

SUPPLEMENTARY INFORMATION: Orphan Medical, Inc., 13911 Ridgedale Dr., suite 475, Minnetonka, MN 55305, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141-075 for ANTIZOL-VET (fomepizole) to Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304. A supplement was also filed to NADA 141-075 to remove a vial of saline diluent from this product. The supplemental NADA is approved as of April 18, 2006, and the regulations are amended in 21 CFR 522.1004 to reflect the change of sponsorship, the removal of a vial of saline diluent from the product, and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

Following these changes of sponsorship, Orphan Medical, Inc., is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Orphan Medical, Inc.

The agency has determined under 21 CFR 25.33(d)(1) 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

21 CFR Part 510

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

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 parts 510 and 522 are 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), remove the entry for

"Orphan Medical, Inc." and alphabetically add a new entry for "Jazz Pharmaceuticals, Inc."; and in the table in paragraph (c)(2) remove the entry for "062161" and numerically add a new entry for "068727" 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	
*	*	*	*	*
Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304.			068727	
*	*	*	*	*
(2) * * *				
Drug labeler code		Firm name and address		
*	*	*	*	*
068727		Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304		
*	*	*	*	*

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. In § 522.1004, revise paragraphs (a), (b), (c)(1), and (c)(3) to read as follows:

§ 522.1004 Fomepizole.

(a) *Specifications.* Each vial contains 1.5 grams fomepizole (1.5 milliliter (mL) of 1.0 gram per mL solution).

(b) *Sponsor.* See No. 068727 in § 510.600(c) of this chapter.

(c) * * *

(1) *Amount.* 20 milligrams per kilogram (mg/kg) of body weight intravenously initially, followed by 15 mg/kg at 12 and 24 hours, and 5 mg/kg at 36 hours.

* * * * *

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 3, 2006.

Steven D. Vaughn,
Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.
[FR Doc. 06-4534 Filed 5-15-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9243]

RIN 1545-BA65

Revision of Income Tax Regulations Under Sections 367, 884, and 6038B Dealing With Statutory Mergers or Consolidations Under Section 368(a)(1)(A) Involving One or More Foreign Corporations, and Guidance Necessary To Facilitate Business Electronic Filing Under Section 6038B; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (TD 9243), that was published in the **Federal Register** on Thursday, January 26, 2006 (71 FR 4276). This final regulation amends the income tax regulations under various provisions of the Internal Revenue Code to account for statutory mergers and consolidations.

DATES: This correction is effective January 23, 2006.

FOR FURTHER INFORMATION CONTACT: Christopher Trump (202) 622-3860 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulation (TD 9243) that is the subject of this correction is under section 367 of the Internal Revenue Code.

Need for Correction

As published, TD 9243 contains an error that may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

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 * * *

§ 1.367(b)-6 [Corrected]

■ **Par. 2.** Section 1.367(b)-6 is amended by removing the third sentence of

paragraph (a)(1) and adding the following sentence in its place to read as follows:

§ 1.367(b)–6 Effective dates and coordination rules.

(a) * * *
(1) * * * Section 1.367(b)–4(b)(1)(ii) applies to all triangular reorganizations and reorganizations described in section 368(a)(1)(G) and (a)(2)(D) occurring on or after January 23, 2006, although taxpayers may apply § 1.367(b)–4(b)(1)(ii) to triangular B reorganizations occurring on or after February 23, 2000, that is not closed by the period of limitations if done consistently with respect to all such triangular B reorganizations.* * *

* * * * *

Guy R. Traynor,

Chief, Publications and Regulations Branch,
Legal Processing Division, Associate Chief
Counsel (Procedures and Administration).

[FR Doc. 06–4533 Filed 5–15–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 206

National Security Education Program (NSEP) Grants to Institutions of Higher Education

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: This document republishes 32 CFR part 206, “National Security Education Program” which was removed from the CFR in error. No changes have been made.

DATES: This rule is effective May 16, 2006.

FOR FURTHER INFORMATION CONTACT: L. Bynum 703–696–4970.

SUPPLEMENTARY INFORMATION: The removal was published in the **Federal Register** on Tuesday, May 9, 2006 (71 FR 26831).

