low power TV or TV translator operating on the same channel or first adjacent channel of its intention to initiate or change wireless operations and the likelihood of interference from the low power TV or translator station within its licensed geographic service area. The notice should describe the facilities, associated service area and operations of the wireless licensee with sufficient detail to permit an evaluation of the likelihood of interference. Upon receipt of such notice, the digital LPTV or TV translator licensee must cease operation within 120 days unless: (1) It obtains the agreement of the wireless licensee to continue operations; (2) the commencement or modification of wireless service is delayed beyond that period (in which case the period will be extended); or (3) the Commission stays the effect of the interference notification, upon request.

47 CFR 74.703(h) requires in each instance where suspension of operation is required, the licensee shall submit a full report to the FCC in Washington, DC, after operation is resumed, containing details of the nature of the interference, the source of the interfering signals, and the remedial steps taken to eliminate the interference.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–5770 Filed 3–19–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. 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 each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 14, 2008.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. Select Bancorp, Inc.; to become a bank holding company by acquiring 100 percent of the voting shares of Select Bank & Trust Company, both of Greenville, North Carolina.

B. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Cross County Bancshares, Inc., Wynne, Arkansas; to acquire additional voting shares of First Southern Bank, Batesville, Arkansas, for a total of up to 13.13 percent.

C. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. CTB Financial Corporation, Ruston, Louisiana; to acquire 100 percent of the voting shares of Community Trust Bank of Texas, Dallas, Texas, a *de novo* bank.

Board of Governors of the Federal Reserve System, March 17, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–5630 Filed 3–19–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Vision Health: Developing an Integrative Approach to Promotion and Protection, Request for Application (RFA) DP08–001

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Date: 12:30 p.m.–3:30 p.m., April 17, 2008 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of ''Vision Health: Developing an Integrative Approach to Promotion and Protection, RFA DP08–001.''

Contact Person for More Information: Susan B. Stanton, D.D.S., Scientific Review Administrator, CDC, 1600 Clifton Road, NE., Mailstop D72, Atlanta, GA 30333, Telephone: (404) 639–4640.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 13, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–5628 Filed 3–19–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0120]

Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking information and comments on issues related to standards for identification, validation, tracking and tracing, and authentication for prescription drug products. Particularly, we are requesting information and comments from drug manufacturers, distributors, pharmacies, other supply chain stakeholders, foreign regulators, standards organizations, and other Federal agencies and interested parties. This request is related to FDA's implementation of the Food and Drug

Administration Amendments Act of 2007 (FDAAA).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled ''Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information.''

DATES: Submit written or electronic comments by May 19, 2008.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of Policy, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, e-mail: *ilisa.bernstein@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, FDAAA (Public Law 3580) was signed into law. Section 913 of this legislation created section 505D of the Federal Food, Drug, and Cosmetic Act (the act), which requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Section 913 directs the Secretary to consult with specific entities to prioritize and develop standards for identification, validation, authentication and tracking and tracing of prescription drugs. Section 913 of this legislation also directs the Secretary to develop a standardized numerical identifier which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier, no later than 30 months after the date of the enactment of FDAAA. This standardized numerical identifier is to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.

FDA has been engaged in an intense effort to address counterfeit drugs for several years. In 2004, FDA's Counterfeit Drug Task Force released a report (Task Force Report) outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs, including implementation of new track and trace technologies to meet and surpass goals of the Prescription Drug Marketing Act, the Federal pedigree law.

In 2006, FDA issued an update report after conducting a fact-finding effort to determine how much progress had been made toward e-pedigree and electronic track and trace. FDA found that although significant progress was made to set the stage for widespread use of e-pedigree in 2007, this goal likely would not be met. Currently, there is no widespread use of e-pedigree.

Currently, e-pedigree is not in widespread use across the supply chain.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled ''Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information.'' This related document seeks information from technology vendors and others regarding available and emerging technologies for identification, validation, track and trace, and authentication of prescription drugs, as set forth in 505D(b)(3) of the act.

With this document, as a first step in developing standards under section 505D(b) of the act, we are seeking information from drug manufacturers, distributors, pharmacies, other supply chain stakeholders, foreign regulators, standards organizations, other Federal agencies, and other interested parties related to identification, validation, authentication, and tracking and tracing of prescription drugs. Consistent with the act, it is FDA's preference that such standards be the result of existing private and public sector collaborative standards processes. FDA intends to use the response to these comments to determine the state of standards development in these areas and determine how aggressively it may move forward. Recognizing the importance of uniform standards as well as the need to allow for updating over time, FDA would consider adopting such standards through a guidance process as quickly as possible.

II. Request for Comments

Please comment on the following questions regarding the development of standards related to section 505D of the act.

A. Standard Numerical Identifier

1. Characteristics

a. Should the standardized numerical identifier contain recognizable characteristics (e.g., National Drug Code number) or be random codes?

b. Should there be a common header for item/product segregation based on product type: biologic, solid oral dosage form, etc.? If so, please elaborate.

c. How can parties in the supply chain ensure that the numbers are unique and are not duplicated?

d. How much value would there be in having the numerical identifier in more than one place for the product (e.g., package and pallet level)?

e. Should the numerical identifier be machine readable, human readable, or both?

f. Should the numerical identifier include the lot number and/or batch number?

2. Standards

a. Do standards currently exist for a standardized numerical identifier of prescription drugs?

1. If so, please describe and comment on their application and use.

2. To what extent do these standards reflect stakeholder consensus?

3. Comment on whether any of these standards should be the standard adopted by FDA.

4. If yes, why? Compare this standard with other standards that exist.

5. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

6. Has this standard been adopted by other countries?

b. Are standards in development or planned for standardized numerical identifiers of prescription drugs in the supply chain? If so, who is developing these standards and what is the timeline for completion?

c. What are the elements, provisions, and particular considerations that should be included in a standardized numerical identifier of prescription drugs? Please be specific in your response and include examples, where possible.

d. Please comment on implementation of standardized numerical identifiers of prescription drugs in the U.S. supply chain.

e. Please comment on any technical or information technology concerns related to a standardized numerical identifier.

f. Comment on any ''lessons learned'' from foreign experience with standardized numerical identifiers.

3. Economic Impact

a. What are the usual practices and associated costs that now exist for applying bar codes and other technologies for standardized numerical identifiers on packages and pallets?

b. What are the associated costs for the application, use, and maintenance of standardized numerical identifiers?

c. What are the associated costs or processes for updating the standards as needed?

d. What are the benefits of using standardized numerical identifiers?

4. Harmonization With Other Countries

a. What standards or unique identification systems do other countries have in place, currently under development, or planned for the future? If they are under development, please include a timeline for completion.

b. Comment on any ''lessons learned'' from foreign experience with standardized numerical identifiers.

B. Standards for Validation

1. Do standards currently exist for validation of prescription drugs?

a. If so, please describe and comment on their application and use.

b. To what extent do these standards reflect stakeholder consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

2. Are standards in development or planned for validation of prescription drugs in the supply chain?

If so, who is developing these standards and what is the timeline for completion?

3. What are the elements, provisions, and particular considerations that should be included in a validation standard for prescription drugs? Please be specific in your response and include examples, where possible.

4. Please comment on implementation of validation of prescription drugs in the U.S. supply chain.

5. Please comment on any technical or information technology concerns related to validation.

6. Comment on any ''lessons learned'' from foreign experience with validation.

C. Standards for Track and Trace

1. Do standards currently exist for track and trace of products in the supply chain, generally?

a. If so, please describe and comment on their application and use.

b. To what extent do these standards reflect stakeholder consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

g. If standards are under development or planned for the future, please include a timeline for completion.

2. Do standards currently exist for track and trace of prescription drug products in the supply chain?

a. If so, please describe and comment on their application and use.

b. To what extent do these standards reflect stakeholders consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

3. Are standards in development for track and trace of prescription drugs in the supply chain?

If so, who is developing these standards and what is the timeline for completion?

4. What are the elements, provisions, and particular considerations that should be included in a track and trace standard for prescription drugs? Please be specific in your response and include examples, where possible.

5. Please comment on implementation of track and trace for prescription drugs in the U.S. supply chain, including, but not limited to, feasibility, costs, timeline, interoperability, information technology, and data storage.

6. Discuss how the data generated from track and trace should be held, where it should be held, concerns related to data security, and means for access to ensure interoperability for data sharing. What elements should be included in such a standard for data exchange, storage, and interoperability?

