

Human Drug Products Under Section 503A of the FD&C Act,” (503A Final Guidance) published in 2014 (79 FR 37742) and revised in 2015 (80 FR 65781). That guidance stated, “Until a bulk drug substances list is published in the **Federal Register** as a final rule, human drug products should be compounded using only bulk drug substances that are components of drugs approved under section 505 of the FD&C Act, or are the subject of USP or NF monographs.”

When FDA issued the interim guidance concerning compounding using certain bulk drug substances under section 503A (Interim 503A Bulks Guidance) as a draft guidance for public comment, FDA announced in the notice of availability that because this draft interim guidance proposed to change the Agency’s policy relating to compounding with bulk drug substances while FDA develops a list of bulk drug substances that can be used in compounding, FDA was adding a footnote to the 503A final guidance referencing this draft interim guidance. FDA stated that once this Interim 503A Bulks Guidance is finalized, FDA would remove that footnote from the 503A final guidance and cross-reference the final Interim 503A Bulks Guidance as establishing the policy for compounding with bulk drug substances during the development of the 503A bulks list.

Therefore, concurrent with the issuance of the final Interim 503A Bulks Guidance, FDA is removing the sentence in the 503A final guidance referenced previously and is replacing it with the following statement, which the Agency proposed for public comment in the draft Interim 503A Bulks Guidance: “FDA’s interim policy concerning bulk drug substances that are not components of drugs approved under section 505 of the FD&C Act or that are not the subject of applicable USP or NF monographs can be found in the guidance, ‘Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug and Cosmetic Act.’” This change is a Level 2 change under 21 CFR 10.115, and comments on the proposed change in policy were solicited as part of the notice of availability of the draft Interim 503A Bulks Guidance.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–13799 Filed 6–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9771]

RIN 1545–BJ14

Guidance Under Section 108(a) Concerning the Exclusion of Section 61(a)(12) Discharge of Indebtedness Income of a Grantor Trust or a Disregarded Entity

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation.

SUMMARY: This document contains final regulations relating to the exclusion from gross income of discharge of indebtedness income of a grantor trust or an entity that is disregarded as an entity separate from its owner. These final regulations provide rules regarding the term “taxpayer” for purposes of applying the exclusion from gross income of discharge of indebtedness income of a grantor trust or a disregarded entity. These final regulations affect grantor trusts, disregarded entities, and their owners.

DATES: *Effective Date:* These regulations are effective on June 10, 2016.

Applicability Date: These regulations apply to discharge of indebtedness income occurring on or after June 10, 2016.

FOR FURTHER INFORMATION CONTACT: Frank J. Fisher or Amy Chang, (202) 317–6850 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

These final regulations contain amendments to the Income Tax Regulations (26 CFR part 1) under section 108 of the Internal Revenue Code (Code). Section 61(a)(12) provides that income from the discharge of indebtedness is includible in gross income. However, such income may be excludable from gross income under section 108 in certain circumstances. Section 108(a)(1)(A) and (B) exclude from gross income any amount that would be includible in gross income by reason of the discharge of indebtedness of the taxpayer if the discharge occurs in a title 11 case or when the taxpayer

is insolvent. Section 108(d)(1) through (3) provide the meaning of the terms “indebtedness of the taxpayer,” “title 11 case,” and “insolvent,” for purposes of applying section 108, and each definition uses the term “taxpayer.” Section 7701(a)(14) defines “taxpayer” as any person subject to any internal revenue tax.

On April 13, 2011, the Treasury Department and the IRS published in the **Federal Register** (76 FR 20593) a notice of proposed rulemaking (REG–154159–09) (the proposed regulations) to provide rules under section 108(a) regarding the term “taxpayer” for purposes of applying section 108 to the discharge of indebtedness income of a grantor trust or an entity that is disregarded as an entity separate from its owner (disregarded entity). The proposed regulations provide that, for purposes of applying section 108(a)(1)(A) and (B) to the discharge of indebtedness income of a grantor trust or a disregarded entity, the term “taxpayer,” as used in section 108(a)(1) and (d)(1) through (3), refers to the owner of the grantor trust or the disregarded entity. The proposed regulations also provide that, in the case of a partnership, the owner rules apply at the partner level to the partners to whom the discharge of indebtedness is allocable. For example, if a partnership holds an interest in a grantor trust or a disregarded entity, the applicability of section 108(a)(1)(A) and (B) to the discharge of indebtedness income is tested by looking to each partner to whom the income is allocable. Lastly, the proposed regulations clarify that, subject to the special rule for partnerships under section 108(d)(6), the insolvency exclusion is available only if the owner is insolvent and the bankruptcy exclusion is available only if the owner is under the bankruptcy court’s jurisdiction.

