

writing an extension of time to respond. This request must include the reason(s) for the requested extension and the length of time of the requested extension. FDA will grant all reasonable requests for an extension. In the event FDA denies a request for an extension of time, FDA may consider the designation request voluntarily withdrawn and, if so, will notify the sponsor in writing.

\* \* \* \* \*

9. Section 316.25 is amended by revising paragraphs (a)(1)(ii) and (a)(3) to read as follows:

**§ 316.25 Refusal to grant orphan-drug designation.**

(a) \* \* \*

(1) \* \* \*

(ii) Where the drug is intended for prevention, diagnosis, or treatment of a disease or condition affecting 200,000 or more people in the United States, the sponsor has failed to demonstrate that there is no reasonable expectation that development and production costs will be recovered from sales of the drug for such disease or condition in the United States. A sponsor's failure to comply with § 316.21 shall constitute a failure to make the demonstration required in this paragraph.

\* \* \* \* \*

(3) The drug is otherwise the same drug as an already approved drug for the same rare disease or condition and the sponsor has not submitted a medically plausible hypothesis for the possible clinical superiority of the subsequent drug.

\* \* \* \* \*

10. Section 316.26 is revised to read as follows:

**§ 316.26 Amendment to orphan-drug designation.**

(a) At any time prior to approval of a marketing application for a designated orphan drug, the sponsor holding designation may apply for an amendment to the designated use if the proposed change is due to new and unexpected findings in research on the drug, information arising from FDA recommendations, or unforeseen developments in treatment or diagnosis of the disease or condition.

(b) FDA will grant the amendment if it finds that the initial designation request was made in good faith and that the amendment is intended to conform the orphan-drug designation to the results of unanticipated research findings, to unforeseen developments in the treatment or diagnosis of the disease or condition, or to changes based on FDA recommendations, and that, as of the date of the submission of the

amendment request, the amendment would not result in exceeding the prevalence or cost recovery thresholds in § 316.21(a)(1) or (a)(2) upon which the drug was originally designated.

11. Section 316.28 is revised to read as follows:

**§ 316.28 Publication of orphan-drug designations.**

Each month FDA will update a publicly available cumulative list of all drugs designated as orphan drugs. This list will be made available on the Agency's Internet site. In addition, a cumulative, annually updated list of all designated drugs will be placed on file at the FDA Division of Dockets Management. These lists will contain the following information:

(a) The name and address of the sponsor;

(b) The generic name and trade name, if any, or, if neither is available, the chemical name or a meaningful descriptive name of the drug;

(c) The date of the granting of orphan-drug designation; and

(d) The designated use in the rare disease or condition.

12. Section 316.31 is amended by revising paragraph (a) introductory text, by redesignating paragraph (b) as paragraph (c), and by adding new paragraph (b) to read as follows:

**§ 316.31 Scope of orphan-drug exclusive approval.**

(a) After approval of a sponsor's marketing application for a designated orphan drug for use in the rare disease or condition, or a subset thereof, concerning which orphan-drug designation was granted, FDA will not approve another sponsor's marketing application for the same drug for the same use before the expiration of 7 years from the date of such approval as stated in the approval letter from FDA, except that such a marketing application can be approved sooner if, and at such time as, any of the following occurs:

\* \* \* \* \*

(b) Orphan-drug exclusive approval protects only the approved indication or use of a designated drug. If such approved indication or use is limited to a particular subset of persons with a rare disease or condition, FDA may later approve the drug for use in one or more additional subsets and, if the sponsor who obtains approval in the additional subset(s) has orphan-drug designation for the drug, FDA will recognize a new orphan-drug exclusive approval for the use in the new subset(s) of persons with the rare disease or condition from the

date of approval of the drug for use in the new subset(s).

\* \* \* \* \*

13. Section 316.34 is amended by adding paragraph (c) as follows:

**§ 316.34 FDA recognition of exclusive approval.**

\* \* \* \* \*

(c) If a drug is otherwise the same drug as a previously approved drug, FDA will not recognize orphan-drug exclusive approval if the sponsor fails to substantiate, at the time of marketing approval, the hypothesis of clinical superiority over the previously approved drug that formed the basis for designation.

Dated: October 13, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-27037 Filed 10-18-11; 8:45 am]

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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

**[REG-146297-09]**

**RIN 1545-BJ23**

**Deduction for Qualified Film and Television Production Costs**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking by cross reference to temporary regulation.

**SUMMARY:** In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to deductions for the costs of producing film and television productions. Those temporary regulations reflect changes to the law made by the Tax Extenders and Alternative Minimum Tax Relief Act of 2008, and affect taxpayers that produce films and television productions within the United States. The text of those temporary regulations also serves as the text of these proposed regulations.

