

\$5,178 per airplane. Based on these figures, the cost impact of this required replacement on U.S. operators is estimated to be \$531,576, or \$5,778 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

### Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, 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, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

### PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

99-23-21 **Boeing:** Amendment 39-11417.  
Docket 99-NM-101-AD.

**Applicability:** Model 757 series airplanes, as listed in Boeing Service Bulletin 757-76-0009, Revision 1, dated December 3, 1998, or Boeing Service Bulletin 757-78-0012, dated August 31, 1989; certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

**Compliance:** Required as indicated, unless accomplished previously.

To prevent operation with an energized sync lock or malfunctioning sleeve locking devices, which could result in deployment of a thrust reverser in flight and subsequent reduced controllability of the airplane, accomplish the following:

(a) For airplanes listed in Boeing Service Bulletin 757-76-0009, Revision 1, dated December 3, 1998: Within 2 years after the effective date of the AD, replace the reverse thrust switches and actuators with improved switches and actuators, and modify the reverse lever links and thrust control levers in accordance with the service bulletin.

**Note 2:** Modifications accomplished prior to the effective date of this AD in accordance with Boeing Service Bulletin 757-76-0009, dated November 8, 1990, are considered acceptable for compliance with the applicable action specified in this amendment.

(b) For airplanes listed in Boeing Service Bulletin 757-78-0012, dated August 31, 1989: Within 2 years after the effective date of the AD, replace the spring bumper assemblies of the thrust reverser sleeve with improved assemblies in accordance with the service bulletin.

### Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

### Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

### Incorporation by Reference

(e) The actions shall be done in accordance with Boeing Service Bulletin 757-76-0009, Revision 1, dated December 3, 1998, or Boeing Service Bulletin 757-78-0012, dated August 31, 1989, as applicable. 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 Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. 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.

(f) This amendment becomes effective on December 21, 1999.

Issued in Renton, Washington, on November 4, 1999.

**D.L. Riggin,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 99-29471 Filed 11-15-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 310

[Docket No. 99N-0188]

### Progestational Drug Products for Human Use; Requirements for Labeling Directed to the Patient

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is revoking its regulation requiring patient labeling for progestational drug products. Patient labeling had been required to inform patients of an increased risk of birth defects reported to be associated with the use of these drugs during the first 4 months of pregnancy. FDA concluded that, based on a review of the scientific data, such labeling for all progestogens is not warranted. In addition, the diversity of drugs that can be described as progestational and the diversity of conditions these drugs may be used to treat make it inappropriate to consider these drugs a single class for labeling purposes. This action is intended to provide consumers with more

appropriate labeling for certain drug products.

**EFFECTIVE DATE:** November 16, 2000.

**FOR FURTHER INFORMATION CONTACT:** Diane V. Moore, Center for Drug Evaluation and Research (HFD-580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4260.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the 1970's, there were several reports suggesting "an association between intrauterine exposure to sex hormone treatment and congenital anomalies, including congenital heart defects and limb reduction defects" (42 FR 37646, July 22, 1977). Based on these reports, FDA published a proposed rule to require patient labeling for progestational drug products (42 FR 37643, July 22, 1977). The category "progestational drug products" included natural progesterone and all synthetic progestins. The regulation was finalized on October 13, 1978 (43 FR 47178), and was codified at § 310.516 (21 CFR 310.516). It required that progestational drug products be dispensed with a patient package insert containing a "brief discussion of the nature of the risks of birth defects resulting from the use of these drugs during the first 4 months of pregnancy" (§ 310.516(b)(4)). The regulation applied to any drug product that contains a progestogen, with the exceptions of contraceptives and oral dosage forms labeled solely for the treatment of advanced cancer<sup>1</sup> (310.516(e)(4)).

**II. The Final Rule**

In the **Federal Register** of April 13, 1999 (64 FR 17985), FDA published a proposed rule to revoke its regulation requiring patient labeling for progestational drug products. FDA concluded that, based on a review of the scientific data, such labeling for all progestogens is not warranted. In addition, the diversity of drugs that can be described as progestational and the diversity of conditions these drugs may be used to treat make it inappropriate to consider these drugs a single class for labeling purposes. For more detailed descriptions of the scientific basis for revoking the rule and the history of the rule's adoption, see the proposed rule (64 FR 17985).

