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Dated: March 3, 1988.
Lloyd K. Brown,
Colonel, Corps of Engineer, District Engineer.

Dated: March 22, 1988.
Richard E. Sanderson,
Director, Office of Federal Activities.
 [FR Doc. 88-6636 Filed 3-25-88; 8:45 am]
BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3355-6]

Agency Paperwork Reduction Act Requests Completed by OMB

AGENCY: Environmental Protection Agency.
ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces Office of Management and Budget (OMB) actions on the Information Collection Requests (ICRs) submitted by EPA.

Approved

EPA ICA #0309: Registration of Fuels and Fuels Additives; OMB action date: 3/3/88; OMB #2060-0150; expires 3/31/91. Revision of existing regulation.

EPA ICR #1078: Information Collection Requirements for Phosphate Rock Plants (NSPS Subpart NN); OMB action date: 2/19/88; OMB #2060-0111; expires 2/29/91. Revision of existing regulation.

EPA ICR #1397: Survey of Municipal Waste Combustors; OMB action date: 2/19/88; OMB #2060-0160; expires 12/31/88. New Collection.

EPA ICR #0276: Application for Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only/Final Reports on EUP'S; OMB action date: 2/23/88; OMB #2070-0040; expires 8/31/90. Revision of existing regulation.

EPA ICR #0857: Polychlorinated Biphenyls (PCBs), Manufacturing, Processing, and Distribution in Commerce Exemptions; OMB action date: 2/23/88; OMB #2070-0021; expires 2/29/91. Reinstatement.

EPA ICR #0976: Hazardous Waste Biennial Reporting System; OMB action date: 2/23/88; OMB #2050-0024; expires 12/31/88. Revision of existing regulation.

EPA ICR #1437: Letter to Governors of 50 States Requesting Review of Summaries of State Mining Waste Regulations; OMB action date 2/19/88; OMB #2050-0082; expires 12/31/88. New Collection.

EPA ICR #1427: Wastewater Permit Compliance Assessment Information; OMB action date: 2/23/88; OMB #2040-0110; expires 2/29/90. New Collection.

Not Approved

EPA ICR #1432: Protection of Stratospheric Ozone. New Collection.

Discontinued

EPA ICR #1233: Asbestos School Hazard Abatement Act Grant and Loan Program; OMB #2070-0062.

FOR FURTHER INFORMATION CONTACT:

Carla Levesque, U.S. Environmental Protection Agency, Information Policy Branch (PM-223), 401 M St., SW., Washington, DC 20460, Telephone No. (202) 382-2840.

or
 Susan Dudley, Office of Management and Budget, Office of Information and Regulatory Affairs, 726 Jackson Place, NW., Washington, DC 20503, Telephone No. (202) 395-3084.

Dated: March 16, 1988.

Odelia Funke,

Acting Director, Information and Regulatory Systems Division.

[FR Doc. 88-6673 Filed 3-25-88; 8:45 am]

BILLING CODE 6560-50-M

[ER-FRL-3355-1]

Intent to Prepare an Environmental Impact Statement (EIS); Designation of Ocean Dredged Material Disposal Site (ODMDS) Off Port Aransas, TX

AGENCY: Region VI, Environmental Protection Agency (EPA).

ACTION: Notice of intent to prepare an environmental impact statement on the final designation of an ODMDS off Port Aransas, Texas.

Purpose: The U.S. Environmental Protection Agency (EPA), Region VI, in accordance with its voluntary EIS policy for ocean dumping site designation, will prepare a Draft EIS on the designation of an ODMDS off Port Aransas, Texas. An EIS is needed to provide the information necessary to designate an ODMDS. This Notice of Intent is issued pursuant to section 102 of the Marine Protection, Research and Sanctuaries Act of 1972 and 40 CFR Part 228 (Criteria for the Management of Disposal Sites for Ocean Dumping).

For Further Information and to be Placed on the ODMDS Project Mailing List Contact: Norm Thomas, (6E-F), EPA, 1445 Ross Avenue, Dallas, Texas 75202-2733, (214) 655-2260 or (FTS) 255-2260.

SUMMARY: The Corps of Engineers, Galveston District is responsible for

maintaining the Corpus Christi Ship Channel. This requires the removal of approximately 955,000 cubic yards of maintenance material per year with a maintenance cycle at approximately 18-month intervals. The Corps has requested that EPA designate an ODMDS offshore Port Aransas, Texas for the continuing disposal of dredged material from the Corpus Christi Ship Channel when ocean disposal is the preferred alternative.

Alternatives: Alternatives to be evaluated include no action (defined as not designating an ODMDS), upland disposal and several offshore disposal site alternatives.

Scoping: A scoping meeting is not contemplated. Scoping with affected federal, state and local agencies and with interested parties is being accomplished by correspondence.

Estimated Date of Release: The Draft EIS will be made available in May 1988.

Responsible Official: Mr. Robert E. Layton Jr., P.E., Regional Administrator, Region VI.

Dated: March 22, 1988.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 88-6635 Filed 3-25-88; 8:45 am]

BILLING CODE 6560-50-M

[FRL 3355-4]

Availability of Report to Congress on Wastes From the Combustion of Coal by Electric Utility Power Plants; Public Hearings

AGENCY: United States Environmental Protection Agency.

ACTION: Notice of availability of report to Congress and announcement of public hearings.

SUMMARY: The Environmental Protection Agency (EPA) recently submitted to the Congress its report entitled "Report to Congress: Wastes from the Combustion of Coal by Electric Utility Power Plants." The report was compiled in response to section 8002(n) of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6982(n). In the report, EPA provides information on: (1) The scope of the exemption for coal-fired utility wastes, (2) sources and volumes of waste, (3) current waste management practices, (4) cases of documented damage, (5) assessment of risk to human health and the environment, (6) potential costs of alternative waste management practices, (7) economic impact on industry of these alternative waste management practices on the use of coal and other natural resources, and (8) current and potential utilization of

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waste materials. The report includes conclusions and recommendations. The purpose of this notice is to solicit public comment on the accuracy of the information and findings and the appropriateness of the recommendations. Public comment is especially invited on: 1. The scope of the exemption and 2. whether low-volume utility wastes should be regulated under Subtitle C of RCRA.

