TIME AND DATE: Approximately 10:30 a.m., Wednesday, March 18, 1998, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any matters carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Joseph R. Coyne, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.bog.frb.fed.us for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: March 11, 1998.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 98–6656 Filed 3–11–98; 11:25 am]

BILLING CODE 6210–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98C–0158]

Linvatec Corp.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Linvatec Corp. has filed a petition proposing that the color additive regulations be amended to provide for the safe use of D&C Violet No. 2 to color absorbable meniscal tacks made from poly(L-lactic acid).

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1)), notice is given that a color additive petition (CAP 8C0255) has been filed by Linvatec Corp., P.O. Box 2917, Largo, FL 33779–2917. The petition proposes to amend the color additive regulations in § 74.3602 *D&C Violet No. 2* (21 CFR 74.3602) to provide for the safe use of D&C Violet No. 2 to color absorbable meniscal tacks made from poly(L-lactic acid).

The agency has determined under 21 CFR 25.32(l) 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: March 2, 1998.

Alan M. Rulis,

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

[FR Doc. 98–6570 Filed 3–12–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0133]

FDA Modernization Act of 1997: Guidance for Industry on Implementation of Section 126, Elimination of Certain Labeling Requirements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Implementation of Section 126, Elimination of Certain Labeling Requirements, of the Food and Drug Administration Modernization Act of 1997.'' The Food and Drug Administration Modernization Act of 1997 (FDAMA) amends the Federal Food, Drug, and Cosmetic Act (the act) to require, at a minimum, that before dispensing, the labels of prescription products contain the symbol ''Rx only'' instead of the ''Caution: Federal law prohibits dispensing without prescription'' statement. In addition, the requirement that the labels of certain habit-forming drugs bear the statement ''Warning—May be habit forming'' has been repealed. This guidance is intended to clarify FDA policy with respect to implementation of these amendments that became effective February 19, 1998. The agency requested comments on this guidance.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance may be obtained on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jerry Phillips, Center for Drug Evaluation and Research (HFD–610), Food and Drug Administration, Office of Generic Drugs, 7500 Standish Pl., Rockville, MD 20855, 301–827–5846.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Implementation of Section 126, Elimination of Certain Labeling Requirements, of the Food and Drug Administration Modernization Act of 1997.'' Section 126 of Title I of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), signed into law by President Clinton on November 21, 1997, amends section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(b)(4)) to require, at a minimum, that prior to dispensing, the label of prescription products contain the symbol ''Rx only.'' In addition, section 502(d) of the act (21 U.S.C. 352(d)) is repealed. This section required the labels of certain habit-forming drugs to bear the statement ''Warning—May be habit forming.'' The amendments to section 503(b)(4) of the act and the repeal of section 502(d) of the act became effective February 19, 1998.

This guidance for industry is intended to: (1) Describe the new prescription drug labeling requirements of the act as amended by FDAMA and (2) advise manufacturers, packers, and distributors of the policy the agency will follow in implementing the requirements of section 126. The guidance advises that, for a limited period of time, FDA does not intend to object if manufacturers, packers, or distributors of already approved products implement section 126 of FDAMA at the time of next printing of its labels, but that such entities should implement the

amendments no later than August 18, 1998, which is 180 days from the effective date of FDAMA. For full or abbreviated applications approved between February 19, 1998, and August 18, 1998, manufacturers, packers, and distributors have until August 18, 1998, to comply with the amendments. The guidance also advises that full or abbreviated applications submitted after February 19, 1998, should provide labels in compliance with the amendments.

This guidance document represents the agency's current thinking on implementation of elimination of certain labeling requirements. 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 requirement of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the dockets Management Branch (address above). 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 guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 3, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–6572 Filed 3–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–417 and HCFA–724]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospice Request for Certification in the Medicare Program; *Form No.:* HCFA–417 (OMB# 0938–0313); *Use:* The Hospice Request for Certification Form is used for hospice identification, screening, and to initiate the certification process. The information captured on this form is entered into a data base which assists HCFA in determining whether providers have sufficient personnel to participate in the Medicare program. The form summarizes data relative to: type of hospice; types of services provided by the hospice; and number of full time equivalents; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, local or tribal government; *Number of Respondents:* 2,286; *Total Annual Responses:* 2,286; *Total Annual Hours:* 572.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare/Medicaid Psychiatric Hospital Survey Data and Supporting Regulations Contained in 42 CFR 482.60, 482.61 and 482.62; *Form No.:* HCFA–724 (OMB# 0938–0378); *Use:* The Medicare/Medicaid Psychiatric Hospital Survey Data Form is used for hospital identification, and program planning and evaluation. The information captured on this form is entered into a data base which assists HCFA in maintaining accurate information on all free-standing psychiatric hospitals participating in the Medicare program. The form summarizes data relative to: hospital characteristics; types of services provided by the hospital; and hospital statistics; *Frequency:* Annually; *Affected Public:* Federal government, Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; *Number of Respondents:* 350; *Total Annual Responses:* 350; *Total Annual Hours:* 175.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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 Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 5, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–6453 Filed 3–12–98; 8:45 am]

BILLING CODE 4120–03–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–26]

Agency Information Collection Activities: Submission for OMB Review; 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