The Treasury Department and the IRS received written comments responding to the notice of proposed rulemaking. The comments are available for public inspection at www.regulations.gov. No public hearing was requested or held. The comments are discussed in this preamble.

Summary of Comments and Explanation of Revisions

After consideration of all the comments, the final regulations adopt the proposed regulations as modified by this Treasury decision. The purpose and scope of the proposed regulations and these final regulations are primarily limited to defining the term “taxpayer” for purposes of applying the bankruptcy and the insolvency exclusions from

gross income, under section 108(a)(1)(A) and (B), to the discharge of indebtedness income of a grantor trust or a disregarded entity. These final regulations are not intended to address section 108 in general and are not intended to address liabilities in general.

1. Other Exclusions Under Section 108(a)

Two commenters recommended that the final regulations apply the provisions of the proposed regulations to all exclusions in section 108(a), not only to the bankruptcy and the insolvency exclusions. Guidance on the other exclusions in section 108(a) is beyond the scope of these regulations.

2. Whether, Under Section 108(d)(2), the Owner Is “Under the Jurisdiction” of the Court in a Title 11 Case

Section 108(a)(1)(A) provides, in part, that gross income does not include any amount which would be includible in gross income by reason of the discharge of the indebtedness of the taxpayer if the discharge occurs in a title 11 case. Section 108(d)(2) defines “title 11 case” as a case under title 11 of the United States Code (relating to bankruptcy), but only if the taxpayer is under the jurisdiction of the court in such case and the discharge of indebtedness is granted by the court or is pursuant to a plan approved by the court.

Consistent with the proposed regulations, these regulations provide that the bankruptcy exclusion is available only if the owner of the grantor trust or the owner of the disregarded entity is under the jurisdiction of the court in a title 11 case. It is insufficient for the grantor trust or the disregarded entity to be under the jurisdiction of the court in a title 11 case. These regulations further clarify that the owner of the grantor trust or the owner of the disregarded entity must be under the jurisdiction of the court in a title 11 case of that owner as the “debtor,” as that term is defined in title 11 of the United States Code (the title 11 debtor).

The commenters suggested that section 108(d)(2) does not require that the taxpayer be a title 11 debtor to be considered under the jurisdiction of the court in a title 11 case. One commenter recommended that an owner of a grantor trust or a disregarded entity be considered under the jurisdiction of the court in a title 11 case when that owner is indirectly liable for the debt of the grantor trust or the disregarded entity and the court in a title 11 case eliminates the owner’s liability in conjunction with the cancellation of the

debt of the grantor trust or disregarded entity. Another commenter recommended that an owner of a grantor trust or a disregarded entity be considered under the jurisdiction of the court in a title 11 case when either the owner has taken affirmative actions, such as filing a proof of claim or a proof of interest, that place the owner under the court’s jurisdiction in a title 11 case, or the court otherwise asserts jurisdiction over the owner in connection with a title 11 case. A third commenter recommended that the owner of a disregarded entity be considered under the jurisdiction of the court in a title 11 case when: (1) The court asserts jurisdiction over that owner during the title 11 proceeding of the disregarded entity; (2) the owner’s liability on the discharged debt had been previously established (by contract or otherwise); (3) the owner is liable for all, or substantially all, of the discharged debt; and (4) qualifying for the bankruptcy exclusion was not a principal purpose of the owner’s undertaking of such liability.

The Treasury Department and the IRS have not adopted these recommendations because extending the bankruptcy exclusion to the owner of a grantor trust or a disregarded entity when that owner is not itself in bankruptcy would be inconsistent with the intended purpose of section 108(a)(1)(A), as reflected in the legislative history of that provision. Congress added the bankruptcy exclusion to the Code to allow insolvent debtors a “fresh start” after they have liquidated their assets to pay off creditors. S. Rep. No. 1035, 96th Cong., 2d Sess. 9–10 (1980), 1980–2 CB 620, 624, provides:

The rules of the [Bankruptcy Tax Act of 1980, Public Law 96–589, 94 Stat. 3389 (1980)] concerning income tax treatment of debt discharge in bankruptcy are intended to accommodate bankruptcy policy and tax policy. To preserve the debtor’s “fresh start” after bankruptcy, the bill provides that no income is recognized by reason of debt discharge in bankruptcy, so that a debtor coming out of bankruptcy (or an insolvent debtor outside bankruptcy) is not burdened with an immediate tax liability.