DATES: Public comments on this report must be received on or before May 16, 1988. EPA will conduct two public hearings on this report: April 26, 1988 in Denver, Colorado; and April 28, 1988 in Cincinnati, Ohio. Registration for all hearings will start at 8:00 a.m. The hearings will begin at 9:00 a.m. and will end at approximately 5:00 p.m.

ADDRESSES: The locations of the public hearings are:

The Regency, 3900 Elati Street, Denver, Colorado 80216
U.S. Environmental Protection Agency, Andrew W. Breidenbach Auditorium, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268

FOR FURTHER INFORMATION CONTACT: RCRA/Superfund Hotline (800) 424-9346 or (202) 382-3000. For technical information, contact Mr. Patrick Pesacreta at (202) 382-7915.

SUPPLEMENTARY INFORMATION: A block of hotel rooms for public hearing attendants will be set aside up to two weeks prior to the hearings. Attendants should make their hotel reservations in advance. Request for additional details on the hearings or to preregister to present testimony at a hearing should be addressed in writing to Hearing Clerk, Office of Solid Waste, WH-565, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Preregistration is not required to speak at a hearing, but is highly recommended.

The public must send an original and two copies of their comments on the report to: Docket Clerk, Office of Solid Waste (WH-565), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Place the docket number F-88-PATA-FFFFF on your comments.

Copies of the full report to Congress will be available for purchase through the National Technical Information Service (NTIS). Information on how to purchase this report is available from: U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161; (703) 487-4650. Please use the full title of the document when ordering. The report to Congress is available for viewing at all EPA Regional libraries and in the EPA RCRA Docket. Also, major supporting documents cited in the report to

Congress are available for public review beginning March 31, 1988 in the RCRA Docket (sub-basement), Office of Solid Waste, WH-565-E, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, from 9:00 to 4:00, Monday through Friday except Federal holidays, by appointment only. Appointments can be made by calling (202) 475-9327. The public may copy a maximum of 50 pages of material from any one regulatory docket at no cost. Additional copies cost 20 cents per page.

Dated: March 16, 1988.

J.W. McGraw,

Acting Assistant Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. 88-6674 Filed 3-25-88; 8:45 am]

BILLING CODE 6560-50-M

[AD-FRL-3353-5]

National Air Pollution Control Techniques Advisory Committee; Open Meeting

ACTION: Notice of open meeting.

SUMMARY: A meeting of the National Air Pollution Control Techniques Advisory Committee will be held at the Sheraton Imperial Hotel and Towers, Empire Ballroom, I-40 Exit 282 at Page Road, Research Triangle Park, North Carolina 27709. The commercial telephone number is (919) 941-5050.

DATES: May 18 and 19, 1988.

FOR FURTHER INFORMATION CONTACT:

All meetings are open to the public. Anyone wishing to make a presentation should contact Ms. Mary Jane Clark at the Emission Standards Division (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, by May 10, 1988. The commercial telephone number is (919) 541-5571, and the FTS number is 629-5571.

SUPPLEMENTARY INFORMATION: The agenda for the meeting is as follows:

May 18 (Wednesday)—9:00 a.m.

Asphalt Roofing, Review of Standards of Performance for New Stationary Sources (section 111 of the Clean Air Act)

Volatile Organic Compounds (VOC's) Capture Efficiency, Test Methods and Procedures (sections 110 and 111 of the Clean Air Act)

Municipal Waste Combustion, Status Report to the Committee on Regulatory Development (sections 111 and 111(d) of the Clean Air Act)

Municipal Solid Waste Landfills, Background Information and Regulatory Alternatives (sections 111 and 111(d) of the Clean Air Act)

Treatment, Storage, and Disposal Facilities (TSDf), Background Information and Regulatory Alternatives (Resource Conservation and Recovery Act)

Perchloroethylene Dry Cleaning, Background Information and Regulatory Alternatives (section 112 of the Clean Air Act)

May 19 (Thursday)—9:00 a.m.

Continuation of May 18—as Required Ethylene Oxide Commercial Sterilizers, Background Information and Regulatory Alternatives (section 112 of the Clean Air Act)

Small Steam Generating Units, Status Report to the Committee on Regulatory Development (section 111 of the Clean Air Act)

The dockets containing material relevant to asphalt roofing (A-87-02), capture efficiency (A-87-13), municipal waste combustion (A-86-16), municipal landfills (A-88-09), perchloroethylene dry cleaning (A-88-11), ethylene oxide commercial sterilizers (A-88-03), and small steam generating units (A-86-02) are located in the U.S. Environmental Protection Agency, Central Docket Section, South Conference Center—Room 4, 401 M Street SW., Washington, DC 20460. The docket for treatment, storage, and disposal facilities (F-88-CESP-FFFFF) is located in the U.S. Environmental Protection Agency, RCRA Docket Section, Sub-Basement (Room S-212), 401 M Street SW., Washington, DC 20460. The dockets may be inspected between 8:00 a.m. and 3:30 p.m. on weekdays, and a reasonable fee may be charged for copying.

(Public Law 92-463)

Dated: March 17, 1988.

J. Craig Potter,

Assistant Administrator for Air and Radiation.

[FR Doc. 88-6443 Filed 3-25-88; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3354-4]

Science Advisory Board, Environmental Engineering Committee; Open Meeting

Under Pub. L. 92-463, notice is hereby given that the Science Advisory Board's Environmental Engineering Committee will meet April 14-15, 1988 in the Administrator's Conference Room 1101 West Tower, 401 M Street SW., Washington, DC. The meeting will begin at 9:00 a.m. on Thursday and adjourn no later than 2:30 p.m. on Friday.

The Committee will discuss final changes to the Underground Storage

Tank report and hear the report of the Unsaturated Zone Code Subcommittee. The Committee will discuss a draft resolution on modeling and receive an update on a potential Science Advisory Board review of issues related to the disposal of Municipal Combustion Ash. The Committee will be briefed on a number of other EPA activities related to engineering.

The meeting is open to the public. Any member of the public wishing to attend or submit written comments should notify Mrs. Kathleen Conway, or Marie Miller at 202/382-2552 by April 11, 1988.

Dated: March 18, 1988.

Donald G. Barnes,
Director, Science Advisory Board.
FR Doc. 88-6675 Filed 3-25-88; 8:45 am
BILLING CODE 6560-50-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Information Collection Submitted to OMB for Review

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Notice of Information Collection submitted to OMB for review and approval under the Paperwork Act of 1980.

Title of Information Collection:
Criminal Referral Reporting (OMB No. 3064-0077).

Background: In accordance with requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the FDIC hereby gives notice that it has submitted to the Office of Management and Budget a request for the review and approval of the information collection system identified above.

ADDRESS: Written comments regarding the submission should be addressed to Robert Fishman, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, and to John Keiper, Assistant Executive Secretary, Federal Deposit Insurance Corporation, Washington, DC 20429.

Comments: Comments on this collection of information should be submitted on or before April 27, 1988.

FOR FURTHER INFORMATION CONTACT: Requests for a copy of the submission should be sent to John Keiper, Assistant Executive Secretary, Federal Deposit Insurance Corporation, Washington, DC 20429, telephone (202) 898-3810.

SUMMARY: The FDIC is requesting OMB approval to revise the forms used in the Report of Apparent Crime. FDIC

regulation 12 CFR Part 353 requires insured nonmember banks to use prescribed forms (short form, FDIC 6710/06, or long form, FDIC 6710/06A) to report suspected criminal activity. The purpose of the reporting requirement is to assure that the specific information needed by investigators and prosecutors for effective law enforcement is provided in an orderly and timely fashion. The FDIC and other Federal financial institutions regulatory agencies are revising the criminal reporting forms to:

- (1) Reduce the reporting burden;
 - (2) Incorporate additional criminal statutes; and
 - (3) Standardize the reporting basis.
- The aggregate annual reporting burden imposed on insured nonmember banks in using the revised forms is 2,850 hours.

Dated: March 22, 1988.
Federal Deposit Insurance Corporation.
Hoyle L. Robinson,
Executive Secretary.
[FR Doc. 88-6721 Filed 3-25-88; 8:45 am]
BILLING CODE 6714-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-812-DR]

Amendment to Notice of a Major-Disaster Declaration; California

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of California (FEMA-812-DR), dated February 5, 1988, and related determinations.

DATED: March 15, 1988.

FOR FURTHER INFORMATION CONTACT: Neva K. Elliott, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472 (202) 646-3614.

Notice

Notice is hereby given that, effective this date and pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Tommie C. Hamner of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

This action terminates my appointment of John D. Swanson as Federal Coordinating Officer for this disaster.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Julius W. Becton, Jr.,
Director, Federal Emergency Management Agency.

[FR Doc. 88-6644 Filed 3-25-88; 8:45 am]

BILLING CODE 6718-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Welfare Dependency; Solicitation of Applications for Grants

Pursuant to section 1110A of the Social Security Act, the Assistant Secretary for Planning and Evaluation (hereafter the Assistant Secretary) is seeking applications for research in the area of income security policy from States, public, non-profit, and for-profit organizations. This grant announcement is the result of substantial interagency cooperation and the funds available from the Assistant Secretary may be supplemented by additional funds from other government agencies.

I. Type of Application Requested

This announcement seeks applications for projects to develop and conduct a program of research relating to national policy concerns in the area of welfare dependency. The Assistant Secretary has recently received two syntheses of research in this area that are available to potential applicants; these syntheses have helped determine our areas of interest.¹ The following paragraphs describe this general area of interest in greater detail by enumerating high priority areas of research. The questions they contain are intended as illustrations of specific concerns. Applications should be for projects that will address one or more of the priority areas discussed below; other, closely related issues may also be included if they are shown to be relevant to the general areas of interest.

A broad range of methodologies is acceptable for the purpose of this grant competition. However, all proposed projects should embody a sound theoretical base upon which new and original empirical work, employing the most useful and relevant data bases, is built. Demonstration projects will not be

¹ These syntheses are available from the Grants Officer (see section I):

- 1. Ellwood, David T. "Understanding Dependency: Choices, Confidence or Culture?" Brandeis University, November 1987.
- 2. Kevin R. Hopkins. "Welfare Dependency: Behavior, Culture and Public Policy." Hudson Institute, September 1987.

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funded, though funds may be requested to carry out or supplement evaluation of carefully designed existing demonstrations. Applicants must demonstrate knowledge of past and current research relating to the priority area under consideration, and they must also demonstrate access to data adequate to conduct a proposed study. With the exception of priority area B below, new data collection is inappropriate.

1. *The high priority research areas* for which applications for the proposed program of research are most desired are as follows:

A. Empirical Analysis of Welfare Dependency and Multiple Program Participation Using Monthly Longitudinal Data

Despite the well-known limitations of annual data provided by such longitudinal surveys as the Panel Study of Income Dynamics and the National Longitudinal Surveys in understanding welfare dependency (including underestimation of the prevalence of short spells), little analysis of monthly data has been done. Analysis of other longitudinal data sets providing monthly data (such as State administrative case records linked across assistance programs, the Survey of Income and Program Participation [SIPP], etc.) would be quite useful, though researchers must be aware of the difficulties involved in dealing with household and family composition changes over time. Are the answers we get from administrative data sources consistent with those we get from survey data? Such investigations should not be limited solely to nonelderly female-headed families.

