

Revision level page number	Shown on page	Date shown on page
1, 3	1	June 18, 1996.
2, 4, 5	Original	May 23, 1996.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from AI(R) American Support, Inc., 13850 McLearn Road, Herndon, Virginia 20171. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 5: The subject of this AD is addressed in British airworthiness directive 002-05-96.

(f) This amendment becomes effective on April 23, 1998.

Issued in Renton, Washington, on March 10, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 98-6759 Filed 3-18-98; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs In Food; Carbadox

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for a revised tolerance for residues of carbadox used in Type A medicated articles to make Type C medicated swine feeds.

EFFECTIVE DATE: March 19, 1998.

FOR FURTHER INFORMATION CONTACT:

Lynn G. Friedlander, Center for Veterinary Medicine (HFV-151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-0675.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, is sponsor of NADA 41-061 that provides for the use of Mecadox® 10 (carbadox) Type A medicated articles used to make Type C medicated swine feeds used for control of swine dysentery, control of bacterial swine

enteritis, increased rate of weight gain, and improved feed efficiency. The sponsor filed a supplemental NADA that provides for a revised finite tolerance for residues of carbadox and its metabolites in edible swine tissues. The supplement is approved as of January 30, 1998, and the regulations are revised in § 556.100 (21 CFR 556.100) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

A tolerance for no residues of carbadox or its metabolites and the method to determine said residues in the edible swine tissues had been previously established. Because better and more accurate regulatory procedures are found in general use, the analytical procedure is no longer codified. At this time, the method of analysis is removed and a finite tolerance for residues of quinoxaline-2-carboxylic acid (marker residue) in liver (target tissue) is established by amending § 556.100.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), approval of this supplement qualifies for 3 years of marketing exclusivity beginning January 30, 1998, because the supplement contains substantial evidence of effectiveness of the drug involved, studies of animal safety or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. Exclusivity applies only to the new tolerance as established by human food safety studies (total residue depletion and metabolism) which are summarized in the freedom of information summary.

The agency has determined under 21 CFR 25.33(a)(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.

List of Subjects in 21 CFR Part 556

Animal drugs, Foods.
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 556 is amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.100 is revised to read as follows:

§ 556.100 Carbadox.

A tolerance of 30 parts per billion is established for residues of quinoxaline-2-carboxylic acid (marker residue) in liver (target tissue) of swine.

Dated: February 26, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-7057 Filed 3-18-98; 8:45 am]

BILLING CODE 4160-01-F

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Exchange Visitor Program, Insurance Coverage

AGENCY: United States Information Agency.

ACTION: Notice to sponsors of exchange visitor programs.

SUMMARY: In March 1993, the United States Information Agency ("Agency") published a comprehensive set of final rules governing the exchange visitor program established under the authority of the Mutual Educational and Cultural Exchange Act of 1961 (22 CFR Part 514). Section 514.14 establishes requirements regarding health insurance coverage on exchange visitors who come to the United States on the J visa. Those requirements merely establish criteria for insurance coverage on exchange