

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original new animal drug application (NADA) filed by Boehringer Ingelheim Vetmedica, Inc. The NADA provides for veterinary prescription use of an injectable suspension of protamine zinc recombinant human insulin for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus.

**DATES:** This rule is effective December 14, 2009.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002, filed NADA 141-297 that provides for the veterinary prescription use of PROZINC (protamine zinc recombinant human insulin), an injectable suspension for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus. The NADA is approved as of October 28, 2009, and the regulations are amended in 21 CFR 522.1160 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to

the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

■ 2. In § 522.1160, revise paragraphs (a), (b), and (c)(2)(i) to read as follows:

##### § 522.1160 Insulin.

(a) **Specifications**—(1) Each milliliter (mL) of porcine insulin zinc suspension contains 40 international units (IU) of insulin.

(2) Each mL of protamine zinc recombinant human insulin suspension contains 40 IU of insulin.

(b) **Sponsors.** See sponsors in § 510.600 of this chapter for use as in paragraph (c) of this section.

(1) No. 000061 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

(2) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraphs (c)(2)(i)(B), (c)(2)(ii), and (c)(2)(iii) of this section.

(c) \* \* \*

(2) **Cats**—(i) **Amount**—(A) **Porcine insulin zinc.** Administer an initial dose of 1 to 2 IU by subcutaneous injection. Injections should be given twice daily at approximately 12-hour intervals. For cats fed twice daily, the injections should be concurrent with or right after a meal. For cats fed ad libitum, no change in feeding is needed. Adjust the dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained.

(B) **Protamine zinc recombinant human insulin.** Administer an initial dose of 0.1 to 0.3 IU/pound of body weight (0.2 to 0.7 IU/kilogram) every 12 hours. The dose should be given concurrently with or right after a meal. Re-evaluate the cat at appropriate intervals and adjust the dose based on both clinical signs and glucose nadirs until adequate glycemic control has been attained.

\* \* \* \* \*

Dated: December 8, 2009.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

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**BILLING CODE 4160-01-S**

#### DEPARTMENT OF THE TREASURY

##### Internal Revenue Service

###### 26 CFR Part 1

[TD 9474]

RIN 1545-BF14

#### Reduction in Taxable Income for Housing Hurricane Katrina Displaced Individuals

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

**ACTION:** Final regulations and removal of temporary regulations.

**SUMMARY:** This document contains final regulations relating to the reduction in taxable income under section 302 of the Katrina Emergency Tax Relief Act of 2005. The final regulations also reflect legislation under section 702 of the Heartland Disaster Tax Relief Act of 2008. The final regulations affect taxpayers who provide housing in their principal residences to individuals displaced by certain major disasters.

**Effective Date:** These regulations are effective on December 14, 2009.

**Applicability Date:** For date of applicability, see § 1.9300-1(h).

**FOR FURTHER INFORMATION CONTACT:** Shareen S. Pflanz, 202-622-4920 (not a toll-free number).

##### SUPPLEMENTARY INFORMATION:

##### Background and Explanation of Provisions

This document contains final regulations that replace the temporary regulations in 26 CFR Part 1 relating to the reduction in taxable income for housing provided to displaced individuals under section 302 of the Katrina Emergency Tax Relief Act of 2005 (Pub. L. 109-73, 119 Stat. 2016) (KETRA). This document also applies these rules to individuals displaced in a Midwestern disaster area, as defined in section 702 of the Heartland Disaster Tax Relief Act of 2008 (Title VII of Division C of Pub. L. 110-343, 122 Stat. 3912) (HDTRA).

On December 12, 2006, temporary regulations (TD 9301) were published in the **Federal Register** (71 FR 74467). A notice of proposed rulemaking (REG-152043-05) cross-referencing the temporary regulations was also published in the **Federal Register** (71 FR 74482). No public hearing was requested or held. No written comments responding to the notice of proposed rulemaking were received. The proposed regulations are adopted as amended by this Treasury decision to implement section 702 of HDTRA.