A number of issues related to the Aid to Families with Dependent Children (AFDC) and the Food Stamps programs can be addressed by such an investigation.

- What are the facts regarding administrative churning versus true short-term dependency and what does that tell us about biases in annual measurement? Have the 1981 AFDC amendments changed average spell length? What is the relationship between AFDC benefit levels and spell length?

- What are the reasons for most entrances to and exits from the AFDC and Food Stamps rolls? Which type of former recipient is most likely to return to the rolls (those that leave due to earnings, marriage, or ineligibility)? Are earnings exits and returns gradual or abrupt? Are there correlations between spell length, means of exit, subgroup membership, and recidivism? Does

having additional children while an AFDC recipient affect spell length or the probability of an exit?

- Is there a "welfare trap," that is, does an initial spell increase the likelihood of subsequent spells or is the variation in spell length due entirely to differences in individual characteristics? If there is a trap, through which mechanism(s) does it operate—e.g., does an initial spell make welfare receipt more acceptable; does being on welfare act to constrain the choices available to a potential welfare recipient (that is, does the time out of the labor market reduce skill acquisition so that future labor market opportunities are reduced); does being on welfare reduce marriage prospects? Do AFDC recipients have lower returns to schooling and other human capital investments than other women, and is that a cause or a result of their dependency? How does recidivism fit into the entire life cycle analysis of welfare participation, work, marital decisions?

Further, little has been done with any of the longitudinal data sets to examine multiple transfer program benefit receipt over time. In particular, examination of the longitudinal nature of Food Stamp and AFDC receipt would be useful. What happens to Food Stamp receipt when a household leaves AFDC?

Controlling for income, are former AFDC recipients more likely to return to AFDC if they continue to receive Food Stamps after they leave AFDC, that is, is return to dependency facilitated by continued contact with the welfare system? More broadly, what is the relationship over time of the receipt of cash assistance (including AFDC, Supplemental Security Income, general assistance) to the receipt of in-kind transfers (e.g. Food Stamps, housing assistance)? Why do some individuals who are eligible for AFDC or Food Stamps choose not to participate and is this affected by the benefit reduction rate ("marginal tax rate") on earnings? What is the relative importance of stigma, lack of knowledge, attitudes toward welfare, short-run adversity, hassle, supply factors, etc. on participation? Are non-participants active in the underground economy and do not need welfare benefits?

B. Investigating Exits and Recidivism With Qualitative Data

Recent research has focused on national data sets, such as the Panel Study of Income Dynamics and the National Longitudinal Surveys. Supplementing empirical analysis with qualitative, ethnographic interviews, possibly involving new data collection, could be quite instructive. Such analysis

should focus on life cycle patterns of welfare receipt, work effort, earnings, marital status and conjugal relationships, childbearing, health status and Medicaid use, and so forth for a substantial sample of former welfare recipients.

For example, studying individuals who have recently left the AFDC rolls is of particular importance. Supplementing current cross-sectional findings with longitudinal analyses may yield new insights into exist patterns. For example, we can learn more about recidivism—why those who we thought successfully home "failures" and return to the welfare rolls—by following former recipients over time. What are the characteristics of those who successfully leave AFDC through earnings? Do these women have prior labor market experience? Do they have superior labor market opportunities? Is the process of an earnings exist gradual or abrupt? Why do some mothers work part-time when the income gains are small at best? Are the part-time workers of this period those that leave with full-time jobs next period? How do day care, medical, or other problems get in the way of finding or keeping a job? What mechanisms are used to finance health care in the absence of Medicaid coverage and do significant health care problems lead to a return to dependency on Medicaid alone (in "medically needy" states) or on welfare plus Medicaid?

C. AFDC-Unemployed Parent Program

Assertions have been made that mandating the AFDC-UP program for all states would increase family stability by removing the incentive for unemployed parents to abandon their families. While there is some evidence that the AFDC-Basic program increases the likelihood of divorce, there is no evidence to date whether or not the AFDC-UP program decreases that likelihood. Moreover, the participation rate of eligible families in the UP program is believed to be substantially less than for the Basic program. What are the determinants of participation in AFDC-UP and why is the participation rate in AFDC-UP for eligible families below the participation rate for the AFDC-Basic program? Do eligible non-participants get benefits from other income transfer programs such as Food Stamps? Is there any evidence that AFDC-UP affects family stability and work effort in ways different from AFDC-Basic? What do we know about the interaction of AFDC-Basic and AFDC-UP in states that have both, that is, what is the pattern of movement of families between the two

programs? What can we learn when states change their programs to cover or end coverage of UP families? Is participation in UP related to changes in the Unemployment Insurance extended benefits program?

D. Problems of the Underclass

The recent widespread interest in problems of an underclass in American cities has served to highlight our lack of knowledge about welfare use at the neighborhood level. Clearly, one central issue involves defining the underclass. Almost universally, extant definitions involve geographic concentrations of poverty and/or welfare use.

Two methods can be used to shed light on the problems of the underclass—analysis of both nationally-representative data and geographically-concentrated data. Currently, census tract data are being linked to the Panel Study of Income Dynamics. With these data, one can experiment with alternative definitions of an underclass including aspects of both economic marginality and geographically concentrated poverty. As a consequence, employment and unemployment rates, underemployment, welfare use, and dependency can now be investigated as they differ among neighborhoods. For example, does the fact that a particularly high proportion of a neighborhood's population uses welfare have any effect on marriage and welfare use or on the intergenerational transmission of dependency in that neighborhood? What is the distribution of welfare recipients, long-term welfare recipients, and the long-term poor (as opposed to all poor persons) by neighborhood poverty rate? What is the work history of those living in high poverty areas and how many are receiving Unemployment Insurance? What are the characteristics of the non-poor and non-dependent populations living in high poverty areas? Are these people more at risk of dependency than those with similar characteristics that live in better-off neighborhoods? Are the near-poor in any one year future or past poor? What is known about the relationship between residence in public housing areas and the use of public assistance? Can information from criminal justice statistics for local areas be used to determine whether there is a link between criminality and welfare dependency?

