to comply with the data requirements of a Registration Standard is a basis for suspension under section 3(c)(2)(B) of FIFRA.

The DCNA Registration Standard required each affected registrant to submit materials demonstrating selection by the registrant of the options to address the data requirements. You applied for and were granted a generic data exemption and therefore, you relied on the efforts of others to provide the Agency with the required data. The basic manufacturer of DCNA for use in pesticide products voluntarily cancelled its DCNA products and is no longer generating the required data. As a result, the responsibility for generating the necessary data to support remaining DCNA registrations lies with the remaining registrants.

In a letter dated November 11, 1991, the Agency informed you and other registrants of DCNA products of the above status and required that you inform the Agency within 30 days of your receipt of the letter of the option(s) you were electing to take regarding the data requirements necessary to support your DCNA registration(s). Because the Agency has not received a response from you as a DCNA registrant to undertake the required testing or any other appropriate response (i.e., voluntary cancellation), the Agency is initiating through this Notice of Intent to Suspend the actions which FIFRA requires it to take under these circumstances.

B. EPTC

On September 4, 1990, EPA issued a Data Call-In Notice (DCI) under authority of FIFRA section 3(c)(2)(B) which required registrants of products containing EPTC used as an active ingredient to develop and submit data. These data were determined to be necessary to maintain the continued registration of affected products. Failure to comply with the requirements of a Data Call-In Notice is a basis for suspension under section 3(c)(2)(B) of FIFRA.

This DCI was re-issued to you on August 12, 1991. According to a return receipt, you received the DCI on August 19, 1991. The EPTC Data Call-In Notice required each affected registrant to submit materials relating to the election by the registrant of the options to address the data requirements. That submission was required to be received by the Agency within 90 days of the registrant's receipt of the DCI. Because the Agency has not received a response from you as an EPTC registrant to undertake the required testing or any other appropriate response, the Agency is initiating through this Notice of Intent to Suspend the actions which FIFRA requires it to take under these circumstances.

V. Conclusions

EPA has issued Notice(s) of Intent to Suspend on the dates indicated. Any further information regarding the Notice(s) may be obtained from the contact person noted above.

Dated: Dated May 6, 1992.

Michael M. Stahl,

Director, Office of Compliance Monitoring.

[FR Doc. 92-11237 Filed 5-12-92; 8:45 am]

BILLING CODE 6560-50-F

[OPP-60033; FRL-4064-9]

Intent to Suspend Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of issuance of notices of intent to suspend.

SUMMARY: This Notice, pursuant to section 6(f)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq., announces that EPA has issued Notices of Intent to Suspend pursuant to sections 3(c)(2)(B) and 4 of FIFRA. The Notices were issued following issuance of Section 4 Reregistration Requirements Notices by the Agency and the failure of registrants subject to the Section 4 Reregistration Requirements Notices to take appropriate steps to secure the data required to be submitted to the Agency. This Notice includes the text of a Notice of Intent to Suspend, absent specific chemical, product, or factual information. Table A of this Notice further identifies the registrants to whom the Notices of Intent to Suspend were issued, the date each Notice of Intent to Suspend was issued, the active ingredient(s) involved, and the EPA registration numbers and names of the registered product(s) which are affected by the Notices of Intent to Suspend. Moreover, Table B of this Notice identifies the basis upon which the Notices of Intent to Suspend were issued. Finally, matters pertaining to the timing of requests for hearing are specified in the Notices of Intent to Suspend and are governed by the deadlines specified in section 3(c)(2)(B). As required by section 6(f)(2), the Notices of Intent to Suspend were sent by certified mail, return receipt requested, to each affected registrant at its address of record.

FOR FURTHER INFORMATION CONTACT: Stephen L. Brozena, Office of Compliance Monitoring (EN-342), Laboratory Data Integrity Assurance Division, Environmental Protection Agency 401 M St., SW., Washington, DC 20460, (703) 308-8267.

SUPPLEMENTARY INFORMATION:

I. Text of a Notice of Intent to Suspend

The text of a Notice of Intent to Suspend, absent specific chemical, product, or factual information, follows:

United States Environmental Protection Agency

Office of Pesticides and Toxic Substances

Washington, DC 20460

Certified Mail

Return Receipt Requested

SUBJECT: Suspension of Registration of Pesticide Product(s) Containing _____ for Failure to Comply with the Section 4 Reregistration Requirements Notice for _____ Dated _____.

Dear Sir/Madam:

This letter gives you notice that the pesticide product registrations listed in Attachment I will be suspended 30 days from your receipt of this letter unless you take steps within that time to prevent this Notice from automatically becoming a final and effective order of suspension. The Agency's authority for suspending the registrations of your products is sections 3(c)(2)(B) and 4(d)(6) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Upon becoming a final and effective order of suspension, any violation of the order will be an unlawful act under section 12(a)(2)(J) of FIFRA.

