Limited Partnership, Bryan, Texas; to acquire 51 percent of the voting shares of The First National Bank of Bryan, Bryan, Texas.

Board of Governors of the Federal Reserve System, December 5, 2001.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 01–30512 Filed 12–10–01; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 27, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. FBOP Corporation, Oak Park, Illinois; to acquire Gateway Investment Services, Inc., Los Angeles, California, and thereby engage in securities brokerage activities pursuant to section 225.28(b)(7)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, December 5, 2001.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 01–30510 Filed 12–10–01; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System Federal Register Citation of Previous Announcement: 66 FR 63059, December 4, 2001.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:00 a.m., Friday, December 7, 2001.

CHANGES IN THE MEETING: The open meeting has been canceled.

CONTACT PERSON FOR MORE INFORMATION: Michelle A. Smith, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 for a recorded announcement of this meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement. (The Web site also includes procedural and other information about the open meeting.)

Dated: December 7, 2001.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 01–30663 Filed 12–7–01; 11:23 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0510]

Draft Guidance for Industry on Integration of Dose-Counting Mechanisms Into MDI Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Integration of Dose-Counting Mechanisms into MDI Drug Products.'' This draft guidance makes recommendations to manufacturers to incorporate dose-counters into metered-dose inhalers (MDIs) being developed for the treatment of lung diseases. The recommendations made in this draft guidance are intended to enhance the use of MDIs, specifically to help patients identify when MDIs are no longer delivering reliable doses.

DATES: Submit written or electronic comments on the draft guidance by February 11, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), 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 draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sandra L. Barnes, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Integration of Dose-Counting Mechanisms into MDI Drug Products.'' It is intended primarily for manufacturers of MDI drug products designed to deliver drugs to the lungs (e.g., an MDI for the treatment of asthma). Dose-counters are mechanisms designed to accurately track the number of actuations used by a patient over the life span of an individual MDI. The dose-counter would provide the patient with continuing, accurate data on the amount of medication left in the MDI. Currently, patients do not have an adequate way to track the number of metered-doses left in MDIs, and there is no way to detect when these devices have exceeded their dose limit. The incorporation of a reliable, accurate dose-counter into each MDI will enhance these drug products, which are relied on to deliver important and sometimes life-saving drugs to patients with asthma and other obstructive lung diseases.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the integration of dose-counting

mechanisms into MDI drug products. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the 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. The draft 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: December 3, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–30491 Filed 12–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1681]

Guidance on Use of Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.'' This guidance updates a notice of availability entitled ''Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use'' published in the **Federal Register** on June 29, 1982, concerning the prophylactic use of potassium iodide (KI) in the event of release of radioactive isotopes of iodine. In this guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland and, thus, reduce the risk of thyroid cancer in the event of a radiation emergency. The guidance recommends lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than previously recommended.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rose Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Emergency Management Agency (FEMA) has established roles and responsibilities for Federal agencies in assisting State and local governments in their radiological emergency planning and preparedness activities. The Federal agencies, including the Department of Health and Human Services (DHHS), are intended to accomplish these roles and responsibilities as part of the Federal Radiological Preparedness Coordinating Committee. Among other responsibilities, DHHS is to provide guidance on the use of radioprotective substances to reduce radiation doses to specific organs from the release into the environment of large quantities of radioactivity. FDA is specifically charged with providing guidance on the prophylactic use of KI in the event of release of radioactive isotopes of iodine.

As part of its responsibilities as established by FEMA, on June 29, 1982, FDA published in the **Federal Register** a notice entitled ''Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use'' (47 FR 28158). In that notice, the agency made recommendations regarding the use of KI as a thyroid blocking agent. During 1999 to 2000, the agency reviewed additional data gathered primarily after the Chernobyl reactor accident. On January 4, 2001 (66 FR 801), the agency issued a draft guidance that revised some of the 1982 recommendations. The initial comment period on the draft guidance closed on February 5, 2001. On February 9, 2001 (66 FR 9711), the agency extended the comment period to April 30, 2001. After consideration of all comments, the agency is issuing this final version of the guidance. Other than clarifying edits, the agency has made no substantial changes to the recommendations incorporated in the draft guidance. In this guidance the agency maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland and thus to reduce the risk of thyroid cancer in the event of a radiation emergency. FDA proposes lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than previously recommended. FDA's revised recommendations are in general accordance with those of the World Health Organization, as expressed in its ''Guidelines for Iodine Phrophylaxis Following Nuclear Accidents'' (1999), except for minor modifications.

The recommendations in the guidance were prepared by FDA scientists from the Center for Drug Evaluation and Research and from the Center for Devices and Radiological Health, in consultation with other governmental experts.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the use of potassium iodide as a thyroid blocking agent in radiation emergencies. 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 statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic 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