At the neighborhood level, systematic assessment of the characteristics of neighborhoods and their evolution through time can be used to develop and assess hypotheses about the origins and likely future of economically deprived populations. For example, William Julius Wilson, in a recent paper for the Rockefeller Foundation, has investigated

neighborhoods in Chicago in the detail necessary to examine these issues. Questions that might be addressed include the following: Is it lack of jobs or lack of skills that leads to low employment rates in underclass areas? Are employment and training programs (such as the Job Training Partnership Act) serving inner city populations? Is there any evidence that local self-help programs (such as the Kenilworth-Parkside Resident Management Corporation in Washington, DC) have any effect on welfare use, transition to self-sufficiency, neighborhood quality, or related issues? Do the attitudes of males or females toward welfare in areas with relatively low proportions of the population receiving welfare differ from those areas with relatively high receipt?

Finally, a systematic assessment of ethnographic findings to abstract lower class subculture characteristics may be informative. Currently, researchers include "race" as an explanatory variable in their welfare and poverty regression models with little explanation. Can we understand what this term stands for? Can we explain the significant differences between blacks and whites in these models through differences in educational opportunities, housing quality, etc., or are there underlying cultural differences between races that cannot be explained even when neighborhood influences are taken into account?

E. Topics Related to Teenage Pregnancy

Unmarried women entering welfare as teenagers are often long-term dependent. This series of proposed projects focuses on the antecedent behavior—teenage pregnancy.

1. Examining the "Opportunity Costs" Hypothesis

Teenagers from disadvantaged families and neighborhoods are considerably more likely to become parents during their teen years. One explanation for this pattern is the "nothing to lose" hypothesis. That is, these teens perceive that they lack opportunities for personal advancement and believe they have limited options. Because early parenthood may appear to entail little in the way of lost opportunities, teens lack the motivation to avoid becoming parents as adolescents. We would like to test the validity of this hypothesis. Does it apply equally well to males and females? Are there other important variables which affect young people's attitudes and perceptions about the future?

2. Child Support, Male Responsibility, and Family Involvement

Child support payments can affect the duration and depth of welfare dependency. Yet, 70% of all AFDC recipients have not been awarded any child support. How might increased child support enforcement, paternity establishment, and provision of male and/or female employment opportunities change the patterns of child support payment, employment, and family structure?

Even on a descriptive level, the attitudes, values and concerns of teenage males are not well-documented. Can the rigorous enforcement of existing child support laws affect the behavior of young males? Would widespread imposition of uniform child support awards on fathers change behavior (e.g. reduce illegitimacy or divorce) by increasing the financial risk to males? How might the work effort of both mothers and fathers be affected? How might increased mandatory payments affect informal payments by fathers? Would child support collections increase if fathers were allowed to make in-kind contributions in lieu of cash payments due and thus have greater control over how their payments are used? Would increased child support payments affect the chance that the mothers marry or remarry?

There is some evidence that efforts to establish paternity around the time of birth frequently result in voluntary acknowledgement of paternity. Does such an approach lead to greater involvement of the father in the care and support of his child? Would job counseling of the father at the time of paternity establishment increase the likelihood of child support? Many of the fathers of AFDC children are unemployed or underemployed. They often are not given high priority by child support enforcement officials for paternity establishment or child support enforcement. Furthermore, they are not given any priority in human capital development programs, perhaps because that might create perverse incentives to father children out-of-wedlock. Can integrated child support enforcement and work programs for the fathers increase their support for their children without increasing birth rates? To what extent do welfare, workfare, employment and training rules/regulations and practices discourage rather than encourage father support of children and/or family dissolution. To what extent have job training programs or other human capital investments (e.g.

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schooling) on the part of males affected the likelihood that they will marry?

Variations in State child support enforcement practice toward young absent fathers create "natural experiments"—some AFDC recipients are in a "strict enforcement" group while others are in a "no enforcement" group. Do states or particular communities differ in measurable ways in their child support enforcement or employment practices (e.g. workfare for the fathers) so that meaningful comparisons about outcomes can be made?

F. Influence of Child Care on the Capacity for Independence

Several attitudinal surveys have indicated that lack of affordable, available child care is a significant barrier to the labor force participation of low-income women. On the other hand, several studies indicate that child care is less significant an impediment than charged. Ellwood in his previously-cited synthesis of the welfare dependency literature says, "One of the most talked about but least understood strategies to help people move toward independence involves day care." He adds, "There are surveys of day care arrangements (including SIPP) which could be examined. Some may even have a useful longitudinal component. Moreover, there is already considerable variation in the provision of day care across States. Work-welfare programs are a potentially rich source of information on the role of day care in influencing work decisions."

What types of child care do welfare recipients that work currently use? What are the relative roles of (1) private procurement of services covered, the AFDC child care disregard and (2) provision of day care services by government programs (including both work programs for welfare recipients and Title XX programs)? Can government target fiscal resources to appropriate families for day care in a way to encourage cost-effective labor force participation by welfare recipients? We are also interested in studies that will help us understand whether an inadequate supply of affordable child care is a major barrier to low income women's labor force participation in general. If there is a problem, is it pervasive across the country or are there only pockets where supply, quality, or costs are the problem? Does the demand for child care services differ in type (e.g. family vs. center-based) or quantity among regions?

