

# Rules and Regulations

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 510 and 528

[Docket No. FDA-2009-N-0665]

#### New Animal Drugs; Bc6 Recombinant Deoxyribonucleic Acid Construct

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the original approval of a new animal drug application (NADA) filed by GTC Biotherapeutics, Inc. The NADA provides for use of a recombinant deoxyribonucleic acid (rDNA) construct in a lineage of genetically engineered (GE) goats expressing recombinant human antithrombin in their milk. The subsequently purified antithrombin is a biological product for human therapeutic use. In a separate action, a biologics license application (BLA) has been approved by FDA for use of this antithrombin in humans.

**DATES:** This rule is effective February 11, 2009.

**FOR FURTHER INFORMATION CONTACT:** Larisa Rudenko, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8247, e-mail: [larisa.rudenko@fda.hhs.gov](mailto:larisa.rudenko@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702, filed NADA 141-294 that provides for use of an rDNA construct in a lineage of GE goats expressing recombinant human antithrombin in their milk. The subsequently purified antithrombin is a biological product for human therapeutic use. In a separate action, a

BLA has been approved by FDA for use of this antithrombin in humans. The NADA is approved as of February 6, 2009, and the regulations are amended by adding 21 CFR part 528 to reflect the approval.

In addition, GTC Biotherapeutics, Inc., is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this sponsor.

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 carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 528

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 chapter I is amended as follows:

## PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for "GTC Biotherapeutics, Inc.;" and in the table in paragraph (c)(2), numerically add an entry for "042976" to read as follows:

#### § 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

\* \* \* \* \*  
(c) \* \* \*  
(1) \* \* \*

Firm name and address	Drug labeler code
* * * * *	* * * * *
GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702	042976
* * * * *	* * * * *

(2) \* \* \*

Drug labeler code	Firm name and address
* * * * *	* * * * *
042976	GTC Biotherapeutics, Inc., 175 Crossing Blvd., Framingham, MA 01702
* * * * *	* * * * *

■ 3. Add part 528 to read as follows:

## PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

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

#### § 528.1070 Bc6 recombinant deoxyribonucleic acid construct.

(a) *Specifications and indications for use.* Five copies of a human Bc6 recombinant deoxyribonucleic acid (rDNA) construct located at the GTC 155-92 site in a specific hemizygous diploid line of dairy breeds of domestic goats (*Capra aegagrus hircus*) directing the expression of the human gene for antithrombin (which is intended for the treatment of humans) in the mammary

gland of goats derived from lineage progenitor 155–92.

(b) *Sponsor.* See No. 042976 in § 510.600 of this chapter.

(c) *Limitations.* Food or feed from GTC–155–92 goats is not permitted in the food or feed supply.

Dated: February 6, 2009.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. E9–2881 Filed 2–6–09; 4:15 pm]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9444]

RIN 1545–B142

#### **Application of Section 367 to a Section 351 Exchange Resulting From a Transaction Described in Section 304(a)(1); Treatment of Gain Recognized Under Section 301(c)(3) for Purposes of Section 1248**

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

**ACTION:** Final and temporary regulations.

**SUMMARY:** This document contains final and temporary regulations under sections 367(a), 367(b) and 1248(a) of the Internal Revenue Code (Code). The final regulations under section 367 revise existing final regulations and add cross-references. The final regulations under section 1248 update an effective/applicability date. The temporary regulations under section 367(a) and (b) revise existing final regulations concerning transfers of stock to a foreign corporation that are described in section 351 by reason of section 304(a)(1). The temporary regulations under section 1248(a) provide that, for purposes of section 1248(a), gain recognized by a shareholder under section 301(c)(3) in connection with the receipt of a distribution of property from a foreign corporation with respect to its stock shall be treated as gain from the sale or exchange of the stock of such foreign corporation. The temporary regulations affect certain persons that transfer stock to a foreign corporation in a transaction described in section 304(a)(1), or certain persons that recognize gain under section 301(c)(3) in connection with the receipt of a distribution of property from a foreign corporation with respect to its stock. The text of the temporary regulations serves as the text of the

proposed regulations set forth in the notice of proposed rulemaking on this subject published in the Proposed Rules section in this issue of the **Federal Register**.