Section 702 of HDTRA, enacted on October 3, 2008, applies section 302 of KETRA to the Midwestern disaster area. The Midwestern disaster area is the area for which the President declared (after May 19, 2008, and before August 1, 2008) a major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170) (Stafford Act). The disaster occurred by reason of severe storms, tornados, or flooding in the states of Arkansas, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, and Wisconsin. The applicable disaster date for each state in the Midwestern disaster area is the date of the severe storm, tornado, or flooding giving rise to the Presidential declaration for that state. See **Federal Register** notices for each state at <http://www.FEMA.gov>. The reduction in taxable income for providing housing to a displaced individual in a Midwestern disaster area applies to taxable years beginning in 2008 or 2009.

Accordingly, the final regulations expand the scope of the temporary regulations to include taxpayers who provide housing in their principal residences to Midwestern disaster displaced individuals. The final regulations expand the definitions under § 1.9300-1T(e) of the temporary regulations relating to Hurricane Katrina to include the Midwestern disaster area.

The final regulations also clarify that the limitations on the reduction in taxable income apply separately to the Hurricane Katrina disaster area and the Midwestern disaster area. Thus, for example, a taxpayer may reduce taxable income by up to \$2,000 for providing housing to Midwestern disaster displaced individuals even though the taxpayer reduced taxable income for providing housing to one or more Hurricane Katrina displaced individuals.

The temporary regulations provided that the maximum dollar limitation for a married individual who files a separate income tax return is \$1,000. The final regulations provide that the maximum dollar limitation is \$2,000 for married taxpayers filing jointly or separately. Married taxpayers filing separate income tax returns may allocate the \$2,000 between the returns.

The final regulations authorize the Commissioner to apply these rules in additional guidance of general applicability, see § 601.601(d)(2) of the Internal Revenue Practice Regulations, if Congress extends relief under section 302 of KETRA to other disaster areas in the future.

## Effective/Applicability Date

These regulations apply to taxable years ending after December 11, 2006. Taxpayers who, after filing their tax returns for 2006 or 2008 as married filing separately, want to apply the rule allowing them to allocate the \$2,000 maximum limitation between them, may do so by filing amended returns if the period of limitations on credit or refund under section 6511 has not expired.

## Special Analyses

It has been determined that this Treasury decision 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) 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 Internal Revenue Code, the notice of proposed rulemaking that preceded these final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

## Drafting Information

The principal author of these regulations is Shareen S. Pflanz of the Office of the 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.

## 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 is amended by removing the entry for § 1.9300-1T to read in part as follows:

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

■ **Par. 2.** Section 1.9300-1 is added to read as follows:

#### § 1.9300-1 Reduction in taxable income for housing displaced individuals.

(a) *In general.* For a taxable year beginning in the applicable taxable year (as defined in paragraph (f)(1) of this

section), a taxpayer who is a natural person may reduce taxable income by \$500 for each displaced individual (as defined in paragraph (f)(2) of this section) to whom the taxpayer provides housing free of charge in, or on the site of, the taxpayer's principal residence for a period of at least 60 consecutive days. A taxpayer may claim the reduction in taxable income for any applicable taxable year in which a consecutive 60-day period ends. A taxpayer may not claim the reduction in taxable income unless the taxpayer includes the taxpayer identification number of the displaced individual on the taxpayer's income tax return.

(b) *Provision of housing—(1) Principal residence.* For purposes of this section, the term principal residence has the same meaning as in section 121 and the associated regulations. See § 1.121-1(b)(1) and (b)(2).

(2) *Legal interest required.* A taxpayer is treated as providing housing for purposes of this section only if the taxpayer is an owner or lessee (including a co-owner or co-lessee) of the principal residence.

(3) *Compensation for providing housing.* No reduction in taxable income is allowed under this section to a taxpayer who receives rent or any reimbursement or compensation (whether in cash, services, or property) from any source for providing housing to the displaced individual. For this purpose, lodging, utilities, and other similar items are treated as housing, but telephone calls, food, clothing, transportation, and other similar items are not treated as housing.

(c) *Limitations—(1) Dollar limitation—(i) In general.* The reduction in taxable income under paragraph (a) of this section may not exceed the maximum dollar limitation, and must be reduced by the total amount of all reductions under this section for all prior taxable years (except as provided in paragraph (c)(5) of this section). The maximum dollar limitation is—

(A) \$2,000 in the case of an unmarried individual; or

(B) \$2,000 in the case of a husband and wife, whether the husband and wife file a joint income tax return or separate income tax returns; married taxpayers filing separate income tax returns may allocate this amount in \$500 increments between their respective returns, provided that each spouse is otherwise eligible to claim that reduction in taxable income.

(ii) *Married individuals with separate principal residences.* The limitation in paragraph (c)(1)(i)(B) of this section applies whether or not the married individuals occupy the same principal

residence. A person is treated as married for purposes of this section if the individual is treated as married under section 7703.

(2) *Spouse or dependent of the taxpayer.* No reduction of taxable income is allowed for a displaced individual who is the spouse or a dependent of the taxpayer.

(3) *One reduction per displaced individual.* Except as provided in paragraph (c)(5) of this section, a taxpayer may not reduce taxable income under paragraph (a) of this section for a displaced individual for whom the taxpayer or any taxpayer residing in the same principal residence has reduced taxable income under this section for any prior taxable year.

(4) *Taxpayers occupying the same principal residence.* Except as provided in paragraph (c)(5) of this section, for all taxable years, only one taxpayer occupying the same principal residence may reduce taxable income for a particular displaced individual.

(5) *Limitations applied separately to each disaster.* The limitations of this paragraph (c) apply separately to each disaster area. Thus, a taxpayer may reduce taxable income by \$2,000 for providing housing to Midwestern disaster displaced individuals even though the taxpayer reduced taxable income for providing housing to one or more Hurricane Katrina displaced individuals. For this purpose, all areas within the Midwestern disaster area are treated as one disaster area.

(d) *Substantiation.* A taxpayer claiming a reduction of taxable income under this section must maintain records sufficient to show entitlement to the reduction as provided in forms, instructions, publications or other guidance published by the IRS.

(e) The Commissioner may apply this section in additional guidance of general applicability, see § 601.601(d)(2) of this chapter, to other disaster areas to which Congress extends relief under section 302 of the Katrina Emergency Tax Relief Act of 2005.

(f) *In general.* The following definitions apply for all purposes of this section.

(1) *Applicable taxable year.* The term *applicable taxable year* means—

(i) A taxable year beginning in 2005 or 2006, in the case of housing provided to a Hurricane Katrina displaced individual (as defined in paragraph (f)(2)(ii) of this section); and

(ii) A taxable year beginning in 2008 or 2009, in the case of housing provided to a Midwestern disaster displaced individual (as defined in paragraph (f)(2)(iii) of this section).

(2) *Displaced individual—(i) Scope.* The term *displaced individual* means a Hurricane Katrina displaced individual as defined in paragraph (f)(2)(ii) of this section and a Midwestern disaster displaced individual as defined in paragraph (f)(2)(iii) of this section.

(ii) *Hurricane Katrina displaced individual.* The term *Hurricane Katrina displaced individual* means any natural person (other than the spouse or a dependent of the taxpayer) if the following requirements are met—

(A) The person's principal place of abode on August 28, 2005, was in the Hurricane Katrina disaster area (as defined in paragraph (f)(4)(ii) of this section);

(B) The person was displaced from that abode; and

(C) If the abode was located outside the Hurricane Katrina core disaster area (as defined in paragraph (f)(5)(ii) of this section)—

(1) The abode was damaged by Hurricane Katrina; or

(2) The person was evacuated from that abode by reason of Hurricane Katrina.

(iii) *Midwestern disaster displaced individual.* The term *Midwestern disaster displaced individual* means any natural person (other than the spouse or a dependent of the taxpayer) if the following requirements are met—

(A) The person's principal place of abode on the Midwestern disaster date (as defined in paragraph (f)(3) of this section), was in any Midwestern disaster area (as defined in paragraph (f)(4)(iii) of this section);

(B) The person was displaced from that abode; and

(C) If the abode was located outside the Midwestern core disaster area (as defined in paragraph (f)(5)(iii) of this section)—

(1) The abode was damaged by any Midwestern disaster; or

(2) The person was evacuated from that abode by reason of any Midwestern disaster.

