disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain Confidential Business Information must be provided by the submitter for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments filed pursuant to this notice will be available for public inspection in Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Susan Stanton, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Office location and telephone number: Rm. 716, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703–305–6359).

SUPPLEMENTARY INFORMATION: Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), the Administrator may, at his discretion, exempt a State agency from any registration provision of FIFRA if he determines that emergency conditions exist which require such exemption. The Applicant has requested the Administrator to issue a specific exemption for the use of the fungicide, fluazinam, available as Fluazinam 50WP from ISK Biotech Corporation, to control *Sclerotinia blight* on up to 40,000 acres of peanuts in Virginia. Information in accordance with 40 CFR part 166 was submitted as part of this request.

According to the Applicant, the only fungicide registered to control *Sclerotinia blight* of peanuts is iprodione. Due to the development of fungal isolates resistant to iprodione and increased microbial degradation of iprodione in the soil, this fungicide no longer provides adequate control of Sclerotinia blight. The Applicant estimates that yield losses of between 10 and 50 percent will occur on up to 40,000 acres of peanuts this year if an effective alternative to iprodione is not made available to peanut growers. Yield losses of this magnitude are expected to result in economic losses of approximately $100 to $500 per acre.

Under the proposed exemption, applications of Fluazinam 50WP would be made at 1.0 to 2.0 pounds of product (0.5 to 1.0 pounds a.i.) per acre. Applications would be repeated at approximately 4 week intervals as necessary to control the disease. A maximum of 4.0 pounds of product (2.0 pounds a.i.) would be applied per acre per season. No applications would be made within 30 days of harvest. A maximum of 160,000 pounds of product (80,000 pounds a.i.) may be needed to treat up to 40,000 acres of peanuts.

This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 require that the Agency publish notice of receipt in the Federal Register and solicit public comment on an application for a specific exemption proposing use of a new chemical (i.e., an active ingredient not contained in any currently registered pesticide) [40 CFR 166.24 (a)(1)]. Fluazinam is a new chemical. Accordingly, interested persons may submit written views on this subject to the Field Operations Division at the address above. The Agency will review and consider all comments received during the comment period in determining whether to issue the emergency exemption requested by the Virginia Department of Agriculture and Consumer Services.

Dated: May 5, 1992.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 92–11238 Filed 5–12–92; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL RESERVE SYSTEM

IDC Bancorp, Inc.; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application 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 to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than June 5, 1992.

A. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. IDC Bancorp, Inc., Chicago, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of International Bank of Chicago, Chicago, Illinois.

Board of Governors of the Federal Reserve System, May 7, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92–11196 Filed 5–12–92; 8:45 am]

BILLING CODE 6210–01–F

Dale Erney Pahlke, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 1, 1992.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Dale Erney Pahlke, Hebron, North Dakota; to acquire 33.8 percent of the voting shares of Hebron Banshares, Inc., Hebron, North Dakota, and thereby indirectly acquire Security Bank of Hebron, Hebron, North Dakota.

2. Raymond Edward Reich, Richarton, North Dakota; to acquire 23.1 percent of the voting shares of Hebron Banshares, Inc., Hebron, North Dakota, and thereby

indirectly acquire Security Bank of Hebron, Hebron, North Dakota.

3. Stanley Harold Sayler, Hebron, North Dakota; to acquire 16.9 percent of the voting shares of Hebron Banshares, Inc., Hebron, North Dakota, and thereby indirectly acquire Security Bank of Hebron, Hebron, North Dakota.

Board of Governors of the Federal Reserve System, May 7, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc 92-11195 Filed 5-12-92; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse and Mental Health Administration

Office for Substance Abuse Prevention; Meeting

Pursuant to Public Law 92-463, notice is hereby given of a meeting of an advisory committee of the Office for Substance Abuse Prevention in May 1992.

The National Advisory Committee on Substance Abuse Prevention will be performing review of applications for Federal assistance; therefore, portions of this meeting will be closed to the public as determined by the Acting Administrator, ADAMHA, in accordance with 5 U.S.C. 552b(c)(6) and 5 U.S.C. app. 2 10(d).

