Dated: July 3, 2001.

Norman L. Thompson,

Acting Principal Deputy Assistant Secretary for Aging.

[FR Doc. 01–17116 Filed 7–9–01; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Embargo on Importation of *Dracaena* Shipments in Standing Water

AGENCY: Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Notice of embargo on importation of *Dracaena* shipments in standing water.

SUMMARY: Shipments of *Dracaena* (''lucky bamboo'') in standing water and infested with mosquitoes are currently being imported into the United States. Because of potential public health threats posed by exotic species of mosquitoes, CDC is implementing an immediate embargo on the importation of *Dracaena* that has been shipped in standing water. This embargo only affects importation of *Dracaena* shipments in standing water.

FOR FURTHER INFORMATION CONTACT: Dr. David Kim, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., National Center for Infectious Diseases, Division of Global Migration and Quarantine, Mailstop E–03, Atlanta, Georgia, 30333; (404) 498–1600; E-mail *ddk5@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background

On June 14, 2001, the Centers for Disease Control and Prevention (CDC), was notified by the Los Angeles district office of the U.S. Department of Agriculture (USDA) that it had identified maritime cargo containers of ''lucky bamboo'' (*Dracaena* species), an ornamental plant, that were infested with mosquitoes. CDC subsequently identified the Asian tiger mosquito, *Aedes albopictus,* a species previously not seen in California, and other species of mosquitoes associated with these cargo containers. The *Dracaena* in the infested cargo containers was shipped in small boxes with two to three inches of standing water. Shipments of *Dracaena* with no standing water or associated mosquito infestation have been arriving in the United States from China, Taiwan, Thailand, Indonesia, Malaysia, Costa Rica and other countries as air and maritime cargo for at least 3 years.

Public Health Risks

Dracaena shipments in standing water appears to pose a considerable risk of importing exotic mosquitoes into the United States. Although previously introduced and widely established in the eastern half of the United States, *Aedes albopictus* has not established a population in California. *Aedes albopictus* is capable of transmitting serious human diseases such as western equine encephalitis, St. Louis encephalitis, and dengue viruses. Introduction of new *Aedes albopictus* populations from China, Taiwan, Indonesia, and other countries might include genotypes that are more efficient vectors of human diseases than the genotypes that are currently present in the United States. There have been precedents of accidental introduction of mosquito species of public health importance into the United States by a similar mechanism, i.e., by importation of materials containing standing water.

Immediate Action

Introductions of exotic species of mosquitoes, such as *Aedes albopictus* in California and other species in different parts of the United States, through the importation of *Dracaena* shipments in standing water, pose potentially serious public health threats. Accordingly, pursuant to 42 CFR 71.32(c), CDC is implementing an embargo on the importation of *Dracaena* shipments in standing water, effective immediately. This embargo only affects importation of *Dracaena* shipments in standing water.

Dated: July 3, 2001.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention.

[FR Doc. 01–17152 Filed 7–9–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01098]

Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN); Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN). This program addresses the ''Healthy People 2010'' focus areas of Nutrition and Overweight, Physical Activity and Fitness, Tobacco Use, Heart Disease and Stroke, Diabetes, and Access to Quality Health Services.

The purpose of this program is to use scientifically rigorous methods to test the effectiveness of a behavioral or lifestyle intervention aimed at preventing cardiovascular disease (CVD) and other chronic diseases. The target population consists of women participating in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The major long-term goal is to demonstrate a successful behavioral or lifestyle intervention for the population targeted by the NBCCEDP. Recipients are also expected to work with existing health care systems to identify free or discounted medication for women who require such therapy.

B. Eligible Applicants

Assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, federally recognized Indian tribal governments, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau. NBCCEDP grantees who are currently receiving grants under Program Announcements 99135 and 00115 are not eligible.

