed IRA account balance and may roll it over to an eligible retirement plan in accordance with section 408(d)(3), regardless of whether that employee may receive a distribution of any other plan benefits.

(6) *Nondiscrimination.* The availability of a deemed IRA is not a benefit, right or feature of the qualified employer plan under § 1.401(a)(4)–4.

(7) *IRA assets and benefits not taken into account in determining benefits under or funding of qualified employer plan.* Neither the assets held in the deemed IRA portion of the qualified employer plan, nor any benefits attributable thereto, shall be taken into account for purposes of:

(i) Determining the benefits of employees and their beneficiaries under the plan (within the meaning of section 401(a)(2)); or

(ii) Determining the plan's assets or liabilities for purposes of section 404 or 412.

(g) *Disqualifying defects*—(1) *Single trust.* If the qualified employer plan fails to satisfy the qualification requirements applicable to it, either in form or operation, any deemed IRA that is an individual retirement account and that is included as part of the trust of that qualified employer plan does not satisfy section 408(q). Accordingly, any account maintained under such a plan as a deemed IRA ceases to be a deemed IRA at the time of the disqualifying event. In addition, the deemed IRA also ceases to satisfy the requirements of sections 408(a) and 408A. Also, if any one of the deemed IRAs fails to satisfy the applicable requirements of sections 408 or 408A, and the assets of that deemed IRA are included as part of the trust of the qualified employer plan, section 408(q) does not apply and the plan will fail to satisfy the plan's qualification requirements.

(2) *Separate trusts and annuities.* If the qualified employer plan fails to satisfy its qualification requirements, either in form or operation, but the assets of a deemed IRA are held in a separate trust (or where a deemed IRA is an individual retirement annuity), then the deemed IRA does not

automatically fail to satisfy the applicable requirements of section 408 or 408A. Instead, its status as an IRA will be determined by considering whether the account or the annuity satisfies the applicable requirements of sections 408 and 408A (including, in the case of individual retirement accounts, the prohibition against the commingling of assets under section 408(a)(5)). Also, if a deemed IRA fails to satisfy the requirements of a qualified IRA and the assets of the deemed IRA are held in a separate trust (or where the deemed IRA is an individual retirement annuity), the qualified employer plan will not fail the qualification requirements applicable to it under the Code solely because of the failure of the deemed IRA.

(h) *Definitions.* The following definitions apply for purposes of this section:

(1) *Qualified employer plan.* A *qualified employer plan* is a plan described in section 401(a), an annuity plan described in section 403(a), a section 403(b) plan, or a governmental plan under section 457(b).

(2) *Voluntary employee contribution.* A *voluntary employee contribution* is any contribution (other than a mandatory contribution within the meaning of section 411(c)(2)(C)) which is made by an individual as an employee under a qualified employer plan that allows employees to elect to make contributions to deemed IRAs and with respect to which the individual has designated the contribution as a contribution to which section 408(q) applies.

(3) *Employee.* An *employee* includes any individual who is an employee under the rules applicable to the qualified employer plan under which the deemed IRA is established.

(i) *Effective date.* This section applies to accounts or annuities established under section 408(q) on or after August 1, 2003.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 5.** The authority citation for part 602 continues to read as follows:

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

■ **Par. 6.** In § 602.101, paragraph (b) is amended by adding the following entry in numerical order to the table to read as follows:

CFR Part or section where identified and described	Current OMB control no.
* * * * * * *	
1.408(q)–1	1545–1841
* * * * * * *	

Approved: July 14, 2004.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Gregory F. Jenner,

Acting Assistant Secretary of the Treasury.

[FR Doc. 04–16594 Filed 7–21–04; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05–04–013]

RIN 1625–AA08

Special Local Regulations for Marine Events; Maryland Swim for Life, Chester River, Chestertown, MD

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing permanent special local regulations for the ''Maryland Swim for Life'', an annual marine event held on the waters of the Chester River near Chestertown, Maryland. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of the Chester River during the event.

DATES: This rule is effective August 23, 2004.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD05–04–013 and are available for inspection or copying at Commander (oax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004 between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: S.L. Phillips, Project Manager, Auxiliary and Recreational Boating Safety Branch, at (757) 398–6204.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 6, 2004, we published a notice of proposed rulemaking (NPRM) entitled ''Special Local Regulations for Marine Events; Maryland Swim for Life, Chester River, Chestertown, MD'' in the **Federal Register** (69 FR 18002). We received no letters commenting on the rule. No public hearing was requested, and none was held.

Background and Purpose

The Maryland Swim for Life Association annually sponsors the ''Maryland Swim for Life'', an open water swimming competition held on the waters of the Chester River, near Chestertown, Maryland. The event is held each year on the second Saturday in July. Approximately 120 swimmers start from Rolph's Wharf and swim upriver 3 miles then swim down river returning back to Rolph's Wharf. A fleet of approximately 25 support vessels accompanies the swimmers. To provide for the safety of participants and support vessels, the Coast Guard will restrict vessel traffic in the event area during the swim.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full