A summary of the meeting and roster of committee members may be obtained from: Ms. Dee Herman, OSAP Committee Management Officer, Alcohol, Drug Abuse and Mental Health Administration, Rockwall II, room 630, 5600 Fishers Lane, Rockville, MD 20857 (Telephone: 301-443-4783).

Substantive program information may be obtained from the contact whose name, room number, and telephone number are listed below.

Committee Name: National Advisory Committee on Substance Abuse Prevention.

Meeting Date: May 28-29, 1992.

Place: Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Open: May 28, 9:30 a.m.-12:30 p.m., May 29, 9 a.m.-3 p.m.

Closed: Otherwise.

Contact: Yuth Nimit, Ph.D., room 630, Rockwall II, Telephone: (301) 443-4783.

Dated: May 7, 1992.

Peggy W. Cockrill,

Committee Management Officer, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 92-11130 Filed 5-12-92; 8:45 am]

BILLING CODE 4160-20-M

Centers for Disease Control

[Program Announcement 242]

Cooperative Agreements for Childhood Lead Poisoning Intervention Study; Availability of Funds for Fiscal Year 1992

Introduction

The Centers for Disease Control (CDC), the Nation's prevention agency, announces that cooperative agreement applications are being accepted for Fiscal Year 1992 for the following study: Blood Lead Levels Following Environmental Intervention, BLLFEI, which is a prospective study of blood lead levels in lead-poisoned children following environmental inteventions to reduce household lead exposure from lead paint or household dust contaminated by lead paint.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Environmental Health. (For ordering a copy of Healthy People 2000, see **WHERE TO OBTAIN ADDITIONAL INFORMATION** section.)

Authority

This program is authorized under sections 301(a) [42 U.S.C. 241(a)] and 317A [42 U.S.C. 247b-1] of the Public Health Service Act, as amended. Program regulations are set forth in title 42, Code of Federal Regulations, part 51b.

Eligible Applicants

Eligible applicants are state health departments or their bona fide agents or instrumentalities with active programs to screen, identify, and medically and environmentally manage lead-poisoned children. This includes the district of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau and federally-recognized Indian tribal governments.

Applicants are encouraged to collaborate with academic institutions where appropriate to obtain scientific and technical assistance in study design and implementation. If a state agency applying for cooperative agreement funds is other than the official state health department, written concurrence by the state health department must be provided.

Note: Eligible applicants may enter into contracts, including consortia agreements, as necessary to meet the requirements of the program and strengthen the overall application.

Availability of Funds

Approximately $200,000 will be available in Fiscal Year 1992 to fund up to four new cooperative agreements. Awards of approximately $50,000 to $100,000 each are expected to begin on or about September 30, 1992. Awards will be made for 12-month budget periods within project periods not to exceed 3 years. Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Purpose

This cooperative agreement program is intended to assist state and local health departments in conducting structured studies of changes in blood lead levels in lead-poisoned children following environmental interventions to reduce exposure within households to lead paint and leaded dust. It presumes that a program already exists to screen children for lead poisoning, inspect the dwellings associated with lead-poisoned children, and ensure that some form of lead exposure control is carried out. Funding and technical assistance are intended to enable recipients to conduct additional case-tracking, data-collection, and data-analysis activities which are necessary for the study, but which are not part of routine case-management. These awards are not intended to fund screening, abatement, or other lead exposure control activities.

Goals

1. To obtain quantitative estimates of both short-term and long-term changes in the blood lead levels of lead-poisoned children not requiring chelation therapy, (see CDC Statement, Preventing Lead Poisoning in Young Children, dated October 1991, Chapter 7, "Diagnostic Evaluation and Medical Management of Children with Blood Lead Levels => 20 ug/dL"), following environmental interventions to reduce or eliminate exposure within households to lead paint or dust contaminated by lead paint.

