Littleton, Colorado; FirstBank of Lakewood, N.A., Lakewood, Colorado; FirstBank of Littleton, N.A., Littleton, Colorado; FirstBank of Arapahoe County, N.A., Littleton, Colorado; FirstBank of Silverthorne, N.A., Silverthorne, Colorado; FirstBank of Vail, Vail, Colorado; FirstBank North, N.A., Westminster, Colorado; FirstBank of Wheat Ridge, N.A., Wheat Ridge, Colorado; and FirstBank, N.A., Palm Desert, California.

2. Benedict Enslinger, Trustee, Benedict Enslinger Revocable Trust, both of La Crosse, Kansas; to acquire an additional 1.30 percent, for a total of 11.96 percent, of the voting shares of NSB Bancshares, Inc., La Crosse, Kansas, and thereby indirectly acquire Nekoma State Bank, La Crosse, Kansas.

3. Matthew T. Ley, as Trustee, Portland, Oregon; to acquire an additional 38.2 percent, for a total of 40.9 percent, of the voting shares of State National Bancshares, Inc., Wayne, Nebraska, and thereby indirectly acquire State National Bank and Trust Company, Wayne, Nebraska.

C. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Cecil R. Simmons, San Benito, Texas; to acquire an additional 2.1 percent, for a total of 14.8 percent, and Cecil R. Simmons, as Trustee for the First National Bank Employee Stock Ownership Plan, San Benito, Texas, to acquire an additional 11.4 percent, for a total of 17.3 percent, of the voting shares of First San Benito Bancshares, Inc., San Benito, Texas, and thereby indirectly acquire First National Bank of San Benito, San Benito, Texas.

Board of Governors of the Federal Reserve System, February 18, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–4372 Filed 2-21-97; 8:45 am]

BILLING CODE 6210-01-F

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 that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) 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. Once the notice has been accepted for processing, it will also 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.

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 March 10, 1997.

A. Federal Reserve Bank of Minneapolis (Karen L. Grandstrand, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480-2171:

1. Community First Bankshares, Inc., Fargo, North Dakota; to engage *de novo* through its subsidiary, Community First Financial, Inc., Fargo, North Dakota, in leasing personal property or acting as agent, broker, or adviser in leasing personal property, pursuant to § 225.25(b)(5) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, February 18, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–4373 Filed 2-21-97; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D–0513]

Guidance on Labeling of Foods That Need Refrigeration by Consumers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing guidance on labeling of foods that need refrigeration by consumers to maintain safety or quality. This guidance, which represents FDA's policy on adequate safe handling instructions for food, should reduce the likelihood of temperature abuse of certain foods by consumers, and it is intended to reduce the potential for foodborne illness and death. The guidance also responds to the recommendations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), the National Food Processors Association (NFPA), the Association of Food and Drug Officials (AFDO), and the Centers for Disease Control and Prevention (CDC) for labeling foods needing refrigeration. FDA is soliciting comments on this guidance.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written comments on this 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: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

Refrigeration has long been used to retard deterioration of the flavor, color, and texture of foods. More importantly, refrigeration helps maintain the microbiological safety of potentially hazardous foods. Temperature abuse, i.e., failure to maintain foods at appropriate temperatures, may result in the outgrowth of microorganisms that may have contaminated the foods before, or at the time of, harvest or during processing, handling, or storage. The rate of growth of these microorganisms is reduced as the storage temperature is lowered. Proper refrigeration, therefore, prevents or slows the growth of human pathogens and spoilage microorganisms and reduces the likelihood of foodborne illness.

Refrigeration is only one of many individual factors, called barriers, that can be used to control microbiological risks. It is, for many foods, the only practicable barrier to reduce or prevent pathogen growth. Examples of other types of barriers include acidification ($pH \leq 4.6$), use of preservatives, such as salt, and low water activity ($a_w \leq 0.85$). Barriers used individually, or in combination with each other, may reduce or retard pathogenic microbial growth.