You are receiving this Notice of Intent to Suspend because you have failed to comply with the terms of the Phase 2 Data Requirements for Reregistration Notice imposed pursuant to Section 4 of FIFRA. Section 4(d)(6) provides that the Administrator "shall issue a Notice of Intent to Suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if the Administrator determines that (A) progress is insufficient to ensure submission of the data required for such pesticide under a commitment made under paragraph (3)(B) within the time period prescribed by paragraph (4)(B) or (B) the registrant has not submitted such data to the Administrator within such time period."

The specific basis for issuance of this Notice is stated in the Explanatory Appendix (Attachment III) to this Notice. Affected products and the requirements which you failed to satisfy

are listed and described in the following three attachments:

Attachment I Suspension Report - Product List

Attachment II Suspension Report - Requirement List

Attachment III Suspension Report - Explanatory Appendix

The suspension of the registration of each product listed in Attachment I will become final unless at least one of the following actions is completed.

1. You may avoid suspension under this Notice if you or another person adversely affected by this Notice properly request a hearing within 30 days of your receipt of this Notice. If you request a hearing, it will be conducted in accordance with the requirements of section 6(d) of FIFRA and the Agency's procedural regulations in 40 CFR part 164.

Section 3(c)(2)(B), however, provides that the only allowable issues which may be addressed at the hearing are whether you have failed to take the actions which are the bases of this Notice and whether the Agency's decision regarding the disposition of existing stocks is consistent with FIFRA. Therefore, no substantive allegation or legal argument concerning other issues, including but not limited to the Agency's original decision to require the submission of data or other information, the need for or utility of any of the required data or other information or deadlines imposed, and the risks and benefits associated with continued registration of the affected product, may be considered in the proceeding. The Administrative Law Judge shall by order dismiss any objections which have no bearing on the allowable issues which may be considered in the proceeding.

Section 3(c)(2)(B)(iv) of FIFRA provides that any hearing must be held and a determination issued within 75 days after receipt of a hearing request. This 75-day period may not be extended unless all parties in the proceeding stipulate to such an extension. If a hearing is properly requested, the Agency will issue a final order at the conclusion of the hearing governing the suspension of your products.

A request for a hearing pursuant to this Notice must (1) include specific objections which pertain to the allowable issues which may be heard at the hearing, (2) identify the registrations for which a hearing is requested, and (3) set forth all necessary supporting facts pertaining to any of the objections which you have identified in your request for a hearing. If a hearing is requested by any person other than the registrant, that person must also state specifically why he asserts that he would be adversely affected by the suspension action described in this Notice. Three copies of the request must be submitted to: Hearing Clerk, A-110, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, and an additional copy should be sent to the signatory listed below. The request must be *received* by the Hearing Clerk by the 30th day from your receipt of this Notice in order to be legally effective. The 30-day time limit is established by FIFRA and cannot be extended for any reason. Failure to meet the 30-day time limit will result in automatic suspension of your registration(s) by operation of law and, under such circumstances, the suspension of the registration for your affected product(s) will be final and effective at the close of business 30 days after your receipt of this Notice and will not be subject to further administrative review.

The Agency's Rules of Practice at 40 CFR 164.7 forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding *ex parte* with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives. Accordingly, the following EPA offices, and the staffs thereof, are designated as judicial staff to perform the judicial function of EPA in any administrative hearings on this Notice of Intent to Suspend: The Office of the Administrative Law Judges, the Office of the Judicial Officer, the Administrator, the Deputy Administrator, and the members of the staff in the immediate offices of the Administrator and Deputy Administrator. None of the persons designated as the judicial staff shall have any *ex parte* communication with trial staff or any other interested person not employed by EPA on the merits of any of the issues involved in this proceeding, without fully complying with the applicable regulations.

2. You may also avoid suspension if, within 30 days of your receipt of this Notice, the Agency determines that you have taken appropriate steps to comply with the section 4 Data Requirements for Reregistration. In order to avoid suspension under this option, you must satisfactorily comply with Attachment II, Requirement List, for each product by submitting all required supporting data/information described in Attachment II and in the Explanatory Appendix (Attachment III) to the following address (preferably by certified mail):

Office of Compliance Monitoring (EN-342), Laboratory Data Integrity Assurance Division, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

For you to avoid automatic suspension under this Notice, the Agency must also determine within the applicable 30-day period that you have satisfied the requirements that are the bases of this Notice and so notify you in writing. You should submit the necessary data/information as quickly as possible for there to be any chance the Agency will be able to make the necessary determination in time to avoid suspension of your product(s).

