

company by acquiring 100 percent of the voting shares of Basile State Bank, Basile, Louisiana.

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

1. *Independence Bancshares, Inc.*, Independence, Iowa; to acquire approximately 100 percent of the outstanding voting shares of Fairbank Bancshares Corp., Fairbank, Iowa and thereby indirectly acquire shares of Fairbank State Bank, Fairbank, Iowa.

Board of Governors of the Federal Reserve System, August 31, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

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BILLING CODE 6210-01-P

FEDERAL TRADE COMMISSION

Children's Online Privacy Protection Safe Harbor Proposed Self-Regulatory Guidelines; TRUSTe Application

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed "Safe Harbor" Guidelines and request for public comment.

SUMMARY: The Federal Trade Commission publishes this notice and request for public comment concerning proposed self-regulatory guidelines submitted by TRUSTe, under the safe harbor provision of the Children's Online Privacy Protection Rule, 16 CFR 312.10.

DATES: Written comments must be submitted on or before October 10, 2000.

ADDRESSES: Written comments should be submitted to: Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Avenue, NW., Washington, DC 20580. The Commission requests that commenters submit the original plus five copies, if feasible. To enable prompt review and public access, comments also should be submitted, if possible, in electronic form, on either a 5¼ or 3½ inch computer disk, with a disk label stating the name of the commenter and the name and version of the word processing program used to create the document. (Programs based on DOS or Windows are preferred. Files from other operating systems should be submitted in ASCII text format.) Alternatively, the Commission will accept comments submitted to the following e-mail address, <safeharbor@ftc.gov>. Individual members of the public filing

comments need not submit multiple copies or comments in electronic form. All submissions should be captioned: "TRUSTe Safe Harbor Proposal--Comment, P00450---." Comments will be posted on the Commission's web site: <http://www.ftc.gov>.

FOR FURTHER INFORMATION CONTACT:

Toby Levin, (202) 326-3156, Mamie Kresses, (202) 326-2070, or Karen Muoio, (202) 326-2491, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 601 Pennsylvania Ave., NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Section A. Background

On October 20, 1999, the Commission issued its final Rule¹ pursuant to the Children's Online Privacy Protection Act, 15 U.S.C. 6501, *et seq.* The Rule requires certain web site operators to post privacy policies, provide notice, and obtain parental consent prior to collecting, using, or disseminating personal information from children. The Rule contains a "safe harbor" provision enabling industry groups or others to submit self-regulatory guidelines that would implement the protections of the Rule to the Commission for approval.²

Pursuant to Section 312.10 of the Rule, TRUSTe has submitted proposed self-regulatory guidelines to the Commission for approval. The full text of the proposed guidelines is available on the Commission's website, <www.ftc.gov>.

Section B. Questions on the Proposed Guidelines

The Commission is seeking comment on various aspects of the proposed guidelines, and is particularly interested in receiving comment on the questions that follow. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted. Responses to these questions should cite the numbers and subsection of the questions being answered. For all comments submitted, please provide any relevant data, statistics, or any other evidence, upon which those comments are based.

1. Please provide comment on any or all of the provisions in the proposed guidelines. For each provision commented on please describe (a) the impact of the provision(s) (including any benefits and costs), if any, and (b) what alternatives, if any, TRUSTe

should consider, as well as the costs and benefits of those alternatives.

2. Do the provisions of the proposed guidelines governing operators' information practices provide "the same or greater protections for children" as those contained in Sections 312.2-312.8 of the Rule?³ Where possible, please cite the relevant sections of both the Rule and the proposed guidelines.

3. Are the mechanisms used to assess operators' compliance with the guidelines effective?⁴ If not, please describe (a) how the proposed guidelines could be modified to satisfy the Rule's requirements, and (b) the costs and benefits of those modifications.

4. Are the incentives for operators' compliance with the guidelines effective?⁵ If not, please describe (a) how the proposed guidelines could be modified to satisfy the Rule's requirements, and (b) the costs and benefits of those modifications.

5. Do the guidelines provide adequate means for resolving consumer complaints? If not, please describe (a) how the proposed guidelines could be modified to resolve consumer complaints adequately, and (b) the costs and benefits of those modifications.

By direction of the Commission.

C. Landis Plummer,

Acting Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Workshop in Vaccine Communication

The National Vaccine Program Office (NVPO), of the Centers for Disease Control and Prevention (CDC), announces the following meeting.

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 following meeting.

Name: Workshop on Vaccine Communication.

Times and Dates: 8:30 a.m.—6 p.m., October 5, 2000. 8:30 a.m.—2 p.m., October 6, 2000.

Place: Key Bridge Marriott Hotel, Arlington, Virginia.

Status: Open to the public, limited only by the space available. The meeting

¹ 64 FR 59888 (1999).

² See 16 CFR 312.10; 64 FR at 59906-59908, 59915.

³ See 16 CFR 312.10(b)(1); 64 FR at 59915.

⁴ See 16 CFR 312.10(b)(2); 64 FR at 59915.

⁵ See 16 CFR 312.10(b)(3); 64 FR at 59915.

room accommodates approximately 150 people.

Purpose: The National Vaccine Advisory Committee, the Inter-Agency Vaccine Communications Group and the National Vaccine Program Office will sponsor a Workshop on Vaccine Communication to provide a forum for identifying and discussing more effective approaches to vaccine benefit and risk communication.

This Workshop should be of interest to people working in the vaccine and immunization arena including health communication and public affairs specialists, public and private sector health care providers, parent and consumer groups, vaccine manufacturers, and immunization program managers and directors.

Matters to be Discussed: The Workshop will focus on (1) identifying key issues, forces and trends that are influencing and shaping perceptions about vaccines; (2) determining how to establish more meaningful discussions regarding issues of concern; (3) defining options for establishing more effective mechanisms for communicating vaccine benefits and risks; and (4) examining and discussing the effectiveness, purpose, methods, and timing of current vaccine communications.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Lena Kombo, NVPO, CDC, 1600 Clifton Road, NE, M/S D66, Atlanta, Georgia 30333, telephone 404/687-6672. You may also visit the NVPO website for additional information: www.cdc.gov/od/nvpo/calendar. 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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 31, 2000.

John Burckhardt,

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

[FR Doc. 00-22902 Filed 9-6-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1449]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Changes to an Approved NDA or ANDA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information contained in a guidance for industry entitled "Changes to an Approved NDA or ANDA."

DATES: Submit written or electronic comments on the collection of information by November 6, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the collection of information on the Internet at: <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Changes to an Approved NDA or ANDA (OMB Control No. 0910-0431)—Extension

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act (the Modernization Act) (Public Law 105-115) into law. Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and reporting manufacturing changes to approved new drug applications (NDA's) and abbreviated new drug applications (ANDA's), to new and abbreviated animal drug applications, and to license applications for biological products.

The guidance is intended to assist applicants in determining how they should report changes to an approved NDA or ANDA under section 116 of the Modernization Act, which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes.

The guidance provides recommendations to holders of approved NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations