statistics on the health of the U.S. population. Due to the integration of health surveys in the Department of Health and Human Services, the NHIS also has become the sampling frame and first stage of data collection for other major surveys, including the Medical Expenditure Panel Survey, the National Survey of Family Growth, and the National Health and Nutrition Examination Survey. By linking to the NHIS, the analysis potential of these surveys increases. The NHIS has long been used by government, university, and private researchers to evaluate both general health and specific issues, such as cancer, AIDS, and childhood immunizations. Journalists use its data to inform the general public. It will continue to be a leading source of data for the Congressionally-mandated ''Health US'' and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, ''Healthy People 2000.''

Because of survey integration and changes in the health and health care of the U.S. population, demands on the NHIS have changed and increased, leading to a major redesign of the annual core questionnaire, or Basic Module, and a redesign of the data collection system from paper questionnaires to computer assisted personal interviews (CAPI). Those redesigned elements were partially implemented in 1996 and fully implemented in 1997 and are expected to be in the field until 2006. This clearance is for the fifth full year of data collection using the Basic Module on CAPI, and for implementation of the second ''Periodic Module'', which include additional detail questions on conditions, access to care, disabilities, and health care utilization. The ''Periodic Module'' will repeat a similar survey conducted in 1992, and will help track many of the Health People 2010 objectives. This data collection, planned for January-December 2001, will result in publication of new national estimates of health statistics, release of public use micro data files, and a sampling frame for other integrated surveys. The total cost to respondents is estimated at $70,860 for the whole survey.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden per response	Total burden (in hrs.)
Family	42,000	1	0.35	14,700
Sample adult	42,000	1	0.70	29,400
Sample child	18,000	1	0.25	4,500
Total				48,600

Dated: February 28, 2000.

Charles Gollmar,

Acting Associate Director for Policy, Planning, and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–5132 Filed 3–2–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00F–0792]

The Procter & Gamble Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Procter & Gamble Co. (P&G) has filed a petition proposing that the food additive regulations regarding olestra be amended by removing the requirement for the label statement.

FOR FURTHER INFORMATION CONTACT: Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3102.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (the act) (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 0A4708) has been filed by P&G, Winton Hill Technical Center, 6071 Center Hill Ave., Cincinnati, OH 45224. The petition proposes to amend the food additive regulations in § 172.867 *Olestra* (21 CFR 172.867) by removing the requirement for the label statement prescribed in § 172.867(e).

Olestra is a food additive that is approved for use in place of fats and oils in prepackaged ready-to-eat savory snacks (§ 172.867). Olestra is not digested to any appreciable degree in the human gut and is not absorbed or metabolized by the body.

In the **Federal Register** of June 23, 1987 (52 FR 23606), FDA announced that P&G had filed a petition (FAP 7A3997) proposing that the food additive regulations be amended to provide for the safe use of olestra. FDA subsequently published a final rule approving olestra for use in savory snacks(61 FR 3118, January 30, 1996) after completing its evaluation of the relevant data and information. Prior to the issuance of the final rule, FDA convened a public meeting of its Food Advisory Committee (FAC) on November 14 through 17, 1995, to undertake a scientific discussion of the agency's evaluation of the safety data in the petition. As a result of the 4-day FAC meeting, a substantial portion of the relevant safety data on olestra was publicly discussed in detail by both proponents and opponents of olestra's approval, as well as by members of the FAC.

In issuing the olestra final rule, FDA carefully considered the proper labeling for foods containing the additive. This issue was also discussed in detail before the FAC. As noted, olestra is not absorbed, and it passes through the gastrointestinal (GI) tract intact. Data from clinical studies submitted by P&G in support of its original petition show that consumption of olestra with a meal can affect the absorption of certain fat-soluble vitamins and nutrients, which partition into the olestra. The petitioner and FDA agreed that these fat-soluble vitamins needed to be added to the snacks to compensate for any such effect, and that this addition of vitamins was not equivalent to fortification. These data also show that olestra has the potential to cause certain GI effects such as abdominal cramping and loose stools. FDA determined that consumers needed to know about any potential effects of olestra on the GI system.

In view of the record before the agency, FDA concluded that olestra-containing products would need to carry an information statement in order for such products to avoid being misbranded within the meaning of 21 U.S.C. 343(a)(1) and 321(n). Therefore, the final rule (§ 172.867(e)) required that foods containing olestra be labeled with the following statement in a boxed

format: ''This Product Contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.'' This requirement was established under section 409(c)(3) of the act (61 FR 3118, 3160). As such, the requirement was immediately effective. Although immediately effective, FDA requested comments on the label from interested persons on such issues as the need for labeling, the adequacy of its content, and the agency's current word choices.

