replacement, and that the average labor rate is $65 per work hour. Required parts will be provided by the manufacturer at no charge. Based on these figures, the cost impact of this AD on U.S. operators is estimated to be $27,560, or $520 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. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect 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, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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:

2004–06–01 Fairchild Dornier Gmbh (Formerly Dornier Luftfahrt GmbH): Amendment 39–13527. Docket 2001–NM–400–AD.

Applicability: Model 328–100 series airplanes, certificated in any category, serial numbers (S/Ns) 3005 through 3119 inclusive, equipped with a main landing gear (MLG) leg assembly, main body, or main machined body having a part number (P/N) and S/N listed in Table 1 of this AD.

TABLE 1.—MLG LEG ASSEMBLY, MAIN BODY, AND MAIN MACHINED BODY P/NS AND S/NS

MLG part name	P/N	S/Ns
Leg assembly	22730–000–02	U16 through U22 inclusive.
Leg assembly	22731–000–02	U16 through U22 inclusive.
Main body	22415–000–01	U16 through U22 inclusive.
Main body	22416–000–01	U16 through U22 inclusive.
Main machined body	24284–000–00	U56, U62, U64, U66, U68, U70, U74.
Main machined body	22286–000–00	U51, U57, U59, U65, U67, U73, U85.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue damage of the MLG leg, which could result in collapse of the MLG, accomplish the following:

Replacement of MLG Leg Assembly

(a) Prior to the accumulation of 16,000 total landings on the MLG body, or within 300 flight hours after the effective date of this AD, whichever occurs later, replace the existing MLG leg assembly with a modified leg assembly per Dornier Service Bulletin SB 328–32–344, Revision 1, dated June 11, 2001.

Note 1: Dornier Service Bulletin SB 328–32–344, Revision 1, refers to Messier-Dowty Service Bulletins 800–32–028, dated November 27, 2000; and 800–32–014, dated January 18, 1999; as appropriate sources of service information for modifying the MLG leg assembly.

Alternative Methods of Compliance

(b) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(c) The actions shall be done in accordance with Dornier Service Bulletin SB 328–32–344, Revision 1, dated June 11, 2001. 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 AvCraft Aerospace GmbH, P.O. Box 1103, D–82230 Wessling, Germany. 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 2: The subject of this AD is addressed in German airworthiness directive 2002–001, dated January 10, 2002.

Effective Date

(d) This amendment becomes effective on April 28, 2004.

Issued in Renton, Washington, on March 5, 2004.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–5941 Filed 3–23–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter 1

Change of Name; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect a change in the name of the Dockets Management

Branch to the Division of Dockets Management. This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

DATES: Effective March 30, 2004.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: This document amends FDA's regulations to reflect the Dockets Management Branch address change by removing the entire outdated name wherever it appears and by adding the new name in its place in 21 CFR parts 3, 5, 7, 10, 12, 13, 14, 15, 17, 20, 25, 60, 100, 101, 109, 170, 184, 201, 312, 314, 316, 328, 330, 341, 355, 369, 500, 509, 520, 522, 558, 570, 601, 740, 808, 812, 814, 860, 861, 895, 900, 1010, 1030, 1240, and 1250.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

Chapter I—[Amended]

■ 1. Parts 3, 5, 7, 10, 12, 13, 14, 15, 17, 25, 60, 100, 101, 109, 170, 184, 201, 312, 314, 316, 328, 330, 341, 355, 369, 500, 509, 520, 522, 558, 570, 601, 740, 808, 812, 814, 860, 861, 895, 900, 1010, 1030, 1240, and 1250 are amended by removing ''Dockets Management Branch'' wherever it appears and by adding in its place ''Division of Dockets Management''.

■ 2. Parts 20, 170, 570, and 860 are amended by removing ''Dockets Management Branch's'' wherever it appears and by adding in its place ''Division of Dockets Management's''.

Dated: March 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–6482 Filed 3–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 90N–0309]

Drug Labeling; Sodium Labeling for Over-the-Counter Drugs; Technical Amendment; Termination of Delay of Effective Date; Compliance Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment; termination of delay of effective date; compliance dates.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that established conditions under which the labeling of over-the-counter (OTC) drug products intended for oral ingestion must include the sodium content and a general warning that persons who are on a sodium restricted diet should not take the product unless directed by a doctor. This final rule makes a few minor labeling changes and broadens the conditions for using the descriptive term ''sodium free.'' This document also terminates the delay of the effective date of the provisions concerning sodium labeling (§ 201.64(a) through (h)) and establishes compliance dates for the final rule.

DATES: The effective date for § 201.64(a) through (h), added at 61 FR 17806, April 22, 1996, and delayed at 62 FR 19923, April 24, 1997, as amended by this final rule is April 23, 2004. The amendments in this final rule are effective April 23, 2004.

Compliance Dates: The compliance date for any single entity and combination products subject to drug marketing applications approved on or after April 23, 2004, is immediately upon approval of the application. The compliance date for all other OTC drug products, whether subject to drug marketing applications approved before April 23, 2004, subject to any OTC drug monograph, or not yet the subject of any OTC drug monograph, is September 24, 2005.

FOR FURTHER INFORMATION CONTACT: Robert L. Sherman, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 22, 1996 (61 FR 17798), FDA issued a final rule amending the general labeling provisions for OTC drug products (§ 201.64) to: (1) Require that the sodium content of all OTC drug products intended for oral ingestion be included in labeling when the product contains 5 milligrams (mg) or more sodium per a single dose; (2) require that all OTC drug products intended for oral ingestion containing more than 140 mg sodium in the labeled maximum daily dose bear a general warning that persons who are on a sodium-restricted diet should not take the product unless directed by a doctor; and (3) provide for the voluntary use of certain terms (''sodium free,'' ''very low sodium,'' and ''low sodium'') relating to an OTC drug product's sodium content per labeled maximum daily dose. The effective date of the final rule was April 22, 1997. In the final rule, FDA also sought comments whether the rule should be amended to include sodium content labeling for OTC rectal laxative, vaginal, dentifrice, mouthwash, and mouth rinse drug products.

Interested persons were invited to submit comments by July 22, 1996. In response to two requests for extension of time to file comments to the final rule, FDA published a document in the **Federal Register** of July 22, 1996 (61 FR 38046), extending the comment period until September 20, 1996.

In response to the final rule, FDA received comments from four manufacturers and two trade associations. Two of the comments requested that the effective date of the final rule be extended for at least an additional 6 months, to October 1997 or later. One comment mentioned the need for ongoing technical work, noting that manufacturers have undertaken formal product testing to ascertain precise sodium content before preparing new labels with accurate content declarations. The comment identified several problems with the sodium content of inactive ingredients. Specifications for some OTC drug ingredients do not include limits for sodium; suppliers often do not provide entire formulation information to companies; and sodium content may vary from lot to lot and/or supplier to supplier, especially for ingredients of natural origin. The comment stated that it would be difficult for some companies to complete product testing in time to have new labeling prepared by April 1997. The other comment stated that additional time would reduce label obsolescence, allow the use of already printed labeling, and allow labeling to be changed using current staff levels.

Both comments emphasized that FDA should delay implementation of the