**DATES: Effective Date:** These regulations are effective on February 11, 2009.

**Applicability Date:** These regulations apply to acquisitions of stock occurring on or after February 11, 2009.

**FOR FURTHER INFORMATION CONTACT:**

Sean W. Mullaney, (202) 622–3860 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 367(a)(1) generally provides that if a United States person transfers property to a foreign corporation in an exchange described in section 332, 351, 354, 356, or 361, the foreign corporation shall not be considered a corporation for purposes of determining the extent to which the United States person recognizes gain on such transfer. Exceptions to the general rule are provided by section 367(a)(2) and (3), and the Secretary has broad authority under section 367(a)(6) to promulgate regulations providing exceptions for other transactions.

Section 367(b)(1) provides that in the case of an exchange described in section 332, 351, 354, 355, 356, or 361 in connection with which there is no transfer of property described in section 367(a)(1), a foreign corporation shall be considered to be a corporation except to the extent provided in regulations prescribed by the Secretary which are necessary or appropriate to prevent the avoidance of Federal income taxes. Section 367(b)(2) provides that the regulations prescribed pursuant to section 367(b)(1) shall include (but shall not be limited to) regulations dealing with the sale or exchange of stock or securities in a foreign corporation by a United States person, including regulations providing the circumstances under which gain is recognized, amounts are included in gross income as a dividend, adjustments are made to earnings and profits, or adjustments are made to the basis of stock or securities.

Regulations under section 367(b) generally provide that if the potential application of section 1248 cannot be preserved immediately following the acquisition of the stock or assets of a foreign corporation (foreign acquired corporation) by another foreign corporation in an exchange subject to section 367(b), then certain exchanging shareholders of the foreign acquired corporation must include in income as a dividend the section 1248 amount (as defined in § 1.367(b)–2(c)) attributable

to the stock of the foreign acquired corporation. See § 1.367(b)–4(b).

Section 304(a)(1) generally provides that, for purposes of sections 302 and 303, if one or more persons are in control of each of two corporations and in return for property one of the corporations (the acquiring corporation) acquires stock in the other corporation (the issuing corporation) from the person (or persons) so in control, then such property shall be treated as a distribution in redemption of the stock of the acquiring corporation. To the extent section 301 applies to the distribution, the transferor and the acquiring corporation are treated as if (1) the transferor transferred the stock of the issuing corporation to the acquiring corporation in exchange for stock of the acquiring corporation in a transaction to which section 351(a) applies, and (2) the acquiring corporation then redeemed the stock it is deemed to have issued. Under section 304(b)(2), the determination of the amount of the property distribution that is a dividend (and the source thereof) is made as if the property is distributed by the acquiring corporation to the extent of its earnings and profits, and then by the issuing corporation to the extent of its earnings and profits.

On February 21, 2006, the IRS and Treasury Department issued final regulations (TD 9250) providing that section 367(a) and (b) shall not apply to certain transfers of stock of a foreign or domestic corporation to a foreign acquiring corporation to which section 351 applies (deemed section 351 exchange) by reason of section 304(a)(1) (final 2006 regulations). Specifically, § 1.367(a)–3(a) provides that if, pursuant to section 304(a)(1), a United States person is treated as transferring stock of a domestic or foreign corporation to a foreign corporation in exchange for stock of such foreign corporation in a deemed section 351 exchange, the deemed section 351 exchange is not a transfer to a foreign corporation subject to section 367(a). Similarly, § 1.367(b)–4(a) provides that if, pursuant to section 304(a)(1), a foreign corporation is treated as acquiring the stock of another foreign corporation in a deemed section 351 exchange, the deemed section 351 exchange is not an acquisition subject to section 367(b).

The preamble to the final 2006 regulations explained that the IRS and Treasury Department determined that the policies underlying section 367(a) and (b) are preserved even if a deemed section 351 exchange is not subject to section 367(a) and (b) because generally the income recognized by the transferor in the transaction (dividend income,