7. Comment on any ''lessons learned'' from foreign experience with track and trace.

D. Standards for Authentication

1. Do standards currently exist for authentication of products in the supply chain, generally?

a. If so, please describe and comment on the application and use.

b. To what extent do these standards reflect stakeholders consensus?

c. Comment on whether any of these standards should be the standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

2. Do standards currently exist for authentication of prescription drug products in the supply chain?

a. If so, please describe and comment on the application and use.

b. To what extent do these standards reflect stakeholders consensus?

c. Comment on whether any of these standards should be the numerical identifier standard adopted by FDA.

d. If yes, why? Compare this standard with other standards that exist.

e. If not, is there some aspect that could be changed to make it acceptable as the FDA standard?

f. Has this standard been adopted by other countries?

3. Are standards in development for authentication of prescription drugs in the supply chain?

If so, who is developing these standards and what is the timeline for completion?

4. What are the elements, provisions, and particular considerations that should be included in an authentication standard for prescription drugs? Please be as specific as possible and include examples, where possible.

5. Please comment on implementation of authentication for prescription drugs in the U.S. supply chain, including, but not limited to, feasibility, costs, timeline, interoperability, information technology, and data storage.

6. Comment on any ''lessons learned'' from foreign experience with authentication.

E. Prioritization

Please comment on the priority for development and implementation of identification, validation, authentication, and tracking and tracing standards.

1. Should certain standards be developed and implemented before others?

2. Should certain standards be developed and implemented concurrently?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and information. Submit a single copy of electronic comments and information or two paper copies of any mailed comments and information, except that individuals may submit one paper copy. Comments and information are to be identified with the name of the technology and the docket number

found in brackets in the heading of this document. A copy of this notice and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: March 13, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–5597 Filed 3–19–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0121]

Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments and information regarding technologies used for the identification, validation, tracking and tracing, and authentication of prescription drugs. This request is related to FDA's implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled ''Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments.''

DATES: Submit written or electronic comments and information by May 19, 2008.

ADDRESSES: Submit written comments and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments and information to *http://www.Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–03, Rockville, MD 20857, phone: 301–827–3360, FAX 301–594–6777, e-mail: *ilisa.bernstein@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, FDAAA (Public Law 3580) was signed into law. Section 913 of this legislation requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Specifically, section 913 created section 505D(b) of the Federal Food, Drug, and Cosmetic Act (the act), which directs the development of standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. Section 505D(b)(3) states that the standards developed under 505D ''shall address promising technologies, which may include—(A) radio-frequency identification; (B) nanotechnology; (C) encryption technologies; and (D) other track and trace or authentication technologies.''

FDA has previously identified counterfeit drugs as a threat to the safety of the public and the pharmaceutical supply chain.

1. In 2004, FDA's Counterfeit Drug Task Force issued a report (Task Force Report) on the threat of counterfeit medications and measures that can be taken by private and public stakeholders to make the U.S. drug supply chain more safe and secure. The 2004 Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug ''pedigree,'' which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- Radio Frequency Identification (RFID) is a promising technology as a means to achieve e-pedigree; and
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007.

2. In 2006, the Task Force issued an update report which stated that the goal of widespread use of e-pedigree and track and trace technologies by 2007 would probably not be met. The voluntary approach taken did not provide enough incentives for the adoption and implementation of the technologies and e-pedigree.

As part of the efforts listed above, we received information about various technologies for the identification, track and trace, and authentication of prescription drugs, and we met with companies to learn more about these technologies. We are aware that significant progress has been made and new technologies are emerging for the identification, track and trace, and authentication of prescription drugs. In order to address the ''promising technologies'' related to standards development, as described in section 505D(b)(3) of the act, we are seeking information from technology vendors and others. Rather than meet individually with companies, for efficiency and to further our understanding and knowledge, we are requesting that information be submitted to the docket number listed above.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled ''Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments.'' Under section 505D(b)(1) and (b)(2) of the act, this related document seeks information from drug manufacturers, distributors, pharmacies, other supply chain stakeholders, foreign regulators, standards organizations, and other Federal agencies and interested parties on issues related to standards for identification, validation, tracking and tracing, and authentication for prescription drug products.

We are particularly interested in the following information regarding available and emerging technologies for identification, validation, track and trace, and authentication of prescription drugs:

1. What are the RFID technologies, encrypting technologies, and nanotechnologies that are relevant? What are other relevant technologies?

2. Please provide information related to:

- Strengths for identification, validation, track and trace, or authentication;
- Limitations for identification, validation, track and trace, or authentication;
- Costs of implementation and use;
- Benefits to the public health;
- Feasibility for widespread use;
- Utility for e-pedigree.

3. Is the technology interoperable with other technologies? If so, describe.

4. What standards are necessary for supply chain use of the specific technology? What is the status of development of such standards?