At the time of olestra's approval, P&G informed FDA that the company intended to conduct certain post-marketing studies, which included establishing a system for monitoring complaints associated with the ingestion of olestra-containing products (passive surveillance), a program of active surveillance, and consumer evaluation studies of the required label statement. Since the approval of olestra in January 1996, olestra-containing snacks have been introduced into the marketplace, and P&G has carried out the studies and surveillance it committed to do. The company also sponsored new clinical studies, which provide additional data and information on possible GI effects from consuming olestra-containing snacks in ''real-life'' situations. A substantial amount of additional data and information have been submitted to FDA since the January 1996 olestra approval. Specifically, the agency has received reports from four studies: An Acute Consumption Study (FAP 0A4708, exhibit 1, reference B), a 6-Week Consumption Facilitated *Ad Lib* Study (FAP 0A4708, exhibit 1, reference C), a Rechallenge Study (FAP 0A4708, exhibit 1, reference D), and a Stool Composition Study (FAP 0A4708, exhibit 1, reference E). P&G has also submitted reports and analysis of data collected through passive surveillance, consumer focus group and perception studies, literature reviews on carotenoids and disease, and an analysis of the first year of data collected in the ongoing active surveillance study. In addition, the Center for Science in the Public Interest (CSPI) has submitted new data and information regarding olestra to the agency.

Consistent with its responsibilities to monitor the safety of all food additives, and as set out in § 172.867(f), FDA presented the new data and information concerning olestra, and the agency's evaluation of such new information, to the FAC at a meeting held on June 15 through 17, 1998. At this open public meeting, FDA, P&G, CSPI, and other interested members of the public made presentations to the Committee. At the meeting, there was considerable discussion of the label required by § 172.867(e), with a range of views expressed. The complete set of transcripts of the June 1998 FAC meeting is publicly available through FDA's Internet site at http://www.fda.gov/ohrms/dockets/ac/cfsan98t.htm#Food Advisory Committee (choose June 15, 16, and 17).

Since the June 1998 FAC meeting, P&G as well as other interested parties have submitted additional information and analyses of the required label statement to FDA. The recent submissions include a report from a multi-disciplinary panel assembled by P&G and charged with examining the scientific evidence, as well as the legal and policy precedents, in regard to the label statement. The panel report also includes information from the ongoing passive surveillance, and additional consumer perception studies regarding the olestra label.

On December 2, 1999, P&G submitted the food additive petition that is the subject of this filing notice; the petition requests that the food additive regulations be amended to eliminate the requirement for the olestra label statement. P&G contends that the weight of the scientific evidence collected since the 1996 approval establishes that the label statement contains inaccurate information and is not understood by consumers. Accordingly, P&G claims that the olestra label misleads consumers and thus misbrands the products on which it appears. P&G also asserts that the label statement does not convey material information and, thus, is not authorized under sections 403(a)(1) and 201(n) of the act (21 U.S.C. 343(a)(1) and 321(n)) The material that P&G relies on to support its contentions has been incorporated into its petition, FAP 0A4708. Much of that material has been publicly available since the June 1998 FAC meeting.

In light of the substantial public interest in this matter and the previous public discussion and comment on the olestra label, FDA has determined that it is appropriate to make a copy of FAP 0A4708 available at the agency's Dockets Management Branch, Docket No. 00F–0792. Relevant information incorporated into FAP 0A4708 includes copies of various reports and published studies conducted or sponsored by the petitioner, as well as a report produced by the multi-disciplinary panel assembled by P&G to evaluate the label statement. Also referenced in the petition are consumer perception studies on the olestra label conducted by Frito-Lay, Inc., in 1996 and 1999, as well as a variety of other published scientific references, and various letters submitted to the agency regarding the labeling of olestra-containing snacks. The petition also discusses other information relevant to the olestra label which can be found in Docket No. 87F–0179. These include comments received in response to the agency's request for comments on the label statement in the olestra final rule (January 30, 1996), and reports submitted by CSPI.

FDA often receives comments on food additive petitions, especially those for which there is a high level of public interest. Although section 409 of the act establishes no comment period for food additive petitions, and the agency does not solicit comments in notices announcing the filing of a food additive petition, it is FDA's customary practice to consider any relevant comments submitted regarding such petitions. In the case of olestra, much of the material relevant to the label issue raised by the petition was submitted to the agency since the final rule published, and the bulk of that material was available and discussed at the June 1998 FAC meeting. Consistent with section 409 of the act, FDA will, as part of the review of P&G's petition, fairly evaluate all the evidence of record, including relevant comments received by the agency that become part of the record.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: February 15, 2000.

Alan M. Rulis,

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

[FR Doc. 00–5096 Filed 3–2–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0785]

Draft Guidance for Industry; Guidance on Medical Device Patient Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled