proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects: Comparative Analysis of Caregiving Patterns for Disabled Elders with Long-Term Insurance—New—The Assistant Secretary for Planning and Evaluation (ASPE) is participating in a survey which will compare the usage of formal and informal caregiving services between the disabled elderly with long-term care insurance policies and the disabled elderly in the general population. *Respondents:* Individuals or households—Burden Information for the Home Care Instrument—*Number of respondents:* 700; *Average time per response:* 1.5 hours; *Burden for Home Care Instrument:* 1,050 hours—Burden Information for the Nursing Home Instrument—*Number of respondents:* 350; *Average time per response:* 1.5 hours; *Burden for Nursing Home Instrument:* 525 hours—Burden Information for the Informal Caregiver Telephone Survey: *Number of respondents:* 700; *Average time per response:* 20 minutes; Burden for Informal Caregiver Telephone Survey: 233 hours—Burden Information for the Policy Holder Screening Instrument—*Number of respondents:* 1500; *Average time per response:* 7 minutes; *Burden for Policy Holder Screening Instrument:* 175 hours—*Total Burden:* 1983. hours.

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Written comments should be received within 60 days of this notice.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 97–9883 Filed 4–16–97; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0086]

Food Labeling: Draft Guidance on Diet Plans

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing draft guidance to the marketers of food plans that are represented as a total diet and that have been formulated so that the dietary intake of various nutrients by those who participate in the plan is controlled. The agency hopes that this guidance, if finalized, will help to minimize any problems that may develop should firms proceed to market with these plans.

DATES: Written comments by July 1, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christine J. Lewis, Center for Food Safety and Applied Nutrition (HFS–451), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION: FDA is aware that there is interest in the food industry in offering a food plan in which most of the food in the diet is purchased through the plan. The foods sold in these plans would be formulated so that the total diet of those who comply with the plan provides controlled levels of such nutrients as fat, saturated fat, cholesterol, and sodium.

FDA applauds innovative efforts to help consumers maintain healthy dietary practices. The agency notes that one of the main purposes of the Nutrition Labeling and Education Act (the 1990 amendments) was to encourage such practices, and, thus, such plans can be seen, at least conceptually, as consistent with that statute. The agency also recognizes that diets can be structured to be useful in the management of certain chronic conditions. The agency has no desire to do anything that would discourage efforts to achieve these innovative goals.

While these plans have the potential to be useful, they also have the potential to create a number of significant concerns under the Federal Food, Drug, and Cosmetic Act (the act). The purveyors of such programs will need to take care to ensure that, in presenting these programs to the American consumer, they do not run afoul of any of the provisions of the act. Given this need for care, FDA has concluded that it would be useful to companies that either have decided, or who may decide, to offer such programs, and that it would help to prevent regulatory problems, if the agency outlined the statutory concerns that it can foresee could be created by these programs. The agency is also setting out its thoughts on these concerns. The agency would welcome comments on these preliminary views from interested persons. The major concerns that FDA has at least preliminarily identified follow.

A. Health Claims

Under section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)) and 21 CFR 101.14(a)(1), a health claim is:

> * * * any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including ''third party'' references, written statements (e.g., a brand name including a term such as ''heart''), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

Thus, for a claim to be a health claim, one of the essential elements is that it be, expressly or by implication, about a particular substance and not about the total diet. The agency points out that, in adopting the health claim final rule, it said that:

> * * * phrases on labeling such as ''eat a variety of foods to _____,'' ''eat a variety of fresh fruits and vegetables to _____,'' or ''follow the food pyramid to _____,'' without any reference, either express or implied, to a substance that might be in the foods, would not satisfy this element. The latter types of claims would not be subject to regulation as health claims.

(58 FR 2478 at 2480, January 6, 1993). The agency thus recognizes that claims about the effects of a diet plan, depending on how the claim is made, would arguably not be subject to regulation as a health claim.