FDA received only three comments on the proposed rule, two from university

professors and one from a trade association of pharmacists. Two comments commended FDA's action. The third comment stated that each individual progestational drug product should carry warnings appropriate to that particular product and that a teratogenic warning might be appropriate for a particular progestin. FDA agrees and will require labeling that is appropriate to the dose and indication of each progestational drug product. Thus, FDA is adopting the rule as proposed.

**III. Guidance Texts**

In 1977, when FDA proposed the rule concerning progestational drug products, it published guidance texts for physician and patient labeling warning of possible heart and limb defects (42 FR 37647 and 37648, July 22, 1977). FDA revised these guidance texts in the **Federal Register** of January 12, 1989 (54 FR 1243). The revised texts deleted the warning about possible congenital heart defects and limb reduction defects and added a warning about an increased risk of certain genital abnormalities. Concurrently with the 1999 proposed rule to revoke § 310.516, FDA published a notice announcing that it intended to revoke the guidance texts for physician and patient labeling (64 FR 18035, April 13, 1999). FDA received no comments concerning the revocation of the guidance texts. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice revoking those guidance texts.

**IV. Analysis of Impacts**

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have a significant impact on small entities, the agency must analyze regulatory options that would minimize the impact of the rule on small entities. The Unfunded Mandates Reform Act (in section 202) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the

private sector, of \$100 million or more (adjusted annually for inflation).

The agency has reviewed this final rule and has determined that it is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and these two statutes. With respect to the Regulatory Flexibility Act, the agency certifies that the rule will not have a significant effect on a substantial number of small entities. Because the final rule does not impose any mandates on State, local, or tribal governments or the private sector that will result in a 1-year expenditure of \$100 million or more, FDA is not required to perform a cost-benefit analysis under the Unfunded Mandates Reform Act. FDA received no comments on the proposed Analysis of Impacts.

The final rule removes the requirement that sponsors include certain information in the professional labeling of affected drug products. The revised labeling may be filed in the next annual report. The agency has identified 13 sponsors and 16 distinct professional labeling inserts that will need to be changed to comply with this rule. Any professional skills necessary for implementation of this rule should already exist within the sponsor's firm and should not need to be newly acquired. Using a pharmaceutical labeling cost model developed for the agency by its contractor, Eastern Research Group, Inc., the average cost for this labeling change is \$1,317 per insert, assuming a compliance period of 1 year. Applying this cost to the 16 professional labeling inserts results in a one-time cost of compliance of \$21,000. There will also be an additional minor cost of lost inventory. Of the 13 sponsors affected, fewer than 5 would meet the Small Business Administration's definition of a small entity. No additional burdens are imposed upon manufacturers. Therefore, in accordance with the Regulatory Flexibility Act, FDA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

**V. Paperwork Reduction Act of 1995**

FDA concludes that this final rule contains no collections of information. The final rule removes the requirement that certain information be included in the labeling of affected drug products. The revised labeling may be filed in the next annual report, which is already required under FDA regulations and is already approved by the Office of Management and Budget (OMB) as a collection of information (OMB control no. 0910-0001). Therefore, clearance by

<sup>1</sup> The original regulation exempted contraceptives, which were required to comply with the labeling requirements of 21 CFR 310.501. In 1981, the regulation was amended to exempt advanced cancer drugs (46 FR 53656, October 30, 1981).

OMB under the Paperwork Reduction Act of 1995 is not required.

## VI. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a class of actions 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.

## VII. Effective Date

This final rule becomes effective 1 year after its date of publication in the **Federal Register**.