G. Effects of Child Support Enforcement on AFDC and of Financing Arrangements on Program Effectiveness and Efficiency

Federal financing arrangements for child support enforcement (CSE) activities are very generous—a 68 percent administrative cost match rate, a 90 percent match for ADP systems, an incentive payment of 6 to 10 percent of all child support collections, plus the return to the State of its share of all collections made on behalf of AFDC recipients (an average of about 36% when the \$50 per month pass-through and other payments to families have been excluded). These monies flow into the State's general revenues. Consequently, there is no need for a State to link the generosity of its AFDC program to the effectiveness of its CSE program. Nevertheless, State legislators may make such a link in setting the AFDC benefit level or in determining some other aspect of the AFDC program. Is there any evidence of such a link? (The effectiveness of CSE is not to be construed simply as the total amount of collections or the ratio of collections to administrative cost, but also the degree to which paternity and support awards are established, the proportion of support awards which are in collection status, the degree to which States concentrate on current collections versus arrears, and the extent to which States have backlogs of unworked or inactive cases.)

It has not been documented that the current financing arrangements have any effect on the CSE program's effectiveness or efficiency. Further, because of the complex nature of the program, administrative and financial interactions between AFDC and CSE may make it difficult for States and counties to determine the long-run benefit of increasing CSE activities, especially for the AFDC population. It is also suggested that there may be conflict between the State-level view of how child support and AFDC should interact and how this interacting is perceived at the county level, especially where one or both of the CSE and AFDC programs are county-administered or operated. Consequently, we are interested in an examination of how the administrative structures for AFDC and CSE within States and the particular Federal and State financing arrangements may be affecting the effectiveness of the CSE program.

2. Products

The applicant should present a schedule for delivery of interim progress reports and a final report. For any

project that significantly enhances a data base or creates a new data base in the course of the work, a well-documented public use file should also be prepared.

3. Potential Users

Potential users of the research include policy makers at Federal, State, and local levels of government, as well as professionals in social services, demography, economics, sociology, social work, and related fields. Because many of those who will be interested in this research lack advanced technical training, it is important that the results of projects be presented in a fashion accessible to such an audience. This may involve the submission of a separate, non-technical executive summary.

4. Types of Projects Excluded

In consideration of the intent of this announcement, applications concentrating on a narrow programmatic or policy focus, or on one that is not directed to concerns of national interest, will not be considered for funding.

In addition, this announcement seeks empirical analysis of the individual issues founded on a sound theoretical base. Applications that are limited to theoretical development or involve new demonstrations will not be considered. In addition, applications that include new data collection efforts are unlikely to be approved, except in priority area B.

5. Content and Organization of the Applications.

The application must begin with a cover sheet followed by the required application forms and an abstract (of not more than two pages) of the application. Failure to include the abstract may result in delays in processing the application. Each application should include a discussion of the relevant literature, a description of the models to be analyzed, the data sources to be used, and the methodologies proposed to test the models. Resumes of staff should be included, as should a full budget and a schedule of tasks for the proposed projects.

II. Applicable Regulations

1. "Grants Programs Administered by the Office of the Assistant Secretary for Planning and Evaluation" (45 CFR Part 63), Code of Federal Regulations, October 1, 1980.

2. "Administration of Grants" (45 CFR Part 74), Code of Federal Regulations on June 9, 1981.

III. Effective Date and Duration

1. The grants awarded pursuant to this announcement are expected to be made on or about July 1, 1988; however some may be made subsequent to this date (see Section D below).

2. In order to avoid unnecessary delays in the preparation and receipt of applications, this notice is effective immediately. The closing dates for applications are specified in Section F and G below.

3. It is expected that most projects will be completed within a twelve- or an eighteen-month period. Longer projects, particularly those addressing priority area B, can be considered but will be subject to the availability of funds.

IV. Statement of Funds Available

1. \$450,000 has been set aside for grants to be awarded in Fiscal Year 1988 as a result of this announcement. Applications may be for any amount, but it is expected that most awards will be for single projects of no more than \$100,000. Up to \$500,000 of additional funds in both Fiscal Years 1988 and 1989 may be made available for unfunded proposals which are of exceptional quality.

Applicants are encouraged to seek additional funds from other sources for this project. Applicants should discuss any commitments, plans, or hopes for additional funds, including size and sources. When it is judged that successful completion of a proposed project depends on outside funding, this office's funding commitment will be made contingent on complete demonstration of that outside funding.

2. Funds may be obligated fully at the time of award of these grants or incrementally.

3. The government reserves the right to select for funding more than one application in a given priority area. Further, the selection of the priority areas from the entire set, for which awards will be made, will be made in accordance with the quality of proposals received. However, nothing in this application should be construed as committing the Assistant Secretary to make any award.

V. Application Processing

1. Applications will be initially screened for relevance to the needs defined in section A (as well as additional areas of interest persuasively shown to be relevant by the grantee). If judged relevant, the application will then be reviewed by a government

review panel, possibly augmented by outside experts. *Three (3) copies* of each application are required. Applicants are encouraged to send an additional *seven (7) copies* of their application to ease processing, but applicants will not be penalized if these extra copies are not included. Applicants should clearly indicate on their cover sheet into which of the priority topics listed above their application falls, or if none, indicate "OTHER".

2. Applications will be judged as to eligibility, quality, and relevance, according to the criteria set forth in item 5.

3. An unacceptable rating on any individual criterion may render the application unacceptable. Consequently, applicants should take care to ensure that all criteria are fully addressed in the application.

4. Applications should be as brief and concise as is consistent with the information requirements of the reviewers. Applications should be limited to 25 double-spaced typed pages, exclusive of forms, abstract, resumes, and proposed budget; they should neither be unduly elaborate nor contain voluminous supporting documentation.

