through a docket that FDA has established.

In the **Federal Register** of October 27, 2015 (80 FR 65768), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on December 28, 2015. FDA received 11 comments on the draft guidance. In response to received comments or on its own initiative, FDA made several changes to the guidance to clarify particular points. In addition, FDA has made the following updates to the lists on its Web site of bulk drug substances that were nominated for inclusion on the 503A bulks list: [2]

- 503B Category 2: FDA has added one bulk drug substances to Category 2, germanium sesquioxide, because FDA identified significant safety risks relating to the use of this bulk drug substance in compounding.
- 503B Category 4: The draft interim guidance included a fourth category of bulk drug substances that would have identified substances that FDA evaluated for inclusion on the 503B bulks list but, after obtaining and considering public comments, decided not to place on the 503B bulks list. In the final interim guidance, FDA removed this fourth category because the Agency intends to identify the bulk drug substances that will not be placed on the 503B bulks list in the **Federal Register** notice that establishes the 503B bulks list. Therefore, we do not believe it is necessary to also include them in the categories identified in this guidance.

II. Electronic Access

Persons with access to the Internet may obtain the document 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. 2016–13798 Filed 6–9–16; 8:45 am]

BILLING CODE 4164–01–P

[2] In the future, if FDA makes changes to the categories of bulk drug substances on its Web site, we intend to follow the procedure identified in the guidance.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2015–D–3517]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' The guidance describes FDA's interim regulatory policy regarding the use of bulk drug substances by licensed pharmacists in State-licensed pharmacies or Federal facilities and by licensed physicians to compound human drug products while FDA develops the list of bulk drug substances that can be used in compounding under section 503A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (*see* ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3517 for ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access

the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993–0002, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act:

- Section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications);
- Section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and
- Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements).

One of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist, or licensed physician, compounds the drug product using bulk drug substances that:

(1) Comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;

(2) If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(3) If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A (503A bulks list).

(See section 503A(b)(1)(A)(i) of the FD&C Act).

This guidance describes the conditions under which FDA does not intend to take action against a licensed pharmacist or licensed physician for compounding a drug product from a bulk drug substance that is not the subject of an applicable USP or NF monograph, is not a component of an FDA-approved drug, or does not appear on the list of bulk drug substances that can be used in compounding under section 503A(b)(1)(A)(i)(III) of the FD&C Act while FDA is developing the 503A bulks list.[1] The guidance also describes FDA's process to establish the 503A bulks list and describes categories of substances that were nominated for inclusion on the 503A bulks list. The guidance includes a link to FDA's Web site listing bulk drug substances in each of the following categories:

503A Category 1—Bulk Drug Substances Under Evaluation: These bulk drug substances may be eligible for inclusion on the 503A bulks list, were nominated with sufficient supporting information for FDA to evaluate them, and do not appear on any other list.

503A Category 2—Bulk Drug Substances That Raise Significant Safety Risks: These bulk drug substances were nominated with sufficient supporting information to permit FDA to evaluate them and they may be eligible for inclusion on the 503A bulks list. However, FDA has identified significant safety risks relating to the use of these bulk substances in compounding, and therefore does not intend to adopt the policy described for the bulk substances in Category 1.

503A Category 3—Bulk Drug Substances Nominated Without Adequate Support: These bulk drug substances may be eligible for inclusion on the 503A bulks list, but were nominated with insufficient supporting information for FDA to evaluate them. These substances can be re-nominated with sufficient supporting information through a docket that FDA has established.

In the **Federal Register** of October 27, 2015 (80 FR 65781), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on December 28, 2015. FDA received 14 comments on the draft guidance. In response to received comments or on its own initiative, FDA made several changes to the guidance to clarify particular points. In addition, FDA has made the following updates to the lists on its Web site of bulk drug substances that were nominated for inclusion on the 503A bulks list: [2]

1. 503A Category 2: FDA has added two bulk drug substances to Category 2, quinacrine hydrochloride for intrauterine administration and germanium sesquioxide, because FDA identified significant safety risks relating to the use of these bulk substances in compounding.

2. 503A Category 3: FDA removed bulk drug substances from Category 3 that the Agency previously included on this list in error. Many of these substances are components of FDA-approved drugs or the subject of an applicable USP or NF monograph, and, therefore, can be used in compounding under section 503A without being placed on the 503A bulks list.

3. 503A Category 4: The draft interim guidance included a fourth category of bulk drug substances that would have identified substances that FDA evaluated for inclusion on the 503A bulks list but, after notice-and-comment rulemaking, decided not to place on the 503A bulks list. In the final interim guidance, FDA removed this fourth category because the Agency intends to identify the bulk drug substances that will not be placed on the 503A bulks list in the final rule that establishes the 503A bulks list. Therefore, we do not believe it is necessary to also include them in the categories identified in this guidance.

In this document, FDA is also announcing a Level 2 change to the final guidance, ''Pharmacy Compounding of

[1] Elsewhere in this issue of the **Federal Register**, the Agency is making available a final guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act,'' which describes the conditions under which FDA does not intend to take action against an outsourcing facility for compounding a drug product from certain bulk drug substances while FDA develops the list of bulk drug substances that can be used in compounding under section 503B(a)(2)(A)(i) of the FD&C Act.

[2] In the future, if FDA makes changes to the categories of bulk drug substances on its Web site, we intend to follow the procedure identified in the guidance.

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