Here, Congress was referring to “debtor” as that term is defined in title 11. See 11 U.S.C. 101(12) (1980) (defining “debtor” as a person or municipality concerning which a case under title 11 has been commenced).

The Bankruptcy Tax Act of 1980 was enacted to supplement the Bankruptcy Reform Act of 1978, Public Law 95–598, 92 Stat. 2549 (1978). See S. Rep. No. 1035, 96th Cong., 2d Sess. 9 (1980), 1980–2 CB 620, 624. As indicated in the

legislative history of the Bankruptcy Reform Act of 1978, the debtor’s “fresh start” is conditioned upon the debtor committing all of its nonexempt assets to the jurisdiction of the bankruptcy court, either for sale by the trustee or to determine an appropriate plan to repay creditors. See H.R. Rep. No. 595, 95th Cong., 1st Sess. 118, 125–26, 176 (1977). Congress did not intend that a solvent, non-debtor owner of a grantor trust or a disregarded entity, which has committed some but not all of its nonexempt assets to the bankruptcy court’s jurisdiction, have an exclusion from discharge of indebtedness income merely by virtue of having some of its assets subject to the jurisdiction of the bankruptcy court.

The commenters’ recommendations are thus inconsistent with the Congressional intent underlying the Bankruptcy Tax Act of 1980 because those recommendations would provide a non-debtor owner that conducts only some of its activities through the grantor trust or disregarded entity with an unwarranted benefit when that owner is not a title 11 debtor and is able to pay its tax liability.

Accordingly, these regulations clarify that the owner of the grantor trust or disregarded entity must itself be under the jurisdiction of the court in a title 11 case as the title 11 debtor to qualify for the bankruptcy exclusion.

3. The Gracia Cases and the Application of the Bankruptcy Exclusion at the Partner Level

A commenter noted uncertainty under existing law as to whether the holding in certain case law would be followed by the IRS. See *Gracia v. Commissioner*, T.C. Memo. 2004–147; *Mirarchi v. Commissioner*, T.C. Memo. 2004–148; *Price v. Commissioner*, T.C. Memo. 2004–149; *Estate of Martinez v. Commissioner*, T.C. Memo. 2004–150 (collectively, the Gracia Cases). Because the bankruptcy court had asserted jurisdiction over non-debtor partners for certain matters, the Tax Court in the Gracia Cases upheld the application of the bankruptcy exclusion to the partners of a partnership that was a title 11 debtor, despite the fact that the partners were not title 11 debtors. The IRS’s position is that the Gracia Cases failed to interpret correctly the limited scope of section 108(a)(1)(A), which applies only to partners that are also title 11 debtors. See Action on Decision 2015–01 (2015–6 IRB 579) (nonacquiescence in the Gracia Cases).

These regulations provide that, in the case of a partnership that holds an interest in a grantor trust or a disregarded entity, the owner rules

apply at the level of the partners to whom the income is allocable. These regulations provide that the owner must be under the jurisdiction of the court in a title 11 case as the title 11 debtor to qualify for the bankruptcy exclusion. Accordingly, when the owner of the grantor trust or disregarded entity is a partnership, the partner to whom the income is allocable must be under the jurisdiction of the court in a title 11 case of that partner as the title 11 debtor to qualify for the bankruptcy exclusion.

4. *Whether a Grantor Trust Can Be a Debtor in a Title 11 Case*

One commenter noted that a trust cannot generally be a debtor in a title 11 case. On the other hand, a business trust can be a debtor in a title 11 case but is generally treated as a business entity for both bankruptcy and Federal tax purposes. As such, the commenter noted uncertainty as to whether these regulations concerning the bankruptcy exclusion could ever apply to the bankruptcy of a grantor trust.

These regulations account for the possibility that a trust that is treated as a grantor trust for Federal tax purposes may be treated as a business trust for purposes of eligibility to be a debtor in a title 11 case. To provide comprehensive guidance, the Treasury Department and the IRS have retained references in these regulations to grantor trusts in the provisions concerning the bankruptcy exclusion.

5. *Multiple-Owner Grantor Trusts*

A grantor trust is any portion of a trust that is treated, under subpart E of part I of subchapter J of chapter 1, as being owned by a grantor or another person. One commenter recommended that future guidance specify how a grantor's share of a multiple-owner grantor trust's liability should be determined for purposes of determining insolvency under section 108(d)(3). Specifically, that commenter recommended that future guidance or tax forms provide that a grantor trust is required to report the owner's share of the trust's liabilities. These regulations do not address these issues but the Treasury Department and the IRS invite comments regarding the application of section 108(d)(3) to the owners of a multiple-owner grantor trust.

