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 proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, 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 copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Safety.

**The Proposed Amendment**

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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:

**McDonnell Douglas:** Docket 2003–NM–32–AD.

*Applicability:* Model DC–9–31 airplanes having manufacturer's fuselage numbers 1039 and 1046, and Model DC–9–32 airplanes having manufacturer's fuselage numbers 0268 and 0505; certificated in any category.

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

To prevent internal arcing of the left and right generator power relays, auxiliary power relays, and external power relays, and consequent smoke and/or fire in the cockpit and cabin, accomplish the following:

**Inspection**

(a) Within 24 months after the effective date of this AD, perform a one-time inspection of the left and right generator power relays, auxiliary power relays, and external power relays, to determine if Sundstrand (Westinghouse) part number (P/N) 914F567–3 or –4 is installed, per Boeing Alert Service Bulletin DC9–24A191, Revision 02, dated January 7, 2003.

**Replacement or Modification/Reidentification of Any Generator Power Relay, Auxiliary Power Relay, or External Power Relay, P/N 914F567–3**

(b) If any generator power relay, auxiliary power relay, or external power relay, Sundstrand (Westinghouse) P/N 914F567–3, is found installed during the inspection required by paragraph (a) of this AD, within 24 months after the effective date of this AD, do either action specified in paragraph (b)(1) or (b)(2) of this AD per the Accomplishment Instructions of Boeing Alert Service Bulletin DC9–24A191, Revision 02, dated January 7, 2003.

(1) Replace the power relay having Sundstrand (Westinghouse) P/N 914F567–3 with either a serviceable power relay having Sundstrand (Westinghouse) P/N 9008D09 series or 914F567–4.

(2) Modify the power relay, Sundstrand (Westinghouse) P/N 914F567–3, to a –4 configuration.

**Maintenance or Replacement of Any Generator Power Relay, Auxiliary Power Relay, or External Power Relay, P/N 914F567–4**

(c) If any generator power relay, auxiliary power relay, or external power relay, Sundstrand (Westinghouse) P/N 914F567–4, is found installed during the inspection required by paragraph (a) of this AD, clean, inspect, repair, and test the relay, or replace the power relay with a serviceable power relay having Sundstrand (Westinghouse) P/N 9008D09 series or 914F567–4; per Boeing Alert Service Bulletin DC9–24A191, Revision 02, dated January 7, 2003; at the time specified in paragraph (c)(1) of this AD, except as provided by paragraph (c)(2) of this AD.

(1) Within 7,000 flight hours after installation of the generator power relay, auxiliary power relay, or external power relay, Sundstrand (Westinghouse) P/N 914F567–4, or within 24 months after the effective date of this AD, whichever occurs later.

(2) For airplanes on which the flight hours since installation of any generator power relay, auxiliary power relay, or external power relay, Sundstrand (Westinghouse) P/N 914F567–4, cannot be determined: Within 24 months after the effective date of this AD.

**Repetitive Maintenance of Generator Power Relay, Auxiliary Power Relay, or External Power Relay, Sundstrand (Westinghouse) P/N 914F567–4**

(d) Before or upon the accumulation of 7,000 flight hours on any generator power relay, auxiliary power relay, or external power relay, Sundstrand (Westinghouse) P/N 914F567–4 since accomplishing the action(s) required by either paragraph (b) or (c) of this AD, as applicable, clean, inspect, repair, and test; per Boeing Alert Service Bulletin DC9–24A191, Revision 02, dated January 7, 2003. Thereafter, repeat these actions at intervals not to exceed the accumulation of 7,000 flight hours on the power relay.

**Credit for AD 2002–26–13, Amendment 39–13001**

(e) Accomplishment of the actions specified in AD 2002–26–13 is acceptable for compliance with the requirements of this AD.

**Alternative Methods of Compliance**

(f) In accordance with 14 CFR 39.19, the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, is authorized to approve alternative methods of compliance (AMOCs) for this AD.

Issued in Renton, Washington, on October 23, 2003.