**DATES:** Written comments and requests for a public hearing must be received by January 17, 2012.

**ADDRESSES:** Send submissions to: CC:PA:LPD:PR (REG-146297-09), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-146297-

09), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS REG-146297-09).

**FOR FURTHER INFORMATION CONTACT:** Concerning the regulations, Bernard P. Harvey, (202) 622-4930; concerning submissions and to request a hearing, [Richard.A.Hurst@irs.counsel.treas.gov](mailto:Richard.A.Hurst@irs.counsel.treas.gov), (202) 622-7180 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 181 was added to the Code by section 244 of the American Jobs Creation Act of 2004, Public Law 108-357 (118 Stat. 1418) (October 22, 2004), and was modified by section 403(e) of the Gulf Opportunity Zone Act of 2005, Public Law 109-135 (119 Stat. 2577) (December 21, 2005). Section 502 of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008, Public Law 110-343 (122 Stat. 3765) (October 3, 2008) further modified section 181 for film and television productions commencing after December 31, 2007, and extended section 181 to film and television productions commencing before January 1, 2010. Section 181 was extended again to film and television productions commencing before January 1, 2012, by section 744 of the Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010, Public Law 111-312 (December 17, 2010).

**Explanation of Provisions**

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR part 1) to add regulations under section 181 of the Internal Revenue Code. The temporary regulations provide rules specific to film and television productions commencing on or after January 1, 2008, to reflect the Tax Extenders and Alternative Minimum Tax Relief Act of 2008. The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains these proposed regulations.

**Special Analyses**

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) and (d) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. Because

these proposed 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, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

**Comments and Requests for a Public Hearing**

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronically generated comments that are submitted timely to the IRS. The IRS and the Treasury Department request comments on the clarity of the proposed rule and how it may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by a person who timely submits comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

**Drafting Information**

The principal author of these regulations is Bernard P. Harvey, Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the IRS and the Treasury Department participated in their development.

**List of Subjects in 26 CFR Part 1**

Income taxes, Reporting and recordkeeping requirements.

**Proposed Amendments to the Regulations**

Accordingly, 26 CFR part 1 is proposed to be 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 1.181-0 is added as follows:

**§ 1.181-0 Table of contents.**

[The text of this proposed amendment to § 1.181-0 is the same as the text of § 1.181-0T published elsewhere in this issue of the **Federal Register**.]

**Par. 3.** Section 1.181-1 is amended by adding paragraphs (a)(1)(ii), (a)(6), (b)(1)(ii), (b)(2)(vi) and (c)(2) to read as follows:

**§ 1.181-1 Deduction for qualified film and television production costs.**

(a) \* \* \* (1) \* \* \*  
(ii) [The text of this proposed amendment to § 1.181-1(a)(1)(ii) is the same as the text for § 1.181-1T(a)(1)(ii) published elsewhere in this issue of the **Federal Register**.]

\* \* \* \* \*  
(6) [The text of this proposed amendment to § 1.181-1(a)(6) is the same as the text for § 1.181-1T(a)(6) published elsewhere in this issue of the **Federal Register**.]

\* \* \* \* \*  
(b) \* \* \* (1) \* \* \*  
(ii) [The text of this proposed amendment to § 1.181-1(b)(1)(ii) is the same as the text for § 1.181-1T(b)(1)(ii) published elsewhere in this issue of the **Federal Register**.]

\* \* \* \* \*  
(2) \* \* \*  
(vi) [The text of this proposed amendment to § 1.181-1(b)(2)(vi) is the same as the text for § 1.181-1T(b)(2)(vi) published elsewhere in this issue of the **Federal Register**.]

\* \* \* \* \*  
(c) \* \* \*  
(2) [The text of this proposed amendment to § 1.181-1(c)(2) is the same as the text for § 1.181-1T(c)(2) published elsewhere in this issue of the **Federal Register**.]

**Steven T. Miller,**  
*Deputy Commissioner for Services and Enforcement.*

[FR Doc. 2011-26972 Filed 10-18-11; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R05-OAR-2011-0017; EPA-R05-OAR-2011-0106; FRL-9480-7]

**Approval and Promulgation of Air Quality Implementation Plans; Ohio and Indiana; Redesignation of the Cincinnati-Hamilton Area to Attainment of the 1997 Annual Standard for Fine Particulate Matter**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve Ohio's and Indiana's requests to redesignate their respective portions of the Cincinnati-Hamilton OH-IN-KY nonattainment area (for Ohio: Butler, Clermont, Hamilton, and Warren Counties, Ohio; for IN: a portion of