

name of the product, if any, and identifies the product as an “ingrown toenail relief product” or as an “ingrown toenail discomfort reliever.”

(b) *Indications.* The labeling of the product states, under the heading “Use,” the following: “for temporary relief of” [select one or both of the following: ‘pain’ or ‘discomfort’] “from ingrown toenails”. Other truthful and nonmisleading statements, describing only the use that has been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings”:

(1) “For external use only” in accord with § 201.66(c)(5)(i) of this chapter.

(2) “Do not use [bullet]¹ on open sores”.

(3) “Ask a doctor before use if you have [bullet] diabetes [bullet] poor circulation [bullet] gout”.

(4) “When using this product [bullet] use with a retainer ring”.

(5) “Stop use and ask a doctor if [bullet] redness or swelling of your toe increases [bullet] discharge is present around the nail [bullet] symptoms last more than 7 days or clear up and occur again within a few days”.

(d) *Directions.* The labeling of the product contains the following statements under the heading “Directions”:

(1) “[Bullet] adults and children 12 years and over:”

(i) “[Bullet] wash the affected area and dry thoroughly [bullet] place retainer ring on toe with slot over the area where the ingrown nail and the skin meet. Smooth ring down firmly. [bullet] apply enough gel product to fill the slot in the ring [bullet] place round center section of bandage strip directly over the gel-filled ring to seal the gel in place. Smooth ends of bandage strip around toes.”

(ii) “[Bullet] repeat twice daily (morning and night) for up to 7 days until discomfort is relieved or until the nail can be lifted out of the nail groove and easily trimmed”.

(2) “[Bullet] children under 12 years: ask a doctor”.

Dated: April 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9058]

RIN 1545–AY48

Guidance Under Section 817A Regarding Modified Guaranteed Contracts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations affecting insurance companies that define the interest rate to be used with respect to certain insurance contracts that guarantee higher returns for an initial, temporary period. Specifically, the final regulations define the appropriate interest rate to be used in the determination of tax reserves and required interest for certain modified guaranteed contracts. The final regulations also address how temporary guarantee periods that extend past the end of a taxable year are to be taken into account.

DATES: *Effective Date:* These regulations are effective as of May 7, 2003.

Applicability Date: For dates of applicability, see § 1.817A–1(d).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Ann H. Logan, 202–622–3970 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On June 3, 2002, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–248110–96) under section 817A of the Internal Revenue Code (Code) in the **Federal Register** (67 FR 38214). The notice was corrected in the **Federal Register** (67 FR 41653) on June 19, 2002. The proposed regulations were designed, in part, to reflect the addition of section 817A to the Code by section 1612 of the Small Business Job Protection Act of 1996, Public Law 104–188 (110 Stat. 1755). No one requested to speak at the public hearing scheduled for August 27, 2002. Accordingly, the public hearing was canceled on August

15, 2002 (67 FR 53327). Comments in response to the notice of proposed rulemaking were received and are addressed in the following Explanation and Summary of Comments. After consideration of all the comments, this document adopts the proposed regulations as revised by this Treasury decision. In addition, previous guidance under section 817A is revoked.

Explanation and Summary of Comments

Two comments were filed with the Office of the Chief Counsel of the Internal Revenue Service. Both commentators generally agreed with the decisions incorporated in the proposed regulations. However, both commentators raised concern as to the interaction of the interest rates to be used for the reserve computations for modified guaranteed contracts (MGCs) with the reserve computation rules of section 811(d). That provision imposes an additional reserve computation rule for contracts that guarantee beyond the end of the taxable year payment or crediting of amounts in the nature of interest in excess of the greater of the prevailing state assumed interest rate or the applicable Federal interest rate. In those circumstances, section 811(d) requires that the contract's future guaranteed benefits be determined as though the interest in excess of the greater of the prevailing state assumed interest rate or the applicable Federal rate were guaranteed only to the end of the taxable year.

Material was submitted as to the possible distortion of taxable income with respect to MGCs in declining interest rate environments. Notably, in cases where the interest rate required to be used under the regulations as proposed falls below the contract crediting rate during the guarantee period, section 811(d) will operate in a manner that does not match taxable income to actual income. As section 811(d) precludes taking future guaranteed interest amounts into account, examples showed that income distortion could occur under this fact pattern.

After review of the comments, the proposed regulations have been amended to waive section 811(d) throughout the guarantee period of non-equity-indexed MGCs.

Effect on Other Documents

Notice 97–32 is revoked as of May 7, 2003. Accordingly, the notice may continue to be used by taxpayers if they wish through the effective date of these final regulations.

¹ See § 201.66(b)(4) of this chapter for definition of bullet.