2. To obtain estimates of short-term and long-term changes in amounts or levels of house dust lead in dwellings that have undergone interventions to reduce household exposure to lead paint or leaded dust.

3. To identify factors that may modify changes in blood lead levels or dust lead

exposure following environmental interventions to reduce household exposure to lead paint or leaded dust.

4. If possible, to evaluate and compare alternative environmental intervention strategies and, where applicable, to evaluate new or revised local regulations, procedures, or standards, directed towards reducing household exposure to lead paint of leaded dust.

Program Requirements

To be able to fulfill the objectives and carry out the activities of this cooperative agreement, the recipient must:

1. Have direct responsibility for, or have and maintain a close working relationship with, an ongoing program that screens children for elevated blood lead levels (or monitors screening performed by others), identifies children with elevated blood lead levels, and provides for or ensures the appropriate medical and environmental management of such children, including obtaining follow-up blood lead measurements at appropriate intervals.

2. Have direct responsibility for, or have and maintain, close connection with, inspection/intervention activities, which include inspecting residences of children with elevated blood lead levels for lead paint hazards and providing or ensuring some form of intervention intended to reduce household exposure to lead paint or leaded dust using generally acceptable practices. These intervention activities must meet the following minimal criteria:

- Strategies for lead paint abatement must use acceptable, safe methods of lead paint removal, enclosure, encapsulation, or repair of non-intact lead paint surfaces;
- Strategies for household dust control must use acceptable, safe methods of reducing lead dust burdens on household surfaces;
- all strategies should prevent the exposure of children to the abatement process;
- all strategies should protect abatement workers from excessive lead exposure;
- all strategies should provide for containment and cleanup of dust and debris generated by the intervention; and
- dwellings should be inspected after intervention to ensure adequate compliance with the intervention standards.

3. Recipients must demonstrate the capacity to collect and analyze data needed to fulfill the study objectives, including ability to obtain follow-up blood and dust lead measurements at required intervals.

4. Recipients must have experience in conducting relevant epidemiologic studies.

5. Recipients must have access to a laboratory with demonstrated proficiency in performing lead measurements.

Cooperative Activities

In addition to meeting the above program requirements, the recipient will be responsible for conducting all activities listed under A., below and CDC will be responsible for conducting all activities listed under B., below.

A. Recipient Activities:

1. enroll study subjects meeting specified eligibility criteria after obtaining informed consent;

2. collect demographic, behavioral, and household inspection data using structured interviews and data collection forms;

3. measure baseline blood lead levels, amounts or levels of house dust lead, and soil lead levels;

4. measure follow-up blood lead levels and amounts or levels of house dust lead at defined intervals; and

5. analyze collected data.

B. CDC Activities:

1. collaborate with recipient in revising and refining the approved study protocol;

2 provide technical advice on data collection and management;

3. assist in assessment of quality of laboratory measurements;

4. collaborate on data analysis and interpretation;

5. assist in preparation, provide editorial review, and assist in seeking publication of the report of study results.

Evaluation Criteria

Application will be reviewed and evaluated according to the following criteria (Maximum of 100 points):

1 *Study Protocol* (30%): The protocol's scientific soundness, its feasibility, its consistency with the project goals, and the extent to which it provides adequate detail for evaluation. Applicants should demonstrate the ability to carefully measure the impact and effectiveness of the intervention(s), while controlling for the effect of factors not part of the environmental intervention(s) (such as changes in other lead exposures, and nutritional and educational interventions). The ability to measure and compare different intervention strategies would be an asset but not a requirement for the study protocol.

2. *Access to Study Subjects* (20%): The extent to which the application documents the presence of an ongoing childhood lead poisoning screening program with the ability to identify and follow-up the number of lead poisoning cases required to meet study criteria.

3. *Ability to Ensure Inspection and Intervention* (25%): The extent to which the application documents the ability to inspect dwellings for lead hazards, to define proposed or existing environmental intervention(s), and to ensure completion of the intervention(s) in accordance with any established local guidelines, statutes, or regulations.