List of Subjects in 32 CFR Part 206

Colleges and universities, Grant programs—education.

■ Accordingly, 32 CFR part 206 is added to read as follows:

PART 206—NATIONAL SECURITY EDUCATION PROGRAM (NSEP) GRANTS TO INSTITUTIONS OF HIGHER EDUCATION

Sec.

206.1 Major characteristics of the NSEP institutional grants program.

206.2 Eligibility.

206.3 Overall program emphasis.

206.4 Proposal development and review.

206.5 Final proposal process.

Authority: 20 U.S.C. 1141(a).

§ 206.1 Major characteristics of the NSEP institutional grants program.

(a) The Institutional Grants Program provides support in the form of grants to U.S. institutions of higher education. During the 1994–95 and 1995–96 academic years, a program of pilot grants is being initiated with an annual competition for grants held during the spring of each year. Grants to institutions will complement NSEP scholarship and fellowship programs. NSEP encourages the development of programs and curricula which:

(1) Improves the quality and infrastructure of international education;

(2) Addresses issues of national capacity; and

(3) Defines innovative approaches to issues not addressed by NSEP scholarship and fellowship programs.

(b) The NSEP Grants Program is designed to address a number of important objectives critical to the United States:

(1) To equip Americans with an understanding of less commonly taught languages and cultures and enable them to become integrally involved in global issues.

(2) To build a critical base of future leaders in the marketplace and in government service who have cultivated international relationships and worked and studied along-side foreign experts.

(3) To develop a cadre of professionals with more than the traditional knowledge of language and culture who can use this ability to help the U.S. make sound decisions and deal effectively with global issues; and

(4) To enhance institutional capacity and increase the number of faculty who can educate U.S. citizens toward achieving these goals.

(c) Grants will be awarded for initial 1- or 2-year periods. Potential follow-on commitments will be based on a rigorous evaluation and assessment process. Between 15 and 25 awards are expected to be made in the first year ranging from approximately \$25,000 to \$250,000. These are only estimates and do not bind the NSEP to a specific number of grants or to the amount of the grant.

(d) The following key characteristics will be emphasized in the NSEP Institutional Grants Program:

(1) *Programmatic in emphasis.* The purpose of the grants is to address weaknesses and gaps in programs and

curricula. The grants should be used to strengthen the national capacity in international education. While “operational” support for already existing centers and projects may be a component of a grant, NSEP emphasizes commitment of its limited resources to projects that establish and improve educational programs available to students and teachers.

(2) *Demand and requirements oriented.* Grants are designed to address national needs. These needs must be clearly articulated and defended in a grant proposal. It must be clear that the following questions are addressed:

(i) Who will benefit from the program funded by the grant?

(ii) What need does the program address?

(iii) How will this program augment the capacity of the Federal Government or of the field of education in areas consistent with the objectives of the NSEP? How does it fit the national requirement?

(3) Cooperation and collaboration among institutions is mandated in order to ensure that a wider cross-section of colleges and universities benefit from a program funded under NSEP. NSEP is committed to providing opportunities to the widest cross-section of the higher education population as is feasible. Cooperation can be in the form of formal consortia arrangements or less formal but equally effective agreements among institutions. Both vertical (among different types of institutions) and horizontal (among similar institutions across functional areas) integration are encouraged. Outreach to institutions that do not normally benefit from such programs is also strongly favored.

(4) Complementary to other Federal programs such as Title VI of the Higher Education Act. NSEP is designed to address gaps and shortfalls in Higher Education and to build and expand national capacity. NSEP recognizes that base capacity currently exists in some foreign languages and area studies. It also recognizes that funding shortfalls and other factors have contributed to tremendous gaps and weaknesses. Funding for expansion of the international education infrastructure remains limited. Duplication of effort is not affordable. NSEP encourages new initiatives as well as expansion of existing programs to increase supply in cases where the demand cannot be met and encourages efforts that increase demand.

(5) NSEP encourages proposals that address two categories of issues relating to the mission of NSEP:

(i) Programs in specific foreign languages, countries or areas; and/or