

(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.

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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