(3) *Midwestern disaster date.* The term *Midwestern disaster date* means—

(i) In Arkansas, May 2 through May 12, 2008;

(ii) In Illinois, June 1 through July 22, 2008;

(iii) In Indiana, May 30 through June 27, 2008;

(iv) In Iowa, May 25 through August 13, 2008;

(v) In Kansas, May 22 through June 16, 2008;

(vi) In Michigan, June 6 through June 13, 2008;

(vii) In Minnesota, June 6 through June 12, 2008;

(viii) In Missouri, May 10 through May 11, 2008, and June 1 through August 13, 2008;

(ix) In Nebraska, April 23 through April 26, 2008, May 22 through June 24, 2008, and June 27, 2008; or

(x) In Wisconsin, June 5 through July 25, 2008.

(4) *Disaster area—(i) Scope.* The term *disaster area* means the Hurricane Katrina disaster area as defined in paragraph (f)(4)(ii) of this section and the Midwestern disaster area as defined in paragraph (f)(4)(iii) of this section.

(ii) *Hurricane Katrina disaster area.* The term *Hurricane Katrina disaster area* means the states of Alabama, Florida, Louisiana, and Mississippi.

(iii) *Midwestern disaster area.* The term *Midwestern disaster area* means an area for which the President declared a major disaster on or after May 20, 2008, and before August 1, 2008, under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170) (Stafford Act) by reason of severe storms, tornados, or flooding occurring in any of the states of Arkansas, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, and Wisconsin.

(5) *Core disaster area—(i) Scope.* The term *core disaster area* means the Hurricane Katrina core disaster area as defined in paragraph (f)(5)(ii) of this section and the Midwestern core disaster area as defined in paragraph (f)(5)(iii) of this section.

(ii) *Hurricane Katrina core disaster area.* The term *Hurricane Katrina core disaster area* means the portion of the Hurricane Katrina disaster area designated by the President to warrant individual or individual and public assistance from the federal government under the Stafford Act.

(iii) *Midwestern core disaster area.* The term *Midwestern core disaster area* means the portion of the Midwestern disaster area designated by the President to warrant individual or individual and public assistance from the federal government under the Stafford Act for damages attributable to the severe storms, tornados, or flooding in the Midwestern disaster area.

(g) *Examples.* The provisions of this section are illustrated by the following examples. In each example, a taxpayer provides housing within the meaning of paragraph (b) of this section in, or on the site of, the taxpayer's principal residence for a period of at least 60 consecutive days (the 60th day being in the applicable taxable year) for each displaced individual, none of whom is a spouse or dependent of the taxpayer. The examples are as follows:

*Example 1.* Taxpayer A provides housing to N, a Hurricane Katrina displaced individual, from September 1, 2005, until March 10, 2006. Under paragraphs (a) and (c)(3) of this section, A may reduce A's taxable income by \$500 on A's income tax return for calendar year 2005 or 2006 (but not both) for providing housing to N.

*Example 2.* The facts are the same as in *Example 1*, except that A and A's unmarried roommate B are co-lessees of their principal residence. Both A and B provide housing to N. Under paragraphs (a) and (c)(4) of this section, either A or B, but not both, may reduce taxable income by \$500 for 2005 or 2006 for providing housing to N. If A or B reduces taxable income for 2005 for providing housing to N, neither A nor B may reduce taxable income for 2006 for providing housing to N.

*Example 3.* The facts are the same as in *Example 2*, except that in 2009 A and B provide housing to N, who in 2009 is a Midwestern disaster displaced individual. Under paragraph (c)(5) of this section, the limitation of paragraph (c)(4) of this section applies separately to each disaster. Therefore, either A or B may reduce taxable income by \$500 for 2009 for providing housing to N.

*Example 4.* During 2008, unmarried roommates and co-lessees C and D provide housing to eight Midwestern disaster displaced individuals. Under paragraphs (a) and (c)(1)(i)(A) of this section, C may reduce taxable income by \$2,000 on C's 2008 income tax return for providing housing to any four of these displaced individuals and D may reduce taxable income by \$2,000 on D's 2008 income tax return for providing housing to the other four displaced individuals.

