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

of this reassessment are set forth in the report entitled ''Food and Drug Administration Nutrition Labeling Information Study—December 1996, Raw Fruit/Vegetables and Raw Fish.''

Based upon the results of this study that was conducted under contract, FDA once again concludes that substantial compliance by food retailers in providing nutrition labeling information for raw fruit and vegetables and for raw fish has been met. On a store count basis, more than 70 percent (73.0 percent for raw produce and 71.2 percent for raw fish) of the sampled stores selling raw fruit, vegetables, and fish voluntarily provided nutrition labeling information in an appropriate manner for these raw foods.

Data were also reported on an all commodity volume (ACV) basis. ACV data are weighted estimates that represent annual store sales volumes and reflect the percent of the market serviced. ACV data approximate more representatively than store counts the percent of the population exposed to the nutrition labeling information. ACV values were higher than those for sampled store counts.

For raw fruit/vegetables, stores in compliance account for 77.8 percent of the annual sales of all food stores. For raw fish, stores in compliance account for 74.0 percent of the annual sales of all food stores. A possible interpretation of these data is that about three-fourths of U.S. consumers are exposed to nutrition labeling information for raw fruit, vegetables, and fish. Because many consumers shop in more than one store, the actual level of consumer exposure is most likely to be even higher.

FDA will again survey retail stores in 1999 to determine whether substantial compliance in the provision of voluntary labeling information for raw fruit, vegetables, and raw fish continues to exist. If, at that time, substantial compliance is not met, the agency will propose to modify § 101.43 to make the program mandatory.

Dated: April 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12158 Filed 5–8–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–142]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements Contained in BPD–393, Examination and Treatment for Emergency Medical Conditions and Women in Labor, 42 CFR 488.18, 489.20 and 489.24; *Document:* HCFA–R–142; *Use:* BPD–393 contains information collection requirements for hospitals that would seek to prevent them from inappropriately transferring individuals with emergency medical conditions, as mandated by Congress. HCFA will use this information to help assure compliance with this mandate. This information is not contained elsewhere in regulations. *Frequency:* On occasion; *Affected Public:* Individuals or households, Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents: 7,000; Total Annual Responses: 7,000; Total Annual Hours Requested:* 8,818,577.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's web site address at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850

Dated: May 1, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 97–12072 Filed 5–8–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Institute Initial Review Group:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: Subcommittee F—Manpower and Training Subcommittee.

Date: June 18–20, 1997.

Time: June 18—6:30 p.m. to Adjournment, June 19, 20—8:00 a.m. to Adjournment.

Place: St. James Hotel, 950 24th Street, N.W., Washington, DC 20037.

Contact Person: Mary Bell, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, 6130 Executive Blvd. Room 611A, Bethesda, MD 20892, Telephone: 301–496–7978.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers