

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 530****[Docket No. 01N-0499]****Topical Nitrofurans; Extralabel Animal Drug Use; Order of Prohibition****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (we) is issuing an order prohibiting the extralabel use of topical nitrofurans in food-producing animals. We are issuing this order based on evidence that extralabel use of topical nitrofurans in food-producing animals may result in the presence of residues that we have determined to be carcinogenic and to not have been shown to be safe. We find that such extralabel use "presents a risk to the public health" for the purposes of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA).

**DATES:** This rule is effective May 7, 2002. We invite your written or electronic comments. We will consider all comments that we receive by April 8, 2002.

**ADDRESSES:** Submit your written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Gloria J. Dunnava, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1726, e-mail: [gdunnava@cvm.fda.gov](mailto:gdunnava@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:****I. AMDUCA**

AMDUCA (Public Law 103-396) was signed into law on October 22, 1994. It amended the Federal Food, Drug, and Cosmetic Act (the act) to permit licensed veterinarians to prescribe extralabel uses of approved animal and human drugs in animals. However, section 512(a)(4)(D) of the act (21 U.S.C. 360b(a)(4)(D)) gives us authority to prohibit an extralabel drug use in animals if, after affording an opportunity for public comment, we find that such use presents a risk to the public health.

We published the implementing regulations (codified at part 530 (21 CFR

part 530)) for AMDUCA in the **Federal Register** of November 7, 1996 (61 FR 57732). The sections regarding prohibition of extralabel use of drugs in food-producing animals are found at §§ 530.21 and 530.25. These sections describe the basis for issuing an order prohibiting an extralabel drug use in food-producing animals and the procedure to be followed in issuing an order of prohibition. We may issue a prohibition order if we find that extralabel use in animals presents a risk to the public health. Under § 530.3(e), this means that we have evidence that demonstrates that the use of the drug has caused or likely will cause an adverse event.

Section 530.25 provides for a public comment period of not less than 60 days. It also provides that the order of prohibition will become effective 90 days after the date of publication, unless we revoke the order, modify it, or extend the period of public comment. The list of drugs prohibited from extralabel use is found in § 530.41. The current list of drugs prohibited from extralabel use in food-producing animals includes furazolidone and nitrofurazone, but it contains the parenthetical statement "(except for approved topical use)".

**II. Nitrofurans**

In 1991, and after a full evidentiary hearing, we withdrew the approvals for furazolidone and nitrofurazone labeled for antiprotozoal use in a wide variety of conditions in poultry and swine. (See the **Federal Register** of August 23, 1991 (56 FR 41902).) These withdrawals were based on our determination that use of the drugs resulted in residues in edible tissues for human food and that residues of these drugs were not shown to be safe, in part because both drugs are carcinogenic. We did not, however, withdraw the approvals of these products for use in nonfood animals or for topical use in food-producing animals. Moreover, while our current regulations in § 530.41 prohibit extralabel use of approved furazolidone and nitrofurazone products in food-producing animals, this prohibition does not extend to topical use in food-producing animals. These topical uses in food-producing animals were allowed because there was no evidence that such use of furazolidone and nitrofurazone resulted in residues in edible tissues.

However, a recent carbon-14 (C-14) radio-label residue depletion study that we conducted showed that detectable levels of nitrofurans derivatives are present in edible tissues (milk, meat, kidney, liver) of cattle treated by the ocular (eye) route (Ref. 1). This study,

coupled with our findings in our prior withdrawal action, means that residues, which are carcinogenic and have not been shown to be safe, will likely be present at slaughter as a result of topical uses of nitrofurans, including furazolidone and nitrofurazone, in food-producing animals.

We advised all manufacturers of nitrofurans drugs that were approved for ocular use in food-producing animals of the evidence and the manufacturers revised their labels to remove those indications. (See, for example, 65 FR 41587 (July 6, 2000).) Some lot numbers of these drugs may remain in commercial distribution channels with the former labels that contain indications for food-producing animals. These products, however, are not approved for use in food-producing animals and, therefore, are adulterated and misbranded. Some topical and ophthalmic nitrofurans products are still approved for certain uses in nonfood animals. Under the current regulations governing extralabel use, these remaining approved topical and ophthalmic products are not prohibited from extralabel topical use in food-producing animals. However, as stated previously, there is evidence that these uses will result in residues in edible tissues. Because of the likelihood of this adverse event, by this order of prohibition, we are prohibiting all extralabel uses, including extralabel topical use, in food-producing animals of nitrofurans products that are approved for use in nonfood animals or humans. Therefore, no nitrofurans product may be legally used in food-producing animals.

**III. Request for Comments**

We are providing 60 days from the date of this publication for you to comment. The order will become effective May 7, 2002, unless we revoke or modify the order or extend the comment period. You may submit written or electronic comments to the Dockets Management Branch (address above) by April 8, 2002. Please identify your comments with the docket number found in brackets in the heading of this document. You may read any comments that we receive at our Dockets Management Branch reading room (address above). The reading room is open from 9 a.m. to 4 p.m., Monday through Friday, except for Federal holidays.