In the past, consumers could generally tell if a product were perishable by its packaging or lack of packaging. Products in a can or a jar were generally considered to be shelf-stable (i.e., products that can be stored on the shelf without spoilage), at least until opened. However, today's new packaging technologies have changed this situation. Many liquids or semi-liquids in flexible packages have airtight

liners and are shelf-stable. Vacuum packed foods or foods packaged in modified (oxygen reduced) atmospheres, which are shelf-stable, may appear to the consumer to be safe to eat, even if they have been temperature abused. These foods may not have developed organoleptic signs (such as deterioration of color, flavor, texture, etc.) that consumers associate with spoiled or unsafe foods. However, foods in these packages may present a potential hazard if, once opened, they are stored unrefrigerated.

Recently, there have been reports of botulism food poisonings resulting from consumption of food that had been temperature abused by consumers, even though the products were labeled ''keep refrigerated.'' FDA is concerned that such foods are not labeled adequately or conspicuously enough to advise consumers that the product must be refrigerated to maintain its safety. The specific foods implicated in the botulism poisonings were clam chowder and black bean dip. Packaging for both of these products could have made the food appear shelf-stable to the consumer.

The potential for foodborne illness from temperature abused foods is widely recognized. Efforts to reduce this health risk in potentially hazardous foods that need refrigeration to ensure their safety and quality have included voluntary use of label statements such as ''keep refrigerated'' and ''refrigerate after opening.'' Use of such label statements no longer provides meaningful consumer information because the same label statements appear both on foods needing refrigeration to ensure safety and foods needing refrigeration to maintain quality. NACMCF has made specific recommendations for label statements on potentially hazardous foods (Ref. 1) to address this problem. NFPA has developed guidelines for the food industry for voluntary label statements using the language in the NACMCF recommendation (Ref. 2). AFDO has endorsed the guidelines developed by NFPA (Ref. 3) and has recommended them to State regulatory agencies to assist those agencies in requiring and enforcing improved labeling (Ref. 4). Finally, CDC sent FDA a memorandum expressing concern about the recent botulism outbreaks and recommending, among other things, better labeling for foods requiring refrigeration (Ref. 5).

II. Inadequacy of Current Labeling

Because of the recent reports of botulism food poisonings from consumption of foods that had been temperature abused by consumers, FDA has evaluated the labeling on foods that must be refrigerated to prevent outgrowth of pathogens and has found that most of this labeling does not adequately advise the consumer of the need to keep the food refrigerated or of the health risk if it is not. For example, the packaging for the clam chowder and black bean dip that were implicated in the recent botulism poisonings made the foods appear shelf-stable. The clam chowder was packaged in a plastic bag inside a cardboard carton. The bean dip was packaged in a resealable plastic tub. These items were displayed in refrigerated cases in the supermarket. While both items had a ''keep refrigerated'' statement on their labels, consumers failed to maintain these products under refrigeration.

Most consumers seem to understand that foods that are displayed only in the refrigerated section of a grocery store, such as dairy products, eggs, cold cuts, fresh meats, poultry, and seafood, must be refrigerated to maintain their quality. While it is unlikely that a majority of consumers are aware of the hazards and food safety issues that temperature abuse of these products can present, it is likely that most consumers will refrigerate these foods even in the absence of labeling instructions to do so for safety. Therefore, the fact that these foods are refrigerated does not really provide evidence of the effectiveness of the ''keep refrigerated'' instructions in their labeling.

Foods such as mustard, salad dressings, jams, jellies, salsa, and spaghetti sauce bear a statement advising refrigeration once the product is opened to retard deterioration in the quality of the food. Nonetheless, consumers often do not refrigerate these foods. Although consumers may notice a deterioration in flavor, color, or texture over time, they may not associate foodborne illness with consumption of these products. Therefore, consumers do not seem to associate safety concerns with the ''keep refrigerated'' or ''refrigerate after opening'' statements.

The agency is concerned that consumers may not be aware that some newer, less traditional, packaged foods need refrigeration to maintain their safety. Some examples are fresh cut fruits and vegetables, food packaged in cardboard containers resembling shelf-stable packages (such as the previously mentioned clam chowder and bean dip), and vacuum or modified (reduced oxygen) atmosphere packaged products in clear flexible packaging. Consumer understanding of the significance or reason for advising that a product be kept refrigerated is likely hampered by the rapidly expanding marketing of foods having convenient preparation and ''close to fresh'' product characteristics.

In addition, as previously mentioned, the food industry is developing new types of foods with extended shelf life (i.e., the length of time that a product may be stored without deterioration) that have to be refrigerated. Foods known as ''partially processed'' or ''minimally processed'' may have received a heat process or other preservation treatment during manufacturing that reduces the microbiological load in the food but that does not render the food ''commercially sterile.'' These partially processed foods share the hazard common to all potentially hazardous foods, i.e., ability to support the growth of pathogens, unless they are refrigerated. Thus, if only a ''keep refrigerated'' label appears on these types of foods, and consumers choose not to pay attention to it, the consumers would be taking a significant risk.

The agency is also concerned about the potential abuse of a category of products (e.g., low acid canned foods that are not otherwise preserved) that need refrigeration after being opened. The potential for temperature abuse of these products may be even greater than that for foods that need constant refrigeration. These products are generally displayed in a section of the store that is not refrigerated, and these products are provided in packaging similar to foods that do not need refrigeration even after opening. Even though these shelf-stable foods may bear storage instructions for the unused portion, the need for refrigeration is frequently not conveyed on the label, or not conveyed in a way that consumers can see and understand.

Current labeling of shelf-stable packaged foods is not adequate because the same label statements, e.g., ''keep refrigerated'' or ''refrigerate after opening,'' appear both on foods that are potentially hazardous and on foods that do not pose a hazard but that are refrigerated to retard deterioration in quality. The labeling of potentially hazardous foods that need refrigeration should distinguish these products from products for which refrigeration is only to protect quality. FDA is concerned that, without adequate labeling on these potentially hazardous products, efforts by the food industry to develop new types of foods with extended shelf life prior to being refrigerated and while under refrigeration will result in more illnesses.

Further, different formulations and processing methods for different

versions of the same food, such as pumpkin pie, may or may not need refrigeration for safety. In addition, different versions of these foods can be displayed in different sections of the retail store, with the ''keep refrigerated'' statement on the version of the food that needs refrigeration as the only indication that there is a difference in safety considerations among the versions of the product. Furthermore, the ''keep refrigerated'' statement often appears in small print and is placed on an obscure part of the label. Therefore, the consumer may not understand or interpret the ''keep refrigerated'' statement as an instruction about what must be done to maintain the safety of the product.

Moreover, ''keep refrigerated'' or ''refrigerate after opening'' statements generally do not include the reason the product is to be refrigerated. The agency regards it as unlikely that most consumers know and are able to distinguish the underlying reasons for a ''keep refrigerated'' label statement when comparing products that bear that statement to maintain microbiological safety with products that bear that statement for maintaining quality. Therefore, consumers would have no reason to consider one such statement any more important for product safety than another. Thus, the statements ''keep refrigerated'' or ''refrigerate after opening'' alone are not adequate to appropriately alert consumers to the importance of properly handling potentially hazardous foods.

III. Labeling Options Considered

The agency has considered the recommendations offered by CDC, NACMCF, AFDO, and NFPA. In a memorandum dated February 14, 1995 (Ref. 5), CDC recommended that food labels advising refrigeration should be reviewed. CDC maintained that labels advising ''keep refrigerated'' may not be sufficient to warn consumers about the health risks associated with noncompliance. Further, CDC advised that for foods for which refrigeration is the only barrier to prevent growth of *C. botulinum*, the label should identify the risks of botulism if mishandled.