4. *Laboratory Capacity* (10%): The extent to which the application documents access to a laboratory with demonstrated proficiency in performing lead measurements. The adequacy of available facilities to support the project will also be evaluated.

5. *Project Personnel* (10%): The extent to which the application documents qualifications and time commitments adequate to complete the study and meet the project goals.

6. *Experience* (5%): The extent of the applicant's experience in conducting similar studies.

7. *Budget Justification and Adequacy of Facilities* (unscored): The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of cooperative agreement funds.

Continuation Awards

Noncompeting continuation awards for the second and third budget periods will be made on the basis of the availability of funds and the following criteria:

1. Satisfactory progress is made towards achieving first budget year objectives for implementation of the study protocol.

2. The proposed activities for the new budget period are consistent with the study protocol and project goals.

3. The budget request is clearly explained, adequately justified and consistent with the intended use of grant funds.

Other Requirements

Human Subjects

Individual state projects may include research on human subjects, including access to personal identifiers to link relevant data sets. Therefore, if applicable, applicants must comply with Public Law 93–148 regarding the protection of human subjects. Assurances must be provided that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be

responsible for providing evidence of this assurance in accordance with the appropriate guidelines and forms provided in the application kit.

Executive Order 12372 Review

Applications are subject to the Intergovernmental review of Federal programs as governed by Executive Order 12372. Executive Order 12372 sets up a system for state and local government review of proposed Federal assistance applications. Applicants (other than federally-recognized Indian tribal governments) should contact their state Single Point of Contacts (SPOCs) as early as possible to alert them to the prospective applications and receive any necessary instructions on the state process. For proposed projects serving more than one state, the applicant is advised to contact the SPOC of each affected state. A current list of SPOCs is included in the application kit. If SPOCs have any state process recommendations on applications submitted to CDC, they should forward them to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., room 300, Mailstop E–14, Atlanta, Georgia 30305, no later than 60 days after the deadline date for new and competing awards. The funding agency does not guarantee to "accommodate or explain" state process recommendations it receives after that date.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.283.

Application Submission and Deadlines

The original and two copies of the application PHS Form 5161–1 must be submitted to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., room 300, Mailstop E–14, Atlanta, Georgia 30305, on or before July 1, 1992.

Applicants should follow the guidance provided in PHS Form 5161–1 in preparing the applications, and are encouraged to be concise. You may refer to appendices to provide detailed program descriptions and program protocols.

1. Deadline

Applications shall be considered as meeting the deadline if they are either:

A. Received on or before the deadline date, or

B. Sent on or before the deadline date and received in time for submission for the review process. Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

2. Late Applications

Applications which do not meet the criteria in 1.A. or 1.B. above are considered late applications and will be returned to the applicant.

A one-page, single-spaced, typed abstract must be submitted with the application. The heading should include the title of grant program, project title, organization, name and address, project director, and telephone number. The abstract should include a brief summary of the study protocol, a brief description of the population of study subjects and of laboratory capacity, and a brief synopsis of the applicant's experience in conducting similar studies.

Where to Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management assistance may be obtained from Lisa Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., room 300, Mailstop E–14, Atlanta, Georgia 30305, (404) 842–6630. Programmatic technical assistance may be obtained from Ned Hayes, M.D., Medical Epidemiologist, or Jerry Hershovitz, Deputy Chief, Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health and Injury Control, Centers for Disease Control, 1600 Clifton Road, NE., Mailstop F–28, Atlanta, Georgia 30333, (404) 488–4880.

Please refer to Announcement Number 242 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (Telephone (202) 783–3238).

Dated: May 7, 1992.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 92–11165 Filed 5–12–92; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 92F–0161]

Diversey Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Diversey Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of an aqueous solution of iodine and hypochlorous acid generated by the dilution of an aqueous acidic (21.5 percent nitric acid) solution of iodine monochloride as a sanitizing solution to be used on dairy-processing equipment, in addition to food-processing equipment and utensils.