**IV. Order of Prohibition**

Therefore, I hereby issue the following order under section 512(a)(4)(D) of the act and 21 CFR 530.21 and 530.25. We find that extralabel use of nitrofurans in food-

producing animals likely will cause an adverse event, which constitutes a finding under section 512(a)(4)(D) of the act that extralabel use of these drugs in food-producing animals presents a risk to the public health. Therefore, we are prohibiting all extralabel uses of these drugs in food-producing animals.

## V. Reference

The following information has been placed on display in the Dockets Management Branch (address above). You may view it between 9 a.m. and 4 p.m., Monday through Friday.

1. Smith, D. J., G. D. Paulson, and G. L. Larsen, "Distribution of Radiocarbon After Intermammary, Intrauterine or Ocular Treatment of Lactating Cows With Carbon-14 Nitrofurazone," *Journal of Dairy Science*, vol. 81, pp. 979-988, 1998.

## List of Subjects in 21 CFR Part 530

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

Accordingly, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Veterinary Medicine, 21 CFR part 530 is amended as follows:

## PART 530—EXTRALABEL DRUG USE IN ANIMALS

1. The authority citation for 21 CFR part 530 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e.

### § 530.41 [Amended]

2. Section 530.41 *Drugs prohibited for extralabel use in animals* is amended in paragraphs (a)(7) and (a)(8) by removing the parenthetical phrase "(except for approved topical use)".

Dated: November 9, 2001.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 40

[TD 8983]

**RIN 1545-BA42**

#### Time for Eligible Air Carriers To File The Third Calendar Quarter 2001 Form 720

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

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations relating to the time for eligible air carriers reporting air transportation excise taxes to file Form 720, "Quarterly Federal Excise Tax Return," for the third calendar quarter of 2001. These regulations affect certain air carriers.

**DATES:** *Effective Date:* These regulations are effective February 6, 2002.

*Applicability Date:* For date of applicability of these regulations, see § 40.6071(a)-3(c).

**FOR FURTHER INFORMATION CONTACT:** Susan Athy (202) 622-3130 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

Subchapter C of chapter 33 of the Internal Revenue Code (Code) imposes tax on the amount paid for: taxable transportation by air of any person (section 4261(a)); each domestic segment of taxable transportation (section 4261(b)); use of international air travel facilities (section 4261(c)); and taxable transportation of property by air (section 4271(a)) (air transportation excise taxes). Section 6071 generally provides that return filing dates are prescribed by regulation. Under § 40.6071(a)-2, a return of air transportation taxes was due by the last day of the second month following the quarter for which it was made. On August 8, 2001, the regulations were amended to remove this provision but the provision remained in effect for the third calendar quarter of 2001. Thus, the return of air transportation taxes for that quarter was due on November 30, 2001.

Under section 6151, generally, tax must be paid at the time the return is required to be filed. In general, under section 6601, interest must be paid on any amount of tax not paid by the last day for payment. Accordingly, if the return due date prescribed in § 40.6071(a)-2 remains in effect for the third calendar quarter of 2001, interest would be imposed on third-quarter air

transportation excise taxes not paid by November 30, 2001.

Section 301(a) of the Air Transportation Safety and System Stabilization Act (the Act), Public Law 107-42 (115 Stat. 236) provides relief to eligible air carriers with respect to the semimonthly deposits required for air transportation excise taxes. The relief contained in the Act applies to deposits only and does not extend the return filing and associated payment date. By extending the filing date for eligible air carriers, these final regulations will provide return filing, payment, and interest relief consistent with the deposit relief provided for air transportation excise taxes by section 301(a) of the Act. Notice 2001-77 (2001-50 I.R.B. 576) provided that regulations would change the third calendar quarter 2001 filing date.

#### Explanation of Provisions

These final regulations change the date by which eligible air carriers reporting tax that includes the air transportation excise taxes imposed by subchapter C of chapter 33 must file excise tax returns for the third quarter of 2001. The due date for these returns is postponed from November 30, 2001, to January 15, 2002. For these taxpayers, payment of their third-quarter excise tax liability may also be delayed until January 15, 2002.

#### Special Analyses

This Treasury decision is necessary to provide immediate relief to the eligible air carriers affected by the events of September 11, 2001. This Treasury decision provides additional time for eligible air carriers to file the third calendar quarter 2001 Form 720 and to pay certain taxes due with the return. Therefore, it has been determined that notice and public comment are unnecessary and contrary to the public interest and a delayed effective date under section 553(d) of the Administrative Procedure Act (5 U.S.C. chapter 5) is not required. Also, it has been determined that section 553(b) of the Administrative Procedure Act does not apply to these regulations and, because these regulations do not impose on small entities a collection of information requirement, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. It also 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. Pursuant to section 7805(f) of the Code, these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for