Several dietary supplement marketers and nonprofit organizations that had submitted comments during the health claims rulemakings filed suit in Federal district court on constitutional and statutory grounds seeking, among other things, authorization to make the following health claims for use in the labeling of dietary supplements: (1) ''Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer,'' (2) ''Consumption of fiber may reduce the risk of colorectal cancer,'' (3) ''Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease,'' and (4) ''0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.'' Their constitutional and statutory challenges were rejected in the district court; however, on appeal the district court decision was reversed, and FDA was instructed to reconsider the four health claims (*Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999)).

As a first step in complying with the court's decision, FDA intends to reevaluate the scientific evidence for the four substance-disease claims listed above. The agency is now in the process of preparing scientific summaries on each of these four topics. To ensure that all relevant scientific evidence is considered in the rulemaking process and to allow timely development of these summaries, FDA is requesting that anyone who has or is aware of relevant scientific data, research study results, or information related to these four substance-disease relationships submit the materials to Dockets Management Branch (address above). Such information, if submitted to FDA, must be considered publicly available. If used in the agency's scientific review, information submitted to FDA will become part of the public record for the evaluation of these relationships.

The agency has established four dockets to compile information relating to each of the four topic areas; docket numbers are as specified in Table 1 below. FDA advises that the **Federal Register** documents listed in the footnotes to the table have been incorporated into each of the referenced dockets (Docket Nos. 91N–0101, 91N–0098, 91N–0103, and 91N–100H). FDA is requesting data and information other than the information contained or referred to in these **Federal Register** documents. As a guideline, therefore, the agency is requesting data and information from 1992 to the present for the four topic areas.

FDA is allowing 75 days for the submission of data. Individuals and organizations submitting information or data relating to a specific topic should submit two copies of the information to the Dockets Management Branch (address above) by November 22, 1999. Separate submissions should be made for each topic area, and each submission should be identified with the appropriate docket number given below. Submissions received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

TABLE 1

Topic	Docket No.
Antioxidant vitamins and cancer [1] and [2]	91N–0101
Fiber and colorectal cancer [3] and [4]	91N–0098
Omega-3 fatty acids and coronary heart disease [5] and [6]	91N–0103
Folic acid (dietary supplement vs. food form) and neural tube defects [7] and [8]	91N–100H

[1] ''Food Labeling: Health Claims and Label Statements; Antioxidant Vitamins and Cancer,'' Department of Health and Human Services, Food and Drug Administration, proposed rule, FEDERAL REGISTER (56 FR 60624 to 60651, November 27, 1991).

[2] ''Food Labeling: Health Claims and Label Statements; Antioxidant Vitamins and Cancer,'' Department of Health and Human Services, Food and Drug Administration, final rule, FEDERAL REGISTER (58 FR 2622 to 2660, January 6, 1993).

[3] ''Food Labeling: Health Claims; Dietary Fiber and Cancer,'' Department of Health and Human Services, Food and Drug Administration, proposed rule, FEDERAL REGISTER (56 FR 60566 to 60582, November 27, 1991).

[4] ''Food Labeling: Health Claims and Label Statements; Dietary Fiber and Cancer,'' Department of Health and Human Services, Food and Drug Administration, final rule, FEDERAL REGISTER (58 FR 2537 to 2551, January 6, 1993).

[5] ''Food Labeling: Health Claims and Label Statements; Omega-3 Fatty Acids and Coronary Heart Disease,'' Department of Health and Human Services, Food and Drug Administration, proposed rule, FEDERAL REGISTER (56 FR 60663 to 60689, November 27, 1991).

[6] ''Food Labeling: Health Claims and Label Statements; Omega-3 Fatty Acids and Coronary Heart Disease,'' Department of Health and Human Services, Food and Drug Administration, final rule, FEDERAL REGISTER (58 FR 2682 to 2738, January 6, 1993).

[7] ''Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects,'' Department of Health and Human Services, Food and Drug Administration, proposed rule, FEDERAL REGISTER (58 FR 53254 to 53295, October 14, 1993).

[8] ''Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects,'' Department of Health and Human Services, Food and Drug Administration, final rule, FEDERAL REGISTER (61 FR 8752 to 8781, March 5, 1996).

Dated: September 1, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–23337 Filed 9–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0433]

Draft Guidance for Industry on Average, Population, and Individual Approaches to Establishing Bioequivalence; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Average, Population, and Individual Approaches to Establishing Bioequivalence.'' This draft guidance provides recommendations to sponsors and/or applicants intending to perform in vivo and in vitro bioequivalence (BE) studies based on comparisons of in vivo and in vitro

bioavailability (BA) measures in investigational new drug applications, new drug applications, abbreviated new drug applications, and their amendments and supplements. This draft guidance is a modification of a preliminary draft guidance entitled ''In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Approaches'' published in December 1997, and this draft guidance updates a July 1992 FDA guidance entitled ''Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design''. When finalized, this draft guidance will replace both the 1992 and 1997 guidances.

DATES: Written comments may be submitted on the draft guidance document by November 8, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of ''Average, Population, and Individual Approaches to Establishing Bioequivalence'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mei-Ling Chen, Center for Drug Evaluation and Research (HFD–870), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5919.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Average, Population, and Individual Approaches to Establishing Bioequivalence.'' The draft guidance provides recommendations to sponsors and/or applicants intending to perform in vivo and in vitro BE studies based on comparisons of in vivo and in vitro BA measurements. In an earlier guidance entitled ''Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design,'' FDA recommended that an average BE approach be used to establish BE between test and reference drug products. Because of the limitations in the average BE approach, and after extensive intramural and extramural discussions, the Center for Drug Evaluation and Research (CDER) now recommends that the average BE approach be supplemented by two new approaches, population and individual BE. This draft guidance focuses on how to use each approach once a specific criterion has been chosen.

This draft guidance is one of a set of seven core guidances being developed to provide recommendations on how to meet provisions of part 320 (21 CFR part 320) for orally administered drug products and drug products for local action. Taken together, the seven guidances are designed to clarify the studies needed to document product quality BA/BE for all drug products regulated by CDER in accordance with the provisions in part 320. A further intent is to reduce regulatory burden where feasible.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 2, 1997). It represents the agency's current thinking on average, population, and individual approaches to establishing BE. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 26, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–23228 Filed 9–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2726]

Medical Devices; Draft Guidance on Labeling for Laboratory Tests; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled '' Draft Guidance on Labeling for Laboratory Tests.'' This draft guidance is not final nor is it in effect at this time. The draft guidance is intended to identify the information that should be provided to FDA for labeling the diagnostic performance of laboratory tests. FDA intends to recognize two major categories of endpoints for assessing diagnostic performance of new ''in vitro diagnostic'' assays.

DATES: Written comments concerning this draft guidance must be received by December 7, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Draft Guidance on Labeling for Laboratory Tests'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

The labeling and evaluation of laboratory test performance should compare a new product's test results to some appropriate and relevant diagnostic benchmark that can be used to correlate results from a new test with the clinical status or condition of individuals or patients for whom the test is intended to be used. Determination of the clinical status of patients whose specimens are used in an evaluation may be based on laboratory and/or clinical endpoints. FDA recognizes two major categories of endpoints for assessing performance of new laboratory assays: (1) ''True'' diagnostic state (patient clinical status or condition) or operational ''truth,'' and (2) laboratory equivalence where the test is characterized in terms of a