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

''Guidance on Medical Device Patient Labeling.'' This draft guidance is not final nor is it in effect at this time. This draft guidance describes how to make medical device patient labeling understandable to and usable by patients (or family members or other lay persons caring for patients). It is intended to assist manufacturers in their development and reviewers in their review and evaluation of medical device patient labeling. This draft guidance is designed to help assure safe and effective use of medical devices through medical device patient labeling that informs patients or their lay caregivers about proper use, risks, and benefits of the device in language they can understand.

DATES: Submit written comments on this draft guidance by June 2, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Guidance on Medical Device Patient Labeling'' to the Division of Small Manufacturers Assistance (DSMA) (HFZ–220), Center for Devices and Radiological Health (CDRH), 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 concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Paula G. Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–1217.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance provides information on the content, format, and organization of information that patients need to use medical devices safely and effectively. It also gives principles for writing and presenting patient information in a manner most understandable and usable to patients and their lay caregivers. With an increase in patient use of complex medical devices previously used primarily by skilled and knowledgeable health-care professionals, effective medical device patient labeling has become increasingly important in helping to assure the safe and effective use of devices.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on medical device patient labeling. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance on Medical Device Patient Labeling'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1128) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Intenet. Updated on a regular basis, the CDRH home page includes the Medical Device Patient Labeling, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The document entitled ''Guidance on Medical Device Patient Labeling'' will be available at http://www.fda.gov/cdrh/HumanFactors.html.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by June 2, 2000. 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 draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 28, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–5086 Filed 2–28–00; 4:36 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–197]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration. 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 this 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: Revision of a currently approved collection.

Title of Information Collection: Maximizing the Effective Use of Telemedicine: A Study of the Effects, Cost Effectiveness and Utilization Patterns of Consultations via Telemedicine.

Form No.: HCFA–R–197 (OMB# 0938–0705).

Use: This study deals with several issues of importance to HCFA regarding the recent proliferation of Telemedicine programs. The primary goal of this study is to develop policy recommendations for Medicare concerning utilization review and