

the provisions of § 514.80(b)(4) with respect to more than one approved NADA or ANADA for preparations containing the same new animal drug so that the same information is required to be reported for more than one application, the applicant may elect to submit as a part of the report for one such application (the primary application) all the information common to such applications in lieu of reporting separately and repetitively on each. If the applicant elects to do this, the applicant must do the following:

(1) State when a report applies to multiple applications and identify all related applications for which the report is submitted by NADA or ANADA number.

(2) Ensure that the primary application contains a list of the NADA or ANADA numbers of all related applications.

(3) Submit a completed Form FDA 2301 to the primary application and each related application with reference to the primary application by NADA/ANADA number and submission date for the complete report of the common information.

(4) All other information specific to a particular NADA/ANADA must be included in the report for that particular NADA/ANADA.

(d) *Reporting forms.* Applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report." Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301 "Transmittal of Periodic Reports and Promotional Material for New Animal Drugs," in accordance with directions provided on the forms. Computer-generated equivalents of Form FDA 1932 or Form FDA 2301, approved by FDA prior to use, may be used. Form FDA 1932 and Form FDA 2301 may be obtained on the Internet at <http://www.cvm.fda.gov/cvm>, by telephoning the Division of Surveillance (HFV-210), or by submitting a written request to the following address: Food and Drug Administration, Center for Veterinary Medicine, Division of Surveillance (HFV-210), 7500 Standish Pl., Rockville, MD 20855-2764.

(e) *Records to be maintained.* The applicants and nonapplicants must maintain records and reports of all information required by this section for a period of 5 years after the date of submission.

(f) *Access to records and reports.* The applicant and nonapplicant must, upon request from any authorized FDA officer

or employee, at all reasonable times, permit such officer or employee to have access to copy and to verify all such required records and reports.

(g) *Mailing addresses.* Completed 15-day alert reports, periodic drug experience reports, and special drug experience reports must be submitted to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV-199), 7500 Standish Pl., Rockville, MD 20855-2764. Three-day alert reports must be submitted to the appropriate FDA district office or local FDA resident post. Addresses for district offices and resident posts may be obtained from the Internet at <http://www.fda.gov>.

(h) *Withdrawal of approval.* If FDA finds that the applicant has failed to establish the required records, or has failed to maintain those records, or has refused access to an authorized FDA officer or employee to copy or to verify such records or reports, FDA may withdraw approval of the application to which such records or reports relate. If FDA determines that withdrawal of the approval is necessary, the agency shall give the applicant notice and opportunity for hearing, as provided in § 514.200, on the question of whether to withdraw approval of the application.

(i) *Disclaimer.* Any report or information submitted under this section and any release of that report or information by FDA will be without prejudice and does not necessarily reflect a conclusion that the report or information constitutes an admission that the drug caused or contributed to an adverse event. A person need not admit, and may deny, that the report or information constitutes an admission that a drug caused or contributed to an adverse event.

Dated: January 21, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Parts 1 and 602

[TD 8971]

RIN 1545-BA49

#### New Markets Tax Credit; Correction

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

**ACTION:** Correction to temporary regulations.

**SUMMARY:** This document contains a correction to temporary regulations that was published in the **Federal Register** on December 26, 2001 (66 FR 66307). This document contains temporary regulations that provide guidance for taxpayers claiming the new markets tax credit under section 45D.

**DATES:** This correction is effective December 26, 2001.

**FOR FURTHER INFORMATION CONTACT:** Paul Handleman (202) 622-3040 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

The temporary regulations that are the subject of this correction are under section 45D of the Internal Revenue Code.

##### Need for Correction

As published, the temporary regulations (TD 8971) contains errors that may prove to be misleading and are in need of clarification.

##### Correction of Publication

Accordingly, the publication of the temporary regulations (TD 8971), which is the subject of FR. Doc. 01-31528, is corrected as follows:

On page 66310, column 1, under the paragraph heading "Part 1—Income Taxes", following paragraph 1, please insert in the amendatory instruction "Par. 1a. The undesignated center heading immediately preceding § 1.30-1 is revised to read as follows: Credits Allowable Under Sections 30 through 45D".

**LaNita Van Dyke,**

*Acting Chief, Regulations Unit, Associate Chief Counsel, (Income Tax and Accounting).*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Parts 1 and 602

[TD 8976]

RIN 1545-AX20

#### Dollar-Value LIFO Regulations; Inventory Price Index Computation Method; Correction

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

**ACTION:** Corrections to final regulations.