above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: April 16, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–12255 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D–0028]

International Conference on Harmonisation; Guideline on Stability Testing for New Dosage Forms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guideline entitled ''Stability Testing for New Dosage Forms.'' The guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guideline addresses the generation of stability information for new dosage forms for submission to FDA by the owner of the original application. The guideline is an annex to the ICH guideline entitled ''Stability Testing of New Drug Substances and Products.''

DATES: Effective June 9, 1997. Written comments may be submitted at any time.

ADDRESSES: Submit written comments on the guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the guideline are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Guiragos K. Poochikian, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

Regarding ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of March 6, 1996 (61 FR 9060), FDA published a draft tripartite guideline entitled ''Stability Testing for New Dosage Forms.'' The notice gave interested persons an opportunity to submit comments by June 4, 1996.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies at the ICH meeting held on November 5, 1996.

In the **Federal Register** of September 22, 1994 (59 FR 48754), FDA published a guideline entitled ''Stability Testing of New Drug Substances and Products.'' The guideline addresses the generation of stability information for submission to FDA in new drug applications for new molecular entities and associated drug products. For biotechnological/biological products, see ''Quality of Biotechnological/Biological Products: Stability Testing of Biotechnological/Biological Products'' (60 FR 43501, August 21, 1995).

This guideline is an annex to that guideline and addresses the generation of stability information for new dosage forms for submission to FDA by the owner of the original application, after the original submission for new drug substances and products.

This guideline represents the agency's current thinking on stability testing for new dosage forms. 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 approach satisfies the requirements of the applicable statute, regulations, or both.

As with all of FDA's guidelines, the public is encouraged to submit written comments with new data or other new information pertinent to this guideline. The comments in the docket will be periodically reviewed and, where appropriate, the guideline will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guideline. 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. The guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guideline is available on the Internet using the World Wide Web (WWW) (http://www.fda.gov/cder/guidance.htm).

The text of the guideline follows:

Stability Testing for New Dosage Forms

1. General

This document is an annex to the ICH Harmonized Tripartite Guideline on Stability Testing of New Drug Substances and Products and addresses the recommendations on what should be submitted regarding stability of new dosage forms by the owner of the original application, after the original submission for new drug substances and products.

2. New Dosage Forms

A new dosage form is defined as a drug product which is a different pharmaceutical product type, but contains the same active substance as included in the existing drug product approved by the pertinent regulatory authority.

Such pharmaceutical product types include products of different administration route (e.g., oral to parenteral), new specific functionality/delivery systems (e.g., immediate release tablet to modified release tablet) and different dosage forms of the same administration route (e.g., capsule to tablet, solution to suspension).

Stability protocols for new dosage forms should follow the guidance in the parent stability guideline in principle. However, a reduced stability database at submission time (e.g., 6 months accelerated and 6 months long-term data from ongoing studies) may be acceptable in certain justified cases.

Dated: May 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12157 Filed 5–8–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0155]

Report on Food and Drug Administration Nutrition Labeling Information Study—December 1996, Raw Fruit/Vegetables and Raw Fish; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled ''Food and Drug Administration Nutrition Labeling Information Study—December 1996, Raw Fruit/Vegetables and Raw Fish.'' This report summarizes survey data on actions taken by food retailers to provide consumers with nutrition labeling information for raw fruit, vegetables, and fish. This report is mandated by the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

DATES: Comments may be submitted at any time.

ADDRESSES: Submit written comments and requests for single copies of the report to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments and requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. Copies of the document will be available at cost from the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857. The report and received comments are available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nancy T. Crane, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5615.

SUPPLEMENTARY INFORMATION: The 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) to require, among other things, that under section 403(q)(4) of the act (21 U.S.C. 343(q)(4)), FDA do the following: (1) Identify the 20 most frequently consumed raw fruit, vegetables, and fish in the United States; (2) establish guidelines for the voluntary nutrition labeling of these raw fruit, vegetables, and fish; and (3) issue regulations that define ''substantial compliance'' with respect to the adherence by food retailers with those guidelines.

In the **Federal Register** of November 27, 1991 (56 FR 60880), FDA responded to those requirements by publishing a final rule on the nutrition labeling of raw fruit, vegetables, and fish (corrected on March 6, 1992 (57 FR 8174)). In the **Federal Register** of August 16, 1996 (61 FR 42742), FDA published another final rule that revised the guidelines and updated the nutrition labeling values for the voluntary nutrition labeling of raw fruit, vegetables, and fish. This action made the labeling under the voluntary nutrition labeling program more consistent with mandatory nutrition labeling of other foods regulated by FDA.

FDA lists the 20 most frequently consumed raw fruit, vegetables, and fish in § 101.44 (21 CFR 101.44). In § 101.45 (21 CFR 101.45), FDA set forth guidelines on how these foods are to be nutrition labeled. Under these guidelines, nutrition labeling information may be provided by food retailers in the parts of their stores where raw fruit, vegetables, and fish are sold. Information may be made available in signs, posters, brochures, notebooks, or leaflets and may be supplemented by video, live demonstration, or other media.

In § 101.43 (21 CFR 101.43), FDA defines ''substantial compliance'' to mean that at least 60 percent of the food retailers sampled in a representative survey provide nutrition labeling information (as specified in the guidelines) for at least 90 percent of the foods that they sell that are included on the listing of the most frequently consumed raw fruit, vegetables, and fish. FDA makes separate determinations of substantial compliance for raw fruit and vegetables collectively and for raw fish (§ 101.43(a)).

Section 403(q)(4)(C) of the act directed FDA to issue a report 30 months after enactment of the 1990 amendments that includes a determination of whether there is substantial compliance with the agency's implementing regulations. The act also states that if substantial compliance is achieved by food retailers, FDA is to reassess voluntary labeling compliance every 2 years. If substantial compliance is not achieved, FDA is to propose to require that nutrition information be provided by any person who offers raw fruit and vegetables or raw fish to consumers (section 403(q)(4)(D)(i) of the act).

In the **Federal Register** of May 18, 1993 (58 FR 28985), and May 5, 1995 (60 FR 22400), FDA announced the availability of reports that found that, under the standard in § 101.43, there was substantial compliance by food retailers in the provision of nutrition labeling information for raw fruit, vegetables, and fish. These determinations were based on compliance surveys that were conducted in November/December of 1992 and 1994. For both time periods, aggregate percentages (i.e., percentages over all stores sampled) for both raw fruit and vegetables and for raw fish showed that approximately three-fourths of the retail food stores surveyed provided the voluntary nutrition information.

Because substantial compliance was achieved in 1995, section 403(q)(4)(C)(ii) of the act requires that FDA reassess voluntary labeling compliance and issue a report in 1997. FDA is now announcing that this reassessment has been done. The results