FDA advises that it will carefully scrutinize any claims that are made for a diet plan to determine whether they are health claims. For example, a claim that the diet has been designed to provide high levels of vitamin A to reduce the risk of cancer would be a health claim because the statement links the two basic components of a health claim, a food substance and a disease or health-related condition. Any claims that are made that are health claims must be made in accordance with FDA's authorizing regulations, or they will misbrand the products under section 403(r)(1)(B) of the act.

B. Nutrient Content Claims

A claim that expressly or by implication characterizes the level of a nutrient in a food is a nutrient content

claim (21 CFR 101.13(b)). Such claims must be made in accordance with FDA's regulations defining the claim (section 403(r)(1)(A) of the act). FDA cautions that care must be taken in how claims are made about diet plans to ensure that the foods in the plan are not represented as having lower, or higher, nutrient levels than they actually contain. For example, a claim that a plan has been formulated to provide low fat foods, as compared to a claim that the plan has been formulated to provide a diet that is low in fat, would imply that the foods in the plan are low fat. Thus, every food in the plan would have to meet the definition for ''low fat'' in 21 CFR 101.62(b)(2) to avoid being misbranded.

C. Foods for Special Dietary Use

Foods that purport or are represented as to be used to supply a special dietary need that exists by reason of a physical, physiological, pathological, or other condition are foods for special dietary use under section 411(c)(3)(A) of the act (21 U.S.C. 350(c)(3)(A)). There is a substantial possibility that a diet plan may be represented in a way that subjects the foods in the plan to regulation as foods for special dietary use. For example, a claim that the diet plan provides a modified diet, formulated for those who must restrict their sodium intake, would present the foods in the plan as foods for special dietary use. Under section 403(j) of the act, FDA has authority to require, on the label of such foods, information concerning their dietary properties that it finds necessary to fully inform purchasers about their value for special dietary use.

FDA advises that, if these diet plans appear on the market, FDA will carefully scrutinize the labeling and advertising for such plans to see whether it is necessary for the agency to invoke its authority under section 403(j) of the act.

D. False or Misleading Claims

Under section 403(a)(1) of the act, food is deemed to be misbranded if its labeling is false or misleading in any particular. FDA would expect that any firm that markets a diet plan will have evidence about the effects of following the plan, and that that evidence would establish that any claims that are made about that plan and the food that makes up the plan are truthful and not misleading. FDA also would expect that the firm will share that evidence with FDA. For example, if there is a claim that a plan has been clinically proven to have a certain effect, FDA will expect that at least one properly designed clinical study has been done with the particular diet plan, that the results of the study or studies fully support the claims that are made, and that the results of the studies will be shared with FDA.

E. Drug Claims

FDA is concerned that claims made about a diet plan could evidence an intent that the plan is to be used as a drug. Under section 201(g)(1)(B) of the act (21 U.S.C. 321(g)(1)(B)), articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals are deemed to be drugs. Thus, for example, a claim that a diet plan is a ''therapeutic diet'' could subject the plan to regulation under the provisions of the act that apply to drugs and, in particular, new drugs. FDA therefore cautions that manufacturers who decide to market diet plans with claims that subject the plans to regulation as drugs must be prepared to satisfy the applicable statutory requirements.

F. Meat and Poultry Products

FDA advises that diet plans that include meat or poultry products are also subject to regulation by the Food Safety and Inspection Service of the U.S. Department of Agriculture, under the Meat Inspection Act and the Poultry Products Inspection Act.

G. Conclusion

In conclusion, FDA advises that this document's discussion of the regulatory requirements that apply to diet plans is not intended to discourage such plans. It is intended to ensure that manufacturers who decide to go forward with such plans do so with an understanding of the act and FDA's regulations. The agency hopes that, by laying out its concerns and expectations, it will help to minimize the problems that will develop should firms proceed to market with these plans and thus to maximize the likelihood that consumers will fully appreciate the benefits that they offer.

This draft guidance represents the agency's current thinking on food plans that are marketed as a total diet. 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.

Interested persons may, on or before July 1, 1997 submit to the Dockets Management Branch (address above) written comments on this draft guidance. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 8, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–9876 Filed 4–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0152]

Determination of Regulatory Review Period for Purposes of Patent Extension; OXILAN™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for OXILAN™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and