FOR FURTHER INFORMATION CONTACT: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409B(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 1B245) has been filed by Diversey Corp., 1532 Biddle Ave., Wyandotte, MI 48192. The petition proposes to amend the food additive regulations in § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) to provide for the safe use of an aqueous solution of iodine and hypochlorous acid generated by the dilution of an aqueous acidic (21.5 percent nitric acid) solution of iodine monochloride as a sanitizing solution to be used on dairy-processing equipment, in addition to food-processing equipment and utensils.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: May 4, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-11129 Filed 5-12-92; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 92F-0163]

Mitsubishi Kasei Corp. and Mitsubishi Kasei America, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a petition has been filed on behalf of Mitsubishi Kasei Corp. and Mitsubishi Kasei America, Inc., proposing that the food additive regulations be amended to provide for the safe use of sucrose fatty acid esters as an emulsifier in coffee and tea beverages.

FOR FURTHER INFORMATION CONTACT: Dennis Keefe, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9519.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2A4321) has been filed on behalf of Mitsubishi Kasei Corp., 5-2, Marunouchi 2-chome, Chiyoda-ku, Tokyo, Japan, and Mitsubishi Kasei America Inc., 81 Main St., White Plains, NY 10601. The petition proposes to amend the food additive regulations in § 172.859 *Sucrose fatty acid esters* (21 CFR 172.859) to provide for the safe use of sucrose fatty acid esters as an emulsifier in coffee and tea beverages.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: May 4, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-11128 Filed 5-12-92; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 92D-0137]

Animal Drug Clinical Investigator and Monitor; Draft Guideline; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of a draft document entitled "Guideline on the Conduct of Clinical Investigations: Responsibilities of Clinical Investigators and Monitors for Investigational New Animal Drugs," prepared by the Center for Veterinary Medicine (CVM). This draft guideline applies to clinical investigators and monitors of clinical investigations of new animal drugs and addresses the responsibilities of clinical investigators and monitors.

DATES: Written comments by July 13, 1992.

ADDRESSES: Submit written requests for single copies of the draft guideline to the Communications and Education Branch (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8755. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guideline to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The draft guideline and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Kristi O. Smedley, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8737.

SUPPLEMENTARY INFORMATION: The draft guideline entitled "Guideline on the Conduct of Clinical Investigations: Responsibilities of Clinical Investigators and Monitors for Investigational New Animal Drugs," is being developed for use by clinical investigators and monitors of clinical investigations for guidance in the proper conduct of clinical investigations.

The term clinical investigator includes investigators employed by the sponsoring pharmaceutical firm, investigators under contract to the sponsoring pharmaceutical firm to perform a clinical trial, and sponsor-investigators (individuals who sponsor an investigational new animal drug). Monitors represent the pharmaceutical sponsor and ensure that the study is conducted according to the protocol. Although proper monitoring of new animal drug investigations is covered under an existing general guideline ("Guideline for the Monitoring of Clinical Investigations," January 1988), the current draft guideline will supersede the former guideline insofar as clinical investigations of animal health products are concerned.

The draft guideline addresses the responsibilities under 21 CFR 511.1 of clinical investigators for new animal drugs and monitors of clinical investigations of such drugs. The guideline presents approaches acceptable to FDA for the conduct and monitoring of clinical investigations of new animal drugs by reflecting principles commonly recognized by the scientific community as appropriate and necessary to collecting scientific data. It is equally applicable to intramural and extramural research efforts. A person may follow the guideline or may choose to follow alternate procedures. The person choosing alternate procedures may wish to discuss the matter further with the agency to prevent an expenditure of money and effort on activities that may later be determined to be unacceptable to FDA.

This draft guideline does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person. Where the guideline states a requirement imposed by statute or regulation, however, the requirement is law and its force and effect are not changed in any way by virtue of its inclusion in the guideline.

Dated: May 7, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-11176 Filed 5-12-92; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 92E-0004]

Determination of Regulatory Review Period for Purposes of Patent Extension; Meta II, Model 1204 Cardiac Pacing System*

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Meta II, Model 1204 Cardiac Pacing System* and is publishing this notice of that determination as required by law. FDA

has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John S. Ensign, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 158(g)(3)(B).

FDA recently approved for marketing the medical device Meta II, Model 1204 Cardiac Pacing System®. Meta II, Model 1204 Cardiac Pacing System® is indicated for use in maintaining and regulating cardiac rate in patients exhibiting generally acceptable symptoms and indications for long-term cardiac pacing. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Meta II, Model 1204 Cardiac Pacing System® (U.S. Patent No. 4,702,253) from Telectronics, N.V., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated March 18, 1992, advised the Patent and Trademark Office that this medical device had undergone a regulatory review period, and that the approval of Meta II, Model 1204 Cardiac Pacing System® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Meta II, Model 1204 Cardiac Pacing System® is 448 days. Of this time, zero days occurred during the testing phase of the regulatory review period, while 448 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun:* Not applicable. Applicant did not perform clinical investigations utilizing the patented device, but, rather, sought and was granted marketing approval based on a supplemental filing to a previously approved premarket approval application (PMA).

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act:* July 20, 1990. FDA has verified the applicant's claim that the PMA for Meta II, Model 1204 Cardiac Pacing System® (PMA-P880038/S13) was submitted on July 20, 1990.

3. *The date the application was approved:* October 11, 1991. FDA has verified the applicant's claim that PMA P880038/S13 was approved on October 11, 1991.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 349 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 13, 1992, submit to the Dockets Management Branch (address above) written comments and ask for redetermination. Furthermore, any interested person may petition FDA, on or before November 9, 1992, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 4, 1992.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 92-11127 Filed 5-12-92; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Final Funding Criteria and Priorities for Community and Migrant Health Center Activities for the Provision of Technical and Non-Technical and Non-Financial Assistance to Community and Migrant Health Centers, and for Cooperative Agreements to Support Community and Migrant Health Centers

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final funding criteria and priorities.

SUMMARY: The Health Resources and Services Administration announces final funding priorities for continuation activities and improvements under sections 330 and 329 of the Public Health Service (PHS) Act for Community Health and Migrant Health Centers (C/MHC); section 333(d) cooperative agreements and section 330(f)(1) and 329(g)(1) technical and non-financial assistance.

Proposed funding priorities were published for public comment in the **Federal Register** on March 13, 1992, at 57 FR 8883. Three comments were received during the 30-day comment period.

COMMENT AND RESPONSE: One respondent commented that the criteria for funding major capital improvements contain only one "priority", i.e., for correction of fire and life safety codes. The respondent suggested that other priorities for recruitment and retention projects and for community need should be included.

The Secretary wishes to point out that under the subpart of the notice which discusses C/MHC activities, $15 million is made available to support C/MHC improvement activities that go beyond the current level of activities at C/MHCs. Emphasis for improvement activities will be on: (1) Retention and recruitment of primary care providers; (2) Correction of cited fire and life safety code violations involving imminent danger to patients and staff and that require under $100,000 in additional Federal funds; and (3) Provision of translation and culturally sensitive services.

In addition, within the $15 million for improvement activities, approximately $3 to $5 million will be available to support major capital improvement projects. The preference for funding is for proposals to correct existing fire and life safety code violations for which the grantee has been officially cited and for which the total amount of funds requested exceeds $100,000. However, it should be understood that proposals for other types of major capital improvement projects will be considered.

The Department reviews all C/MHC applications for compliance with standard criteria stipulated in the program regulations (42 CFR part 51c for CHC activities and part 56 for MHC activities) which relate to need and community impact, health service delivery capacity, management and finance, and governance. The Secretary believes that this is clear in the notice and has, therefore, concluded that no action is necessary to address the concern stated in the comment.