5. *Criteria for Evaluation.* Evaluation of applications will employ the following criteria. The relative weights are shown in parentheses.

a. *Usefulness.* The potential usefulness of the objectives and anticipated results of the proposed project for providing individuals and organizations concerned with the issues discussed in Section A above with improved bases for making decisions about these issues. The potential usefulness of the proposed project for the advancement of science. (25 points)

b. *Clarity and Understanding.* Understanding and knowledge of prior work in the area. The cost effectiveness of the proposal and the clarity of statement of objectives, methods, and anticipated results. (15 points)

c. *Research Design.* The appropriateness and soundness of methodology (which may include an interdisciplinary approach), including overall research design, statistical techniques, modeling strategies, choice of data, and other proposed procedures. Probability of successful completion of the study. (30 points)

d. *Experience and Qualifications of Personnel.* Principal Investigator's and other key staff's experience in this or related areas and indications of innovative approaches and creative potential. Indication of the ability of key staff to produce publishable quality reports or articles. (30 points)

VI. Applications Sent by Mail

Applications may be sent by either the U.S. Postal Service or a commercial carrier. Applications sent by U.S. Postal Service will be considered to be received on time by the Grants Officer if the application was sent by first class, registered or certified mail not later than May 19, 1988, as evidenced by the U.S. Postal Service postmark on the wrapper or envelope, or on the original receipt from the U.S. Postal Service.

Applications sent by a commercial carrier will be considered to be received on time by the Grants Officer if sent not later than May 19, 1988, as evidenced by a receipt from the commercial carrier.

VII. Hand-Delivered Applications

An application to be hand-delivered must be taken to the Grants Officer at the address listed at the end of this announcement. Hand-delivered applications will be accepted daily between 9:00 a.m. and 4:30 p.m., Washington, DC, time, except Saturdays, Sundays, or Federal holidays. Applications will not be accepted after close-of-business on May 20, 1988.

VIII. Disposition of Applications

1. *Approval, disapproval, or deferral.* On the basis of the review of the application, the Assistant Secretary will either (a) approve the application as a whole or in part; (b) disapprove the application; or (c) defer action on the application for such reasons as lack of funds or a need for further review.

2. *Notification of disposition.* The Assistant Secretary will notify the applicants of the disposition of their application. A signed notification of grant award will be issued to the contract person listed in block 4 of the application to notify the applicant of the approved application.

IX. Application Instructions and Forms

Copies of applications should be requested from and submitted to: Grants Officer, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 200 Independence Avenue SW., Room 426F, Hubert H. Humphrey Building, Washington, DC 20201, Phone (202) 245-1794. Questions concerning the preceding information should be submitted to the Grants Officer at the same address. Neither questions nor requests for applications should be submitted after April 15, 1988.

X. Federal Domestic Assistance Catalog

This announcement is not listed in the Federal Domestic Assistance Catalog.

XI. Intergovernmental Review of Federal Programs

This program is not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs" or its implementing regulations 45 CFR Part 100.

Date: March 22, 1988.

Robert B. Helms,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 88-6641 Filed 3-25-88; 8:45 am]

BILLING CODE 4150-04-M

Food and Drug Administration

[Docket No. 81P-0361 et al.]

Approved Variances For Laser Light Shows; Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that variances from the performance standard for laser products have been approved by FDA's Center for Devices and Radiological Health (CDRH) for 17 organizations that manufacture and produce laser light shows, light show

projectors, or both. The projectors provide a laser light display to produce a variety of special lighting effects. The principal use of these products is to provide entertainment to general audiences.

DATES: The effective dates and termination dates of the variances are listed in the table below under "Supplementary Information."

ADDRESS: The applications and all correspondence on the applications have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sally Friedman, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION: Under 21 CFR 1010.4 of the regulations governing establishment of performance standards under section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f), FDA has granted each of the 17 organizations listed in the table below a variance from the requirements of 21 CFR 1040.11(c) of the

performance standard for laser products.

Each variance permits the listed manufacturer to introduce into commerce a demonstration laser product assembled and produced by the manufacturer, which is its particular variety of laser light show, laser light show projector, or both. Each laser product involves levels of accessible laser radiation in excess of Class II levels but not exceeding those required to perform the intended function of the product.

CDRH has determined that suitable means of radiation safety and protection are provided by constraints on the physical and optical designs and by warnings in the user manuals and on the products. Therefore, on the effective dates specified in the table below, FDA approved the requested variances by a letter to each manufacturer from the Deputy Director of CDRH.

So that each product may show evidence of the variance approved for the manufacturer of the product, each product shall bear on the certification label required by 21 CFR 1010.2(a) a variance number, which is the FDA docket number, and the effective date of the variance as specified in the table below.