Submissions should be submitted to:

In the case of submissions to the IRS submitted by U.S. Mail: Internal Revenue Service, Attn: Frank J. Fisher, CC:PSI:1, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

In the case of submissions to the IRS submitted by a private delivery service: Internal Revenue Service, Attn: Frank J.

Fisher, CC:PSI:1, 1111 Constitution Ave. NW., Washington, DC 20224.

6. *Extent to Which Indebtedness of a Grantor Trust or a Disregarded Entity Is Treated as Indebtedness of the Owner, Whether Indebtedness Is Recourse or Nonrecourse Debt of the Owner, and the Effect on Insolvency*

For purposes of section 108, section 108(d)(1) defines the term "indebtedness of the taxpayer" as any indebtedness for which the taxpayer is liable or subject to which the taxpayer holds property. One commenter recommended that the final regulations clarify that, for purposes of section 108(d)(1), indebtedness of a disregarded entity is indebtedness of the owner. In addition, a commenter recommended that the Treasury Department and the IRS clarify whether debt of a disregarded entity should be treated as recourse or nonrecourse debt of the owner for purposes of determining the amount of cancellation of debt income realized by the owner. That commenter suggested that the Treasury Department and the IRS issue guidance, in the form of an example in a regulation or a revenue ruling, as to whether the indebtedness of a grantor trust or a disregarded entity is recourse or nonrecourse indebtedness of the owner.

In addition, commenters recommended approaches for determining the extent to which liabilities of a grantor trust or a disregarded entity are taken into account in measuring the owner's insolvency under section 108(d)(3) for purposes of the insolvency exclusion under section 108(a)(1)(B), including applying the principles of Revenue Ruling 92-53 (1992-2 CB 48). For purposes of the insolvency exclusion, section 108(d)(3) defines "insolvency" as the excess of liabilities over the fair market value of assets. Revenue Ruling 92-53 provides that the amount by which a nonrecourse debt exceeds the fair market value of the property securing the debt (excess nonrecourse debt) is taken into account in determining whether a taxpayer is insolvent within the meaning of section 108(d)(3) only to the extent that the excess nonrecourse debt is discharged.

Comprehensive guidance on these issues is beyond the scope of these regulations. However, the Treasury Department and the IRS are of the view that indebtedness of a grantor trust or a disregarded entity is indebtedness of the owner for purposes of section 108(d)(1); assuming the owner has not guaranteed the indebtedness and is not otherwise liable for the indebtedness under applicable law, such indebtedness

should generally be treated as nonrecourse indebtedness for purposes of applying the section 108(a)(1)(B) insolvency exclusion; and accordingly the principles of Revenue Ruling 92-53 apply to determine the extent to which such indebtedness is taken into account in determining the owner's insolvency under section 108(d)(3). The Treasury Department and the IRS continue to study these issues and anticipate publishing additional guidance providing further clarification. Accordingly, the Treasury Department and the IRS invite comments on these issues. Submissions should be submitted to:

In the case of submissions to the IRS submitted by U.S. Mail: Internal Revenue Service, Attn: Seoyeon Sharon Park, CC:ITA:5, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

In the case of submissions to the IRS submitted by a private delivery service: Internal Revenue Service, Attn: Seoyeon Sharon Park, CC:ITA:5, 1111 Constitution Ave. NW., Washington, DC 20224.

7. *Valuation Discounts for Purposes of Section 108(d)(3)*

One commenter requested that the Treasury Department and the IRS clarify whether valuation discounts, if applicable to the owner's interest in a disregarded entity, could apply to the valuation of the assets and liabilities held by a disregarded entity for purposes of determining insolvency under section 108(d)(3). Guidance on this issue is beyond the scope of these regulations.

8. *Effective/Applicability Date*

These final regulations apply to the discharge of indebtedness income occurring on or after the date these final regulations are published in the **Federal Register**.

Some commenters requested that the Treasury Department and the IRS permit taxpayers to apply the final regulations retroactively to taxable years for which the period of limitations remain open. Another commenter requested that the final regulations specifically provide that the IRS will not challenge positions taken by taxpayers that apply the rules in the proposed regulations. The proposed regulations and these regulations are consistent with the existing statute. Accordingly, the IRS will not challenge return positions consistent with the proposed regulations, as clarified in these final regulations, for the period prior to the effective/applicability date of these final regulations.

Availability of IRS Documents

For copies of recently issued Revenue Procedures, Revenue Rulings, notices, and other guidance published in the Internal Revenue Bulletin, please visit the IRS Web site at <http://www.irs.gov>.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. 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, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business, and no comments were received.

Drafting Information

The principal authors of these regulations are Frank J. Fisher and Amy Chang, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the Treasury Department and the IRS participated in the development of these regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

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

■ **Par. 2.** Section 1.108–9 is added to read as follows:

§ 1.108–9 Application of the bankruptcy and the insolvency provisions of section 108 to grantor trusts and disregarded entities.

(a) *General rule*—(1) *Owner is the taxpayer.* For purposes of applying section 108(a)(1)(A) and (B) to discharge of indebtedness income of a grantor trust or a disregarded entity, neither the grantor trust nor the disregarded entity shall be considered to be the

“taxpayer,” as that term is used in section 108(a)(1) and (d)(1) through (3). Rather, for purposes of section 108(a)(1)(A) and (B) and (d)(1) through (3) and subject to section 108(d)(6), the owner of the grantor trust or the owner of the disregarded entity is the “taxpayer.”

(2) *The bankruptcy exclusion.* If indebtedness of a grantor trust or a disregarded entity is discharged in a title 11 case, section 108(a)(1)(A) applies to that discharged indebtedness only if the owner of the grantor trust or the owner of the disregarded entity is under the jurisdiction of the court in a title 11 case as the title 11 debtor. If the grantor trust or the disregarded entity is under the jurisdiction of the court in a title 11 case as the title 11 debtor, but the owner of the grantor trust or the owner of the disregarded entity is not, section 108(a)(1)(A) does not apply to the discharge of indebtedness income.

(3) *The insolvency exclusion.* Section 108(a)(1)(B) applies to the discharged indebtedness of a grantor trust or a disregarded entity only to the extent the owner of the grantor trust or the owner of the disregarded entity is insolvent. If the grantor trust or the disregarded entity is insolvent, but the owner of the grantor trust or the owner of the disregarded entity is solvent, section 108(a)(1)(B) does not apply to the discharge of indebtedness income.

(b) *Application to partnerships.* Under section 108(d)(6), in the case of a partnership, section 108(a)(1)(A) and (B) applies at the partner level. If a partnership holds an interest in a grantor trust or a disregarded entity, the applicability of section 108(a)(1)(A) and (B) to the discharge of indebtedness income is tested by looking to each partner to whom the income is allocable.

(c) *Definitions*—(1) *Disregarded entity.* For purposes of this section, a *disregarded entity* is an entity that is disregarded as an entity separate from its owner for Federal income tax purposes. See § 301.7701–2(c)(2)(i) of this chapter, the Procedure and Administration Regulations. Examples of disregarded entities include a domestic single-member limited liability company that does not elect to be classified as a corporation for Federal income tax purposes pursuant to § 301.7701–3 of this chapter, a corporation that is a qualified REIT subsidiary (within the meaning of section 856(i)(2)), and a corporation that is a qualified subchapter S subsidiary (within the meaning of section 1361(b)(3)(B)).

(2) *Grantor trust.* For purposes of this section, a *grantor trust* is any portion of

a trust that is treated under subpart E of part I of subchapter J of chapter 1 of subtitle A of title 26 of the United States Code as being owned by the grantor or another person.

(3) *Owner.* Notwithstanding any other provision of this section to the contrary, neither a grantor trust nor a disregarded entity shall be considered an owner for purposes of this section.

(4) *Title 11 debtor.* For purposes of this section, a *title 11 debtor* is a debtor in a case under title 11 of the United States Code, as defined in 11 U.S.C. 101(13).

(d) *Applicability date.* The rules of this section apply to discharge of indebtedness income occurring on or after June 10, 2016.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: May 25, 2016.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–13779 Filed 6–9–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2016–0463]

RIN 1625–AA08

Special Local Regulation; Midwest Masters Sprints; Maumee River; Toledo, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation controlling movement of vessels for certain waters of the Maumee River. This action is necessary and is intended to ensure safety of life on navigable waters to be used for a rowing event immediately prior to, during, and immediately after this event. This regulation requires vessels to maintain a minimum speed for safe navigation and maneuvering.

DATES: This temporary final rule is effective from 5 a.m. until 2:30 p.m. on June 11, 2016. For the purposes of enforcement, actual notice will be used on June 11, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2016–