*Example 5.* (i) In 2008, a married couple, H and W, provide housing to a Midwestern disaster displaced individual, O. H and W file their 2008 income tax return as married filing jointly. Under paragraphs (a) and (c)(4) of this section, H and W may reduce taxable income by \$500 on their 2008 income tax return for providing housing to O.

(ii) In 2009, H and W provide housing to O and to another Midwestern disaster displaced individual, P. H and W file their 2009 income tax returns as married filing separately. Because H and W reduced their 2008 taxable income for providing housing to O, under paragraph (c)(3) of this section, neither H nor W may reduce taxable income on their 2009 income tax returns for providing housing to O. Under paragraphs (a) and (c)(4) of this section, either H or W but not both, may reduce taxable income by \$500 on his or her 2009 income tax return for providing housing to P.

*Example 6.* The facts are the same as in *Example 5*, except that in 2009 H and W provide housing to five Midwestern disaster displaced individuals in addition to O. H and W together may reduce taxable income on their 2009 income tax returns by a total of \$2,000 for the Midwestern disaster displaced individuals (other than O). Under paragraph (c)(1)(i)(B) of this section, H and W may allocate the \$2,000 in increments of \$500 between their separate returns. For example, either one may reduce taxable income by \$500 and the other may reduce taxable income by \$1,500, or H and W each may reduce taxable income by \$1,000.

(h) *Effective/applicability date.* This section applies for taxable years ending after December 11, 2006.

#### § 1.9300–1T [Removed]

■ **Par. 3.** Section 1.9300–1T is removed.

Approved: December 8, 2009.

**Steven T. Miller,**

*Deputy Commissioner for Services and Enforcement.*

**Michael F. Mundaca,**

*Acting Assistant Secretary of the Treasury (Tax Policy).*

[FR Doc. E9–29635 Filed 12–11–09; 8:45 am]

**BILLING CODE 4830–01–P**

Terrorism Risk Insurance Program, (202) 622–6770 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Terrorism Risk Insurance Act of 2002 (Pub. L. 107–297, 116 Stat. 2322) was enacted on November 26, 2002. The Act was effective immediately. The Act's purposes are to address market disruptions, ensure the continued widespread availability and affordability of commercial property and casualty insurance for terrorism risk, and allow for a transition period for the private markets to stabilize and build capacity while preserving state insurance regulation and consumer protections.

Title I of the Act establishes a temporary Federal program of shared public and private compensation for insured commercial property and casualty losses resulting from an act of terrorism. The Act authorizes Treasury to administer and implement the Terrorism Risk Insurance Program, including the issuance of regulations and procedures. The Program provides a Federal backstop for insured losses from an act of terrorism. Section 103(e) of the Act directs and gives Treasury authority to recoup Federal payments made under the Program through policyholder surcharges.

The Program was originally set to expire on December 31, 2005. On December 22, 2005, the Terrorism Risk Insurance Extension Act of 2005 (Pub. L. 109–144, 119 Stat. 2660) was enacted, which extended the Program through December 31, 2007. On December 26, 2007, the Terrorism Risk Insurance Program Reauthorization Act of 2007 (Pub. L. 110–160, 121 Stat. 1839) was enacted, which extends the Program through December 31, 2014.

The Reauthorization Act, among other changes, revised the recoupment provisions of the Act. These changes are explained below in the context of discussion of other provisions.

##### II. Previous Rulemaking

To assist insurers, policyholders, and other interested parties in complying with immediately applicable requirements of the Act, Treasury has issued interim guidance to be relied upon by insurers until superseded by regulations. Rules establishing general provisions implementing the Program, including key definitions, and requirements for policy disclosures and mandatory availability, can be found in Subparts A, B, and C of 31 CFR Part 50. Treasury's rules applying provisions of the Act to State residual market insurance entities and State workers'

**FOR FURTHER INFORMATION CONTACT:**  
Howard Leikin, Deputy Director,