FDA has also considered the labeling recommendations for foods requiring refrigeration by consumers that have been offered by NACMCF, NFPA, and AFDO (Refs. 1, 2, and 4). NACMCF maintained that consumers have difficulty distinguishing the differences among various label statements and their relationship to product safety. Therefore, it recommended that the following label statement be used on packaged food that poses a safety hazard if temperature abused: ''IMPORTANT MUST BE KEPT REFRIGERATED''.

Recommendations from NFPA and AFDO recognize two categories of foods. Group A foods are potentially hazardous, packaged, processed foods that must be refrigerated for safety reasons, and Group B foods are products that are intended to be refrigerated but that do not pose a safety hazard if temperature abused. The recommended label statement for Group A foods is: ''IMPORTANT: Must Be Kept Refrigerated''.

The recommended label statement for Group B foods is ''keep refrigerated,'' although such products would be allowed to utilize the Group A suggested label statement.

A. Analysis of Options

FDA agrees with CDC that the label statement ''keep refrigerated'' may not be sufficient to warn consumers about a health risk. However, the agency does not agree that the label should specifically identify the risk of botulism because it is not the only risk if foods that need refrigeration are temperature abused.

While FDA finds considerable merit in the labeling recommendations of NACMCF, NFPA, and AFDO, the agency is concerned that these recommendations do not inform consumers of the reasons for refrigeration of foods and do not fully differentiate the types of foods that should bear a ''keep refrigerated'' label. Moreover, the suggested label statements will not eliminate the confusion generated by the current voluntary label statements used on foods to be refrigerated, especially if foods that do not pose a safety hazard are permitted to bear the same labeling statements as those that do pose a safety hazard if not refrigerated.

Having considered these recommendations, the agency is recommending an approach that is somewhat different than those suggested in the recommendations that it has received. In the agency's view, labeling will be more effective if it is more specific to the types of hazards that are presented, and to the types of storage conditions that are necessary, after the product is opened. In FDA's view, this specificity is provided if foods that need refrigeration are divided into three groups. The first group, Group A, are the foods that were in NFPA's and AFDO's Group A foods that are potentially hazardous and that must be kept refrigerated for safety reasons. Group B includes foods that are shelf-stable but that need refrigeration after opening for safety. Group C (described as Group B foods in the NFPA and AFDO recommendations) include foods that are refrigerated only to retard deterioration in quality.

FDA has sought to craft label statements that will help consumers to differentiate among these types of foods. Phrases such as ''to maintain safety'' and ''for quality'' are essential in drawing a distinction between Groups A and B on the one hand and Group C on the other. Furthermore, the agency agrees with the recommendations of NACMCF, NFPA, and AFDO that the term ''Important'' would help to underscore this distinction and to indicate the significance of the statement. The phrase ''after opening,'' or some similar statement, is essential to distinguish Group B from Group A.

Thus, the agency considers that the statement ''Important must be kept refrigerated to maintain safety'' for Group A foods is appropriate because it can adequately convey to consumers that continued refrigeration is mandatory to reduce safety risks. Similarly, the agency considers ''Important must be refrigerated after opening to maintain safety'' an appropriate label statement for Group B foods because such foods are shelf-stable and may pose a health hazard only after opening. In contrast, ''refrigerate for quality'' or ''keep refrigerated for quality'' for Group C foods is sufficient, in the agency's opinion, to distinguish this category from Groups A and B and to inform consumers that refrigeration is only necessary to retard deterioration in product quality.

B. Labeling Placement and Prominence

In addition to label statements that are focused on the type of product and the risk it represents, placing the statements on the label in a way that gives them appropriate prominence is critical to ensuring that the label statements will be seen, read, and understood. The placement and prominence guidelines suggested by NFPA are particularly useful and helpful in this regard. NFPA recommended that the label statements be set off by the use of hairlines at the top and bottom of the statement area. The type should: (1) Be on a contrasting background; (2) utilize a single, easy-to-read style and size; (3) have at least one point leading (space between two lines of text); and (4) ensure that letters never touch. On Group A and B foods, the word ''IMPORTANT'' should be in all capital letters, while the remaining words should use uppercase and lowercase letters, with the first letter in each word capitalized. The hairlined area should appear on the label

prominently and conspicuously as compared to other words, statements, designs, or devices. FDA strongly agrees and urges all firms to follow these recommendations. In addition, the agency notes that its general approach to type size of label information is that it should be not less than one-sixteenth inch unless the package is too small to accommodate this type size. The agency encourages placement of this statement on the principal display panels, at least for group A and B foods. If the statement does not fit on the principal display, it should be placed on the information panel.

C. FDA Labeling Policy

To clarify this guidance, the agency has delineated each of the three groups and developed model statements for each:

1. *Group A Foods*

Group A foods are potentially hazardous foods, which, if subjected to temperature abuse, will support the growth of infectious or toxigenic microorganisms that may be present. Outgrowth of these microorganisms would render the food unsafe. Foods that must be refrigerated for food safety possess the following characteristics: (1) Product pH > 4.6; (2) water activity a_w > 0.85; (3) do not receive a thermal process or other treatment in the final package that is adequate to destroy foodborne pathogens that can grow under conditions of temperature abuse during storage and distribution; and (4) have no barriers (e.g., preservatives such as benzoates, salt, acidification), built into the product formulation that prevent the growth of foodborne pathogens that can grow under conditions of temperature abuse during storage and distribution.

The appropriate label statement for Group A foods is:

IMPORTANT Must Be Kept Refrigerated To Maintain Safety

2. *Group B Foods*

Group B includes those foods that are shelf-stable as a result of processing, but once opened, the unused portion is potentially hazardous unless refrigerated. These foods possess the following characteristics: (1) Product pH > 4.6; (2) water activity a_w > 0.85; (3) receive a thermal process or other treatment that is adequate to destroy or inactivate foodborne pathogens in the unopened package, but after opening, surviving or contaminating microorganisms can grow and render the product unsafe; and (4) have no barriers (for example, preservatives such as benzoates, salt, acidification) built into the product formulation to prevent the growth of foodborne pathogens after opening and subsequent storage under temperature abuse conditions.

The appropriate label statement for Group B foods is:

IMPORTANT Must Be Refrigerated After Opening To Maintain Safety

3. *Group C Foods*

Group C are those foods that do not pose a safety hazard even after opening if temperature abused, but that may experience a more rapid deterioration in quality over time if not refrigerated. The manufacturer determines whether to include on the label a statement that refrigeration is needed to maintain the quality characteristics of the product to maximize acceptance by the consumer. These foods do not pose a safety problem. Foods in this group possess one or more of the following characteristics to ensure that the food does not present a hazard if temperature abused: (1) Product pH ≤ 4.6 to inhibit the outgrowth and toxin production of *C. botulinum*; or (2) water activity a_w ≤ 0.85; or (3) have barriers built into the formulation (for example, preservative systems such as benzoates, salt, acidification) to prevent the growth of foodborne pathogens if the product is temperature abused.

The suggested optional label statement for Group C foods is:
''Refrigerate for Quality''
or some other statement that explains to the consumer that the storage conditions are recommended to protect the quality of the product. To avoid confusion between refrigeration for safety purposes and refrigeration for quality reasons, Group A and Group B statements should not be used on Group C foods.

The agency is publishing this document to provide this guidance by the quickest means to as many manufacturers as possible, so that they may begin using the label statements. If manufacturers follow this guidance, the consumer will have clear, concise, and prominent labeling information for maintaining the safety of potentially hazardous food products. Inclusion of these statements in the labeling of appropriate foods will help the consumer recognize when appropriate storage temperatures are needed to maintain the safety or quality of those foods. Such information will reduce the likelihood of temperature abuse of the food and, consequently, reduce the potential for foodborne illness and death.