**Ali Bahrami,**

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

[FR Doc. 03–27213 Filed 10–28–03; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 131

**[Docket No. 2000P–0685]**

## Milk and Cream Products and Yogurt Products; Petition to Revoke Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend Standards for Yogurt and Cultured Milk; Reopening of the Comment Period

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

**ACTION:** Advance notice of proposed rulemaking; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening for 90 days the comment period for an advance notice of proposed rulemaking (ANPRM) that announced the filing of a petition asking the agency to revoke the standards of identity for lowfat yogurt and nonfat yogurt; amend the standard of identity for yogurt in numerous respects, including incorporation of provisions for lowfat and nonfat yogurt; and amend the standard of identity for cultured milk in numerous respects, including allowing for the use of the alternate term ''fermented milk.'' This action is being taken in response to a request for more time to submit comments to FDA.

**DATES:** Submit written or electronic comments on the ANPRM by January 27, 2004.

**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*. The ANPRM and the petition are available for review at the Division of Dockets Management or electronically on FDA's Web site at *http://www.fda.gov/ohrms/dockets/98fr/03–16789.pdf* (ANPRM) and *http://www.fda.gov/ohrms/dockets/98fr/00p–0685–cp00001.pdf* (petition). You also may request a copy of these documents from the Division of Dockets Management.

**FOR FURTHER INFORMATION CONTACT:** Ritu Nalubola, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of July 3, 2003 (68 FR 39873), FDA published an ANPRM announcing that a petition was filed on February 18, 2000, requesting that the agency revoke the standards of identity for lowfat yogurt and nonfat yogurt; amend the standard of identity for yogurt in numerous respects, including incorporation of provisions for lowfat and nonfat yogurt; and amend the standard of identity for cultured milk in numerous respects, including allowing for the use of the alternate term ''fermented milk.'' Interested persons were given until October 1, 2003, to comment on the ANPRM.

Following publication of the July 3, 2003, ANPRM, FDA received a request to allow interested persons additional time to comment. The requester asserted that the time period of 90 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues, including those that have emerged since the petition was filed in 2000.

FDA believes that it is sound public policy to reopen the comment period (21 CFR 10.40(b)(3)(i)), given the variety of scientific and other issues raised in the ANPRM.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the ANPRM. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments previously submitted to the Division of Dockets Management do not need to be resubmitted because all comments submitted with that docket number will be considered in any future rulemaking. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 21, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–27188 Filed 10–28–03; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 314 and 320

**[Docket No. 2003N–0341]**

### Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations on submission of bioequivalence data to require an abbreviated new drug application (ANDA) applicant to submit data from all bioequivalence studies (BE studies) that the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets bioequivalence criteria for FDA to approve the ANDA, but have not typically submitted additional BE studies conducted on the same drug product formulation, such as studies that do not show that the product meets these criteria. FDA is proposing this change because we now believe that data from additional BE studies may be important in our determination of whether the proposed formulation is bioequivalent to the reference listed drug (RLD) and are relevant to our evaluation of ANDAs in general. In addition, such data will increase our understanding of how changes in components, composition, and methods of manufacture may affect formulation performance.

**DATES:** Submit written or electronic comments by January 27, 2004. Submit written comments on the information collection requirements by November 28, 2003.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** Aida L. Sanchez, Center for Drug Evaluation and Research (HFD–650), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 505(j)(2)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(2)(A)(iv)) requires that ANDA applicants submit, among other things, information showing that the applicant's drug is bioequivalent to a drug that has previously been approved by FDA and designated as an RLD. The statutory requirement is reflected in FDA's regulations in part 314 (21 CFR part 314) at § 314.94(a)(7). Part 320 (21 CFR part 320) at § 320.24 sets forth the types of evidence acceptable to establish bioequivalence. The most common BE studies are those performed on solid oral dosage forms of drugs that are absorbed into the systemic circulation. Data from BE studies provide an estimate of the rate and extent of drug absorption for a test product compared to a reference product. These data are examined, using statistical procedures, to determine whether the test product meets bioequivalence limits.

A BE study may fail to show that a test product meets bioequivalence limits because the test product has significantly higher or lower relative bioavailability (i.e., measures of rate and extent of absorption compared to the reference product). Where the relative bioavailability of a test product is too low, the concern is that not enough of the active ingredient is reaching the site of action and therefore the product may