

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (the Act) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure of \$100 million or more (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action."

This proposed rule does not contain such a mandate. The requirements of Title II do not apply.

Federalism Implications

The regulations herein will not have substantial direct effects on the State, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, the FAA certifies that this regulation will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

14 CFR Part 91

Aircraft, Airmen, Aviation safety.

14 CFR Part 121

Air carriers, Aircraft, Airmen, Aviation safety, Charter flights, Safety, Transportation.

14 CFR Part 135

Air taxi, Aircraft, Airmen, Aviation safety.

The Amendment

The Federal Aviation Administration proposes to amend 14 CFR parts 91, 121, and 135 as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44101, 44111, 44701, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46502, 46504, 46506–46507, 47122, 47508, 47528–47531.

PART 121—OPERATING REQUIREMENTS: DOMESTIC FLAG, AND SUPPLEMENTAL OPERATIONS

2. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 40119, 41706, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44901, 44903–44904, 44912, 46105.

3. Add SFAR No. 71 to part 121.

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON-DEMAND OPERATIONS

4. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722.

5. In parts 91, 121, and 135, SFAR NO. 71—Special Operating Rules For Air Tour Operators In The State of Hawaii, Section 8 is revised to read as follows:

SFAR NO. 71—Special Operating Rules for Air Tour Operators in the State of Hawaii

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Section 8. *Termination date.* This SFAR NO. 71 shall remain in effect until further notice.

Issued in Washington, DC on August 4, 2003.

John M. Allen,

Acting Director, Flight Standards Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

[Docket No. 2003N–0324]

New Animal Drugs; Removal of Obsolete and Redundant Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing removal of regulations that exempted certain new animal drugs administered in feed from batch certification requirements. FDA is also proposing removal of regulations that required sponsors to submit data regarding the subtherapeutic use of certain antibiotic, nitrofurans, and sulfonamide drugs administered in animal feed. The intended effect of this proposed rule is to remove regulations that are obsolete or redundant. Some of the products and combination uses subject to the listings in these regulations are subject to a notice of findings of effectiveness and

an opportunity for hearing published elsewhere in this issue of the **Federal Register**. One approved product subject to the regulations proposed for removal is being codified elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on the proposed rule by November 6, 2003.

ADDRESSES: Submit written comments to the Division of Dockets Management (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:

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SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, the agency is announcing the effective conditions of use for some of the products or use combinations subject to the listings in parts 510 and 558 (21 CFR part 510 and 558), specifically, §§ 510.515 and/or 558.15, and the agency is proposing to withdraw the new animal drug applications (NADAs) for those products or use combinations lacking substantial evidence of effectiveness following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. One approved product subject to § 558.15 is being codified in part 558, subpart B in a final rule published elsewhere in this issue of the **Federal Register**. Concurrent with that announcement and final rule, the agency is proposing to remove these two sections of the Code of Federal Regulations (§§ 510.515 and 558.15) for the reasons described in sections II and III of this document.

II. Part 510, Subpart F Animal Use Exemptions From Certification and Labeling Requirements and § 510.515 Animal Feeds Bearing or Containing New Animal Drugs Subject to the Provisions of Section 512(n) of the Act

A. History of Part 510, Subpart F and § 510.515

In 1945, Congress added section 507 to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357) requiring the agency to provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin (Public Law 79–139, 59 Stat. 463). No distinction was made