Docket No.	Organization granted the variance	Demonstration laser product	Effective date termination data
81P-0361 (renewal).	Siegfried and Roy Entertainment, Incorporated d.b.a. Beyond Belief, Frontier Hotel, 3120 Las Vegas Boulevard, South Las Vegas, Nevada 89109.	Siegfried and Roy Entertainment, Incorporated "Beyond Belief" laser light show incorporating the Laser Media LMS projector.	January 22, 1988—February 1, 1990.
83P-0085 (renewal).	Hill Development Services Company, 18160 Old Monte Rio Road, Guerneville Park, California 95446.	Laser light shows assembled and produced by Hill Development Services, Company incorporating the Class IV Laserscape II Krypton, the ABP-1 argon, and the CP-1 argon/krypton laser projectors.	Jan. 22, 1988—March 17, 1990.
83V-0412 (renewal).	Western Michigan University, Dalton Center, Kalamazoo, Michigan 49008-5188.	INNOVA 90K Laser Light Shows and the Class IV ion laser projection systems and display devices assembled and produced by Western Michigan University.	Jan. 12, 1988—Jan. 26, 1990.
84V-0335 (renewal).	La Mama Experimental Theatre Club, Incorporated, 74A East 4th Street, New York, New York 10003.	Importation of the Campagna Teatrale Krypton laser projector and laser light show for a two-week presentation in the La Mama Theatre. The projector is a Class IV argon projector.	Dec. 31, 1987—Sept. 28, 1989.
85V-0239 (amendment).	Laser Dreams, 7345 Healdsburg Avenue, Suite 11, Sebastopol, California 95472.	Laser Dreams laser light shows incorporating the Laser Dream Machine Model 1 laser projector with argon, helium-neon, and/or helium-cadmium lasers.	Jan. 20, 1988—May 30, 1988.
85V-0298 (renewal).	Laser Light Systems, Incorporated, 1414 Tilia, San Mateo, California 94402.	Laser Light Systems' laser light shows and the incorporated laser projection system consisting of Laser Systems Development Corporation Model R3, C3, or C6 optics modules and Class IV argon or krypton lasers such as Spectra-Physics' Models 164 or 171 or Laser Light System's Model LLI.	Jan. 5, 1988—Jan. 9, 1990.
85V-0305 (renewal).	Sea World, 1720 South Shores Road, San Diego, California 92109.	Class IV Sea World Model SW-1 ion laser projector and the Sea World laser light shows, such as "Summer Nights" or "Starlight Spectacular" incorporating Laser Media LMS Series and Sea World Model SW-1 laser projectors.	Jan. 5, 1988—Jan. 5, 1989.
86V-0194 (amendment).	Lasertainment, 428 B West County Road D, New Brighton, Minnesota 55112.	Lasertainment laser light show using the Laser Fantasy Class IIIb or IV Rainbow Model Series Ar/HeNe laser projection systems.	Jan. 5, 1988—Oct. 16, 1988.
87V-0308	Laser Entertainment and Display Incorporated, 2939 Arden Way, Sacramento, California 95825.	Class IV argon/krypton Model LED 1 laser projection system and laser light shows produced and assembled by Laser Entertainment and Display, Incorporated incorporating this projection system.	Dec. 6, 1987—Dec. 6, 1989.
87V-0342	Allen County Memorial Coliseum, 4000 Parnell Avenue, Fort Wayne, Indiana 96805.	Allen County Memorial Coliseum laser fiber optic scoreboard	Dec. 1, 1987—Dec. 1, 1989.
87V-0359	Diego's Incorporated, 860 Garnet Avenue, San Diego, California 92109.	Club Diego's laser light show using the Entertainment Technology Industries Class IV Beam Master Model Three argon laser projection system.	Nov. 25, 1987—Nov. 25, 1989.

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Docket No.	Organization granted the variance	Demonstration laser product	Effective date termination data
87V-0377	NASA Ames Research Center, MS 247-2, Moffett Field, California 94035.	NASA Ames Research Center Wind Tunnel laser display using the Class IV argon Model LRVL laser product modified by NASA/ARC for this display.	Dec. 4, 1987—Dec. 4, 1988.
87V-0385	The Bailey Controls Company, 29801 Euclid Avenue, Wickliffe, Ohio 44092.	Bailey Controls Company laser light displays using the Centrak Laser Corporation Model CK-2 laser projector.	Dec. 24, 1987—Dec. 24, 1989.
87V-0388	Benedum Natural Science Theater, Ogle Bay Park, Wheeling, West Virginia 26003.	Benedum Natural Science Theater Laser Light Show incorporating the Laser Fantasy Rainbow 2000 laser projector.	Jan. 21, 1988—Jan. 21, 1990.
87V-0394	Spectra Laser Systems, 10292 Lurline Drive, Huntington Beach, California 92646.	Laser light shows assembled and produced by Spectra Laser Systems and for the firm's Model Series 6000 Computer Controlled Laser Projectors which are incorporated into these shows.	Dec. 16, 1987—Dec. 16, 1989.
87V-0400	Hyperion, 2810 Hyperion Avenue, Los Angeles, California 90027.	Hyperion laser light shows, incorporating an Entertainment Technology Industries Beam Master laser projector.	Dec. 29, 1987—Dec. 29, 1989.
87V-0401	Chameleon Productions, 500 E. Concord Street, Orlando, Florida 32803.	Chameleon Productions laser light shows, such as "Out of the Darkness," incorporating the Model TL24D laser projection system manufactured by Precision Projection Systems, Incorporated.	Jan. 21, 1988—Jan. 21, 1990.

In accordance with § 1010.4, the applications and all correspondence on the applications have been placed on public display under the designated docket number in the Dockets Management Branch (address above) and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.86).

Dated: March 17, 1988.

John C. Villforth,
Director, Center for Devices and Radiological Health.

FR Doc. 88-6638 Filed 3-25-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88N-0066]

IOPTEx, Inc.; Premarket Approval of the Model 304-01 Ultra C-Loop Posterior Chamber Intraocular Lens

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by IOPTEx, Inc., Azusa, CA, for premarket approval, under the Medical Device Amendments of 1976, of the Model 304-01 Ultra C-Loop Posterior Chamber Intraocular Lens. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the application.

DATE: Petitions for administrative review by April 27, 1988.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy C. Brogdon, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-8258.

SUPPLEMENTARY INFORMATION: On April 6, 1987, IOPTEx, Inc., Azusa, CA 91702, submitted to CDRH an application for premarket approval of the Model 304-01 Ultra C-Loop Posterior Chamber Intraocular Lens. The device is indicated for primary implantations in patients 60 years of age and over where a cataractous lens has been removed by extracapsular cataract extraction methods. The device is available in a range of powers from 5 diopters (D) to 33 D in 0.5 D increments.

On July 23, 1987, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On February 12, 1988, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at

CDRH—contact Nancy C. Brogdon (HFZ-460), (address above).

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before April 27, 1988, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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