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

an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product OXILAN™ (loxilan). OXILAN™ is indicated for cerebral arteriography, coronary arteriography and left ventriculography, visceral angiography, aortography, and peripheral arteriography. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for OXILAN™ (U.S. Patent No. 4,954,348) from Cook Imaging Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 28, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of OXILAN™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for OXILAN™ is 2,757 days. Of this time, 1,644 days occurred during the testing phase of the regulatory review period, while 1,113 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: June 5, 1988. The applicant claims April 29, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 5, 1988, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: December 4, 1992. FDA has verified the applicant's claim that the new drug application (NDA) for OXILAN™ (NDA 20–316) was initially submitted on December 4, 1992.

3. *The date the application was approved*: December 21, 1995. FDA has verified the applicant's claim that NDA 20–316 was approved on December 21, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 737 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 16, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 14, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 4, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–9917 Filed 4–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[ORD–098–N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: February 1997

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: No new proposals for Medicaid demonstration projects were submitted to the Department of Health and Human Services during the month of February 1997 under the authority of section 1115 of the Social Security Act. There were no proposals approved, disapproved, or withdrawn during that time period. (This notice can be accessed on the Internet at HTTP://WWW.HCFA.GOV/ORD/ORDHP1.HTML.)

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: Mail correspondence to: Susan Anderson, office of Research and Demonstrations, ealth Care Financing Administration, Mail Stop C3–11–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Susan Anderson (410) 786–3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the *Federal Register* (59 FR 49249) that specified (1) the principles that we ordinarily will consider when approving or disapproving demonstration projects under the