discrepancies, and corrective action, if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

The FAA estimates that 3 Model SAAB 2000 series airplanes of U.S. registry will be affected by this AD, that it will take approximately 4 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $720, or $240 per airplane.

The cost impact figure discussed above is 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:

97–24–14 Saab Aircraft AB: Amendment 39–10221. Docket 97–NM–126–AD.

Applicability: Model SAAB 2000 airplanes, having serial numbers –002 through –043 inclusive, 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 (b) 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 discrepancies of the check valve, which could result in improper functioning of the engine fire extinguishing system, accomplish the following:

(a) Within 2 months after the effective date of this AD, perform an inspection of the two-way check valve on the engine fire extinguishing system for discrepancies, in accordance with Saab Service Bulletin 2000–26–010, dated July 5, 1996. If any discrepancy is found, prior to further flight, install a new two-way check valve in accordance with the service bulletin.

(b) 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, International Branch, ANM–116, 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, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(c) Special flight permits may be issued in accordance with sections 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.

(d) The actions shall be done in accordance with Saab Service Bulletin 2000–26–010, dated July 5, 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 Saab Aircraft AB, SAAB Aircraft Product Support, S–581.88, Linköping, Sweden. 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 3: The subject of this AD is addressed in Swedish airworthiness directive SAD No. 1–099, dated July 8, 1996.

(e) This amendment becomes effective on January 2, 1998.

Issued in Renton, Washington, on November 19, 1997.

Stewart R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–31030 Filed 11–26–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 85N–0214]

Policy on 180-Day Marketing Exclusivity for Drugs Marketed Under Abbreviated New Drug Applications; Clarification

AGENCY: Food and Drug Administration, HHS.

ACTION: Clarification.

SUMMARY: The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is publishing this document to clarify the status of its practices governing 180 days of marketing exclusivity for generic drugs and the approval of abbreviated new drug applications (ANDA's) subject to patent litigation. This document is being published due to recent court decisions interpreting provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments).

FOR FURTHER INFORMATION CONTACT: Jerry Phillips, Center for Drug Evaluation and

Research (HFD–605), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5846.

SUPPLEMENTARY INFORMATION:

I. Background

The 1984 amendments included a provision, codified under section 505(j)(4)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(4)(B)(iv)), granting 180 days of marketing exclusivity to the first applicant to submit an ANDA containing a challenge to a listed patent. Regulations interpreting this provision were proposed in 1989 (54 FR 28872, July 10, 1989), and made final in 1994 (59 FR 50338, October 3, 1994). These regulations are codified under § 314.107(c) (21 CFR 314.107(c)).

The regulations state that for a generic drug to qualify for 180 days of marketing exclusivity, the first ANDA applicant submitting a certification under section 505(j)(2)(A)(vii)(IV) of the act (paragraph IV certification) to the listed patent must, in addition to submitting the certification, be sued for patent infringement and successfully defend that suit (§ 314.107(c)). This interpretation has been the subject of legal action in *Inwood Laboratories, Inc.* v. *Young*, 723 F. Supp. 1523 (D.D.C. 1989), *vacated as moot*, 43 Fed.3d 712 (D.C.Cir. 1989); *Mova Pharmaceutical Corp.* v. *Shalala*, 955 F. Supp. 128 (D.D.C. 1997), and *Granutec, Inc. et al.* v. *Shalala et al.*, No. 5:97–CV–485–BO(1)(E.D.N.C. July 3, 1997). Both the *Inwood* and *Mova* courts held that 180 days of marketing exclusivity should be granted to the first ANDA applicant who files a paragraph IV certification, regardless of whether the applicant is subsequently sued for patent infringement. The *Mova* decision has been appealed to the U.S. Court of Appeals for the District of Columbia Circuit.

Following the *Mova* decision, in June 1997, the Office of Generic Drugs notified applicants with ANDA's for ranitidine hydrochloride (HCl) that the agency would acquiesce to the court's holding in *Mova*, pending an appellate decision. The agency determined that temporarily acquiescing to the court's holding in *Mova* would promote administrative uniformity in the application of section 505(j)(4)(B)(iv) of the act and would prevent forum shopping among disappointed ANDA applicants. Subsequently, the U.S. District Court for the Eastern District of North Carolina addressed the validity of § 314.107(c) in *Granutec* v. *Shalala*, and, in a holding contrary to the earlier *Mova* decision, ordered FDA to follow its regulations in approving ANDA's for ranitidine HCl. The *Granutec* decision was stayed and is on expedited appeal to the U.S. Court of Appeals for the 4th Circuit.

Because the uncertain state of the law makes it difficult for the industry to make business plans and other arrangements, CDER wishes to clarify its policy with respect to these exclusivity issues, pending their final resolution by the courts.

II. 180-Day Marketing Exclusivity

It is the agency's position that, given the uncertainty created by the conflict among the courts, the most reasonable policy is to apply the 180-day exclusivity provisions of the statute as set forth in § 314.107(c) to all ANDA's to which the regulation would, on its face, apply, whether they were submitted before or after the *Mova* decision. The only ANDA's to which the agency applied the *Mova* analysis, other than those ANDA's directly involved in the *Mova* litigation, were those for ranitidine HCl.

The regulations in § 314.107(c) were issued through notice and comment rulemaking with the active participation of the pharmaceutical industry and consumer groups. They are the product of careful consideration by the agency of the complex factors at issue in granting a period of exclusivity to generic drug applicants and in ensuring that the statute is implemented in a manner most consistent with its original purpose. These regulations will be applied until such time as the appellate courts complete their analyses of the agency's interpretation.

III. Approval of ANDA's After Judgment in the District Courts

The agency does not intend to acquiesce to the court's decision in *Torpharm* v. *Shalala*, Civil Action No. 97–1925 (JR) (D.D.C. Sept. 15, 1997), in which the court, finding that the term ''the court'' in section 505(j)(4)(B)(iii) of the act means district court, ordered FDA to approve an ANDA after the applicant had prevailed in patent infringement litigation in the district court, but before either the appeal was resolved or the 30-month stay had lapsed. The U.S. Court of Appeals for the District of Columbia has granted the appeal of *Torpharm* an expedited review. While *Torpharm* is pending on appeal, FDA will continue to interpret the statute as described in § 314.107(e), which defines ''the court'' as ''the court that enters final judgment from which no appeal can be or has been taken.''

Dated: November 7, 1997.

Roger Williams,

Deputy Center Director for Pharmaceutical Science.

[FR Doc. 97–31150 Filed 11–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 47 new animal drug applications (NADA's) from Rhone Merieux, Inc., and 54 NADA's from Merck Research Laboratories, Division of Merck & Co., Inc., to Merial Ltd.

EFFECTIVE DATE: November 28, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Rhone Merieux, Inc., 7101 College Blvd., Overland Park, KS 66210, and Merck Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065 has informed FDA that it has transferred ownership of, and all rights and interests in, the approved NADA's to Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077.

Accordingly, the agency is amending the regulations in 21 CFR parts 510, 520, 522, 524, and 558 to reflect the change of sponsor. The agency is also amending § 510.600(c)(1) and (c)(2) to remove the sponsor name for Rhone Merieux, Inc., and Merck Research Laboratories, Division of Merck & Co., Inc., because the firm no longer is the holder of any approved NADA's. The drug labeler code assigned to Rhone Merieux, Inc., is being retained as the drug labeler code for Merial Ltd.

List of Subjects

21 CFR Part 510

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

21 CFR Parts 520, 522, 524, and 558

Animal drugs.