While this guidance is primarily intended to address the need for safe handling of potentially hazardous foods by consumers, the agency recognizes that there also is a need for safe handling during the transportation and distribution of these foods. The Food Safety and Inspection Service of the U.S. Department of Agriculture and FDA have jointly published an advance notice of proposed rulemaking in the Federal Register of November 22, 1996 (61 FR 59372) to solicit comments on approaches that the two agencies may take to foster safety improvements in the storage and transportation of potentially hazardous foods. Therefore, this guidance does not address how foods that need refrigeration during transportation and storage should be labeled.

IV. Consumer Education

Most consumers are not aware of the hazards associated with temperature abuse of foods needing refrigeration, especially foods that use newer, less traditional means of packaging. If firms follow the guidance set out in this document, it will help consumers to recognize the difference between the messages, ''refrigerate for safety'' and ''refrigerate for quality.'' The agency recognizes, however, that a coordinated public education campaign is needed to ensure that consumers understand the

significance of the differences in these messages. Given the significance of the underlying problem, FDA intends to undertake an educational effort, including press releases and consumer pamphlets. The agency requests the cooperation and assistance of industry and other private groups in this effort. The agency also requests comments on additional ways to educate the consumer.

The guidance represented here reflects FDA's current thinking on safe handling labeling for foods that need refrigeration by the consumer. This document does not bind FDA and does not create or confer any rights, privileges, benefits, or immunities for or on any persons.

Interested persons may 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 the brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Recommendations of the National Advisory Committee on Microbiological Criteria for Foods for Refrigerated Foods Containing Cooked, Uncured Meat or Poultry Products that are Packaged for Extended Refrigerated Shelf Life and that are Ready-To-Eat or Prepared with Little or No Additional Heat Treatment, January 31, 1990.

2. Guidelines for the Development, Production, Distribution, and Handling of Refrigerated Foods, National Food Processors Association, 1989.

3. Letter from J. Corby, New York Department of Agriculture and Markets to A. Dell'Aria, Virginia Department of Agriculture, September 8, 1995.

4. Memorandum from A. Dell'Aria, AFDO, December 20, 1995.

5. Letter from P. Griffin and R. Tauxe, CDC to K. Wachsmuth, FDA, February 14, 1995.

Dated: February 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4364 Filed 2–21–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[R–38]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Conditions of Participation for Rural Health Clinics, 42 CFR 491.9 Subpart A; *Form No.:* HCF–AR–38; *Use:* This information is needed to determine if rural health clinics meet the requirements for approval for Medicare participation. *Frequency:* Other (Initial application for Medicare); *Affected Public:* Individuals or Households; Business or other for profit; Not for profit institutions; Farms; Federal Government; and State, Local or Tribal Government; *Number of Respondents:* 3,076; *Total Annual Hours:* 9,744.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, e-mail your request, including your address and phone number, 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 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: February 13, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–4374 Filed 2–21–97; 8:45 am]

BILLING CODE 4120–03–P

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice.

The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESS: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7057; fax 301/402–0220). A signed Confidential Disclosure Agreement (CDA) will be required to receive copies of the patent applications.

Chromosomal Markers and Diagnostic Tests For Manic-Depressive Illness

S Detera-Wadleigh (NIMH), E Gershon (NIMH), J Badner (NIMH), L Goldin (NIMH), W Berrettini (Thomas Jefferson University), T Yoshikawa (NIMH), A Sanders (NIMH), L Esterling (NIMH)

Serial No. 60/029,278 filed 28 Oct 96

Licensing Contact: Stephen Finley, 301/496–7735, ext. 215.

Bipolar disease, or manic-depressive illness, affects approximately 1% of the population and is generally controlled through medication. Not all patients respond similarly to a given medication. A medication that works well in one individual may be ineffective in another individual. It is unclear why this is, but it has been theorized that bipolar disease may involve multi-genes, possible on several chromosomes. It is not known if one genetic locus dominates over another, but if one does, then it may explain the variable