Three respondents commented about the published priority funding review criteria for national awards funded under sections 329(g)(1) and 330(f)(1) of the PHS Act for providing technical and non-financial assistance to C/MHCs. The respondents suggested that the notice should include a review criterion concerning a grant recipient's capability to provide assistance in the areas of environmental and occupational health services.

The Secretary notes that there are ongoing technical assistance activities in the area of environmental health services and recognizes the importance of these services as well as occupational health services. The Secretary acknowledges the oversight in not including a review criterion addressing these services in the notice and accepts the comments. Therefore, the funding criteria for national awards for technical and non-financial assistance is amended to include an additional criterion as follows: (6) environmental and occupational health services. All other proposed funding preferences and priorities published at 57 FR 8883 remain unchanged.

FOR FURTHER INFORMATION CONTACT: For technical assistance and general program information about the availability of sections 329 and 330 funds, contact Richard C. Bohrer, 9301) 443–2260. For additional information about funding under section 329(g)(1), contact Jack Egan, (301) 443–1153. Additional information about funding under sections 330(f)(1) and 330(d) can be obtained from Bonnie Lefkowitz, (301) 443–2270. For assistance on section 333(d) State-specific cooperative agreement retention and recruitment issues, contact Donald L. Weaver, M.D., (301) 443–2900. Additional information about current comprehensive perinatal care activities can be obtained from Beverly Wright, (301) 443–7587.

SUPPLEMENTARY INFORMATION: In the Catalog of Federal Domestic Assistance, the Community Health Center program is listed as Number 93.224; the Migrant Health Center program is Number 93.246; the program of technical and other non-financial assistance, including national organizations, for development and coordination of comprehensive primary care services is Number 93.130.

Dated: May 7, 1992.

John H. Kelso,

Acting Administrator.

[FR Doc. 92–11175 Filed 5–12–92; 8:45 am]

BILLING CODE 4160–15–M

Final Funding Priorities for Grants to Provide Health Care for the Homeless and Health Care Services for Homeless Children

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final funding priorities.

The Health Resources and Services Administration announces the final funding priorities for fiscal year (FY) 1992 for grants to provide health care for the homeless and health care services for homeless children, authorized under the authority of section 340 of the Public Health Service Act.

Proposed funding priorities were published for public comment in the **Federal Register** dated March 23, 1992, at 57 FR 10034. No comments were received during the 30-day comment period. Therefore, the proposed funding priorities remain unchanged.

Final Funding Priorities for FY 1992—New Starts

For FY 1992, funding priority will be given to:

—Applicants located in those States and other distinct geographic areas (for example, cities, counties, or designated health professional shortage areas) which have not previously received funds under section 340(a) of the PHS Act and/or

—Applicants which intend to serve a primarily rural homeless population.

Applicants which do not meet these priorities will be considered only if sufficient program funds are available.

Final Funding Priorities for FY 1992—Homeless Children

For FY 1992, funding priority will be given to:

—Applicants which currently receive funding under Section 340(a) of the PHS Act;

—Applicants which intend to serve a primarily rural population; and/or

—Public and nonprofit private children's hospitals that provide primary health services to a substantial number of homeless individuals.

Applicants which do not meet these priorities will be considered only if sufficient program funds are available.

Final Funding Priorities for FY 1992—Improvements

For FY 1992, funding priority will be given to: programs which expand the availability of and access to substance abuse services; innovative approaches to enhancing access to entitlement programs, including Supplemental Security Income; programs which develop or enhance relationships with shelters for homeless and runaway youth; programs which develop innovative programs in collaboration with other community-based organizations engaged in health care delivery to homeless clients; programs which develop innovative service arrangements for homeless individuals with HIV/AIDS; and programs which enhance quality assurance systems to improve their appropriateness in assessing services delivered to homeless individuals.

FOR FURTHER INFORMATION CONTACT: For technical assistance and general program information regarding the Health Care for the Homeless program an the Health Care Services for Homeless Children program, contact Ms. Joan Holloway, Director, Division of Special Populations Program Development, Bureau of Health Care Delivery and Assistance, (301)443–8134.