### List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

### PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

#### § 310.516 [Removed]

2. Section 310.516 *Progestational drug products; labeling directed to the patient* is removed.

Dated: November 4, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99–29854 Filed 11–15–99; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF THE TREASURY

### 31 CFR Part 18

#### Agency Organization: Vacancy, Disability, and Absence

**AGENCY:** Office of the Secretary of the Treasury, Department of the Treasury.

**ACTION:** Final rule.

**SUMMARY:** This final rule establishes regulations concerning the functions and duties of certain offices within the Department of the Treasury in case of absence, disability, or vacancy. The rule is consistent with sections 3345 through 3349d of title 5, United States Code, as amended by the Federal Vacancies Reform Act of 1998. Currently codified

at 31 CFR Part 18 are temporary regulations relating to the tax treatment of the Conrail public sale. Although the temporary regulations are no longer needed and are being replaced by the regulation in this document, the temporary regulations continue to apply to transactions that occurred while they were effective.

**EFFECTIVE DATE:** November 16, 1999.

**FOR FURTHER INFORMATION CONTACT:** Randolph B. Sim, Attorney Adviser, Office of the Assistant General Counsel (General Law and Ethics), Department of the Treasury, Washington, DC 20220, (202) 622–0450 (not a toll-free call).

**SUPPLEMENTARY INFORMATION:** Section 3345 of title 5, United States Code, provides that when an officer whose appointment is required to be made by the President, by and with the advice and consent of the Senate (“PAS Office”), dies, resigns, or is otherwise unable to perform the functions and duties of the office, the first assistant to the office of such officer (“First Assistant”) may perform temporarily the functions and duties of the PAS Office. The rule authorizes the Secretary to establish for each office within the Department of the Treasury (including its bureaus) to which appointment is required to be made by the President with the advice and consent of the Senate a First Assistant within the meaning of 5 U.S.C. 3345–3349d. If there is a principal deputy to the PAS Office, that official is the First Assistant. If there is no position with the title “principal deputy,” but there is one, and only one, deputy position to the PAS Office (which deputy may have a different title, such as Deputy Director), that deputy is the First Assistant. If there is no position which qualifies as First Assistant under these tests, the Secretary may designate a First Assistant. Consistent with 5 U.S.C. 3347, the rule does not apply to certain specified offices or if a statute prescribes another means for authorizing an officer or employee to perform the functions and duties of a PAS Office temporarily in an acting capacity.

This rule shall not affect the filing of vacancies that occurred prior to the effective date of the Federal Vacancies Reform Act of 1998.

Because this rule relates to agency management and personnel, it is not subject to notice and public procedure or to a delayed effective date pursuant to 5 U.S.C. 553(a)(2). Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. This document is not a significant

regulatory action for purposes of Executive Order 12866.

### List of Subjects in 31 CFR Part 18

Government employees, Organization and functions (Government agencies).

Accordingly, part 18 of title 31 of the Code of Federal Regulations is revised to read as follows:

### PART 18—OFFICIALS DESIGNATED TO PERFORM THE FUNCTIONS AND DUTIES OF CERTAIN OFFICES IN CASE OF ABSENCE, DISABILITY, OR VACANCY

Sec.

18.1 Designation of First Assistants.

18.2 Exceptions.

**Authority:** 5 U.S.C. 301; 31 U.S.C. 321.

#### § 18.1 Designation of First Assistants.

Except as provided in § 18.2, every office within the Department of the Treasury (including its bureaus) to which appointment is required to be made by the President with the advice and consent of the Senate (“PAS Office”) may have a First Assistant within the meaning of 5 U.S.C. 3345–3349d.

(a) Where there is a position of principal deputy to the PAS Office, the principal deputy shall be the First Assistant.

(b) Where there is only one deputy position to the PAS Office, the official in that position shall be the First Assistant.

(c) Where neither paragraph (a) nor (b) of this section is applicable to the PAS Office, the Secretary of the Treasury may designate in writing the First Assistant.

#### § 18.2 Exceptions.

(a) Section 18.1 shall not apply:

(1) When a statute which meets the requirements of 5 U.S.C. 3347(a) prescribes another means for authorizing an officer or employee to perform the functions and duties of a PAS Office in the Department temporarily in an acting capacity; and

(2) To the office of a member of the Internal Revenue Service Oversight Board.

(b) The Inspector General of the Department of the Treasury shall determine any arrangements for the temporary performance of the functions and duties of the Inspector General of the Department of the Treasury when that office is vacant.

(c) The Treasury Inspector General for Tax Administration shall determine any arrangements for the temporary performance of the functions and duties of the Treasury Inspector General for