The suspension of the registration(s) of your company's product(s) pursuant to this Notice will be rescinded when the Agency determines you have complied fully with the requirements which were the bases of this Notice. Such compliance may only be achieved by submission of the data/information described in the attachments to the signatory below.

Your product will remain suspended, however, until the Agency determines you are in compliance with the requirements which are the bases of this Notice and so informs you in writing.

After the suspension becomes final and effective, the registrant subject to this Notice, including all supplemental registrants of product(s) listed in Attachment I, may not legally distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the product(s) listed in Attachment I.

Persons other than the registrant subject to this Notice, as defined in the preceding sentence, may continue to distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the product(s) listed in Attachment I.

Nothing in this Notice authorizes any person to distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the product(s) listed in Attachment I in any manner which would have been unlawful prior to the suspension.

If the registrations of your products listed in Attachment I are currently suspended as a result of failure to comply with another section 4 Data Requirements Notice or section 3(c)(2)(B) Data Call-In Notice, this Notice, when it becomes a final and effective order of suspension, will be in addition to any existing suspension, i.e., all requirements which are the bases of

the suspension must be satisfied before the registration will be reinstated.

You are reminded that it is your responsibility as the basic registrant to notify all supplementary registered distributors of your basic registered product that this suspension action also applies to their supplementary registered products and that you may be held liable for violations committed by your distributors. If you have any questions about the requirements and procedures set forth in this suspension notice or in the subject section 4 Data Requirements Notice, please contact Stephen L. Brozena at (703) 308–8267.

Sincerely yours,

Director, Office of Compliance Monitoring

Attachments:

Attachment I - Product List
Attachment II - Requirement List
Attachment III - Explanatory Appendix

II. Registrants Receiving and Affected by Notices of Intent to Suspend; Date of Issuance; Active Ingredient and Products Affected

The following is a product list for which a letter of notification has been sent:

TABLE A.—PRODUCT LIST

Registrant Affected	EPA Registration Number	Active Ingredient	Name of Product	Date Issued
Grace Sierra Crop Protection Company	05818500012	Dodemorph and salts	Milban	4/14/92

III. Basis for Issuance of Notice of Intent; Requirement List

The following company failed to submit the following required data or information:

TABLE B.—REQUIREMENT LIST

Active Ingredient	Registrant Affected	Requirement Name	Guideline Reference Number	Original Due-Date
Dodemorph and salts	Grace Sierra Crop Protection Co.	Acute Oral Toxicity - Rat	81-1	8/24/91

IV. Attachment III Suspension Report—Explanatory Appendix

A discussion of the basis for the Notice of Intent to Suspend follows:

Dodemorph and Salts

On May 24, 1989, EPA issued the Phase 2 Data Requirements for Reregistration Notice imposed pursuant to section 4 of FIFRA which required registrants of products containing dodemorph and salts to develop and submit certain data. These data were determined to be necessary to satisfy reregistration data requirements of section 4(d). Failure to comply with the requirements of a Phase 2 Data Requirements Notice is a basis for suspension under sections 3(c)(2)(B) and 4(d)(6) of FIFRA.

The Dodemorph Reregistration Data Requirements Notice dated May 24, 1989 required each affected registrant to submit materials relating to the election of the options to address each of the data requirements. That submission was required to be received by the Agency within 90 days of the registrant's receipt of the Notice. The Agency received on August 24, 1989, a response from you dated August 21, 1989, in which you as a dodemorph registrant committed to undertake the required testing. The Notice further required that data be submitted by the deadline noted for the subject data requirement on Attachment II. This deadline has passed and to date the Agency has not received adequate data to satisfy this data requirement. Because you have failed to provide an appropriate or adequate response within the time provided for the data requirement listed on Attachment II, the Agency is issuing this Notice of Intent to Suspend.

V. Conclusions

EPA has issued Notices of Intent to Suspend on the dates indicated. Any further information regarding these Notices may be obtained from the contact person noted above.

Dated: May 6, 1992.

Michael M. Stahl,

Director, Office of Compliance Monitoring.

[FR Doc. 92–11239 Filed 5–12–92; 8:45 am]

BILLING CODE 6560–50–F

[OPP–180871; FRL 4064–7]

Receipt of Application for Emergency Exemption to use Fluazinam; Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Virginia Department of Agriculture and Consumer Services (hereafter referred to as the "Applicant") for use of the pesticide fluazinam (CAS No. 79622–59–6) to control *Sclerotinia blight* on up to 40,000 acres of peanuts in Virginia. In accordance with 40 CFR 166.24, EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before May 28, 1992.

ADDRESSES: Three copies of written comments, bearing the identification notation "OPP–180871," should be submitted by mail to: Public Response and Human Resource Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. In person, bring comments to: Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information." Information so marked will not be

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