

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