C. Availability of Funds

Approximately $2,000,000 is available in FY 2001 to fund two awards. It is expected that the average amount per award is between $750,000 to $1,250,000. It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month budget period within a project period of three years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

1. Use of Funds

In accordance with Public Law 101–354, an award may not be made unless the State/Territory/Tribe involved agrees that:

a. At least 60 percent of cooperative agreement funds will be expended for screening, lifestyle intervention, public

health case management, appropriate referral for medical treatment, and to ensure, to the extent practicable, the provision of appropriate follow-up services and support services such as medical case management for women with extremely high values. The remaining 40 percent or less will be expended for public education programs, for training of health professionals, for mechanisms to monitor screening procedures, and to evaluate activities conducted under this cooperative agreement through appropriate program surveillance or program-monitoring activities (Sections 1501(a) and 1503(a) (42 U.S.C. 300k(a) and 300m(a)) of the Public Health Service Act (PHS Act), as amended).

b. Use of federal funds for medical care case management of women without alert values is strongly discouraged (see VI. below for definition of alert values). As stated above funds should be expended for screening, appropriate referral for medical treatment, and, to ensure, to the extent practicable, the provision of appropriate follow-up services and support services such as case management (see definitions below). Therefore, it is not required that funds be used to provide follow-up services and support services such as case management. However, programs are encouraged to use funds for screening and intervention case management. When funds must be used for medical care case management, priority is to be given to women with extremely high values (i.e. those with alert values which are defined in Section E.4.e). Because 60–80% of women will have abnormal screening values, the cost of providing medical care case management to women with non-alert screening values is not practicable or cost-efficient.

Case Management: A term for all activities that a physician or other health care professional normally performs to insure the coordination of the public health services or medical services required by a patient.

WISEWOMAN Screening and Intervention Case Management: A term for all activities that a public health professional performs to ensure the coordination of the public health screening, intervention, and referral services required by a client.

WISEWOMAN Medical Care Case Management: A term for all activities that a physician, health care professional, or public health professional performs to ensure the coordination of the medical services required by a patient.

c. All blood pressure, cholesterol, and other preventive health screenings, intervention, referral, follow-up, case management, and evaluation should be initiated by the end of any second fiscal year of payments pursuant to the grant (i.e, by the end of the second year in the budget period). (Section 1503 (a)(3) (42 U.S.C. 300m(a)(3)) of the PHS Act, as amended.)

d. Cooperative agreement funds will not be expended to provide inpatient hospital or treatment services. (Section 1504(g) (42 U.S.C. 300n(g)) of the PHS Act, as amended.) Treatment is defined as any medical, pharmaceutical, or surgical service prescribed by a clinician in the management of a diagnosed condition. Lifestyle and behavioral interventions are included in the definition of case-management but are not considered treatment.

e. Not more than 10 percent of funds will be expended annually for administrative expenses (Section 1504(f) (42 U.S.C. 300n(f)) of the PHS Act, as amended.)

f. The amount paid by a State/Territory/Tribe for a screening procedure may not exceed the amount that would be paid under part B of title XVIII of the Social Security Act (Medicare) (section 1501(b)(3) (42 U.S.C. 300k(b)(3))) of the PHS Act, as amended. These may vary by location and grantee should determine appropriate reimbursement rates.

In accordance with section 1504 (c)(2) (42 U.S.C. 300n(c)(2)) of the PHS Act, as amended, CDC may waive the requirements for specific services/activities if it is determined that compliance by the State/Territory/Tribe would result in an inefficient allocation of resources with respect to carrying out an early detection program (as described in Section 1501(a)). A request from the recipient outlining appropriate and detailed justification would be required before the waiver is approved.

2. Recipient Financial Participation

Recipient financial participation is required for this program in accordance with the authorizing legislation. Section 1502 (42 U.S.C. 300) of the PHS Act states that matching funds are required from non-Federal sources in an amount not less than $1 for each $3 of Federal funds awarded under this program. The non-Federal contributions may be made directly in cash or equivalent in-kind or donated services, including equipment, fairly evaluated, through donations from public or private entities. Matching funds may not include: 1. The payment for treatment services or the donation of treatment services (see note below); 2. services assisted or subsidized by the Federal government; or 3. the indirect or overhead costs of an organization. In some States/Territories/Tribes, non-Federal funds from a variety of sources may presently be used to support one or more of the WISEWOMAN early detection activities described in this program announcement.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for conducting activities under 2. (CDC Activities).

1. Recipient Activities

a. Build a chronic disease screening and intervention program with priority on preventing cardiovascular disease (i.e. WISEWOMAN program that includes hypertension and cholesterol screening). This program should target populations that have not been previously well-studied.

b. Work collaboratively with other WISEWOMAN programs and partners to develop methods which have the potential to be implemented in other WISEWOMAN programs.

c. Develop program and research protocols (see Attachment I in the application kit).

d. Implement screening, referral, and follow-up according to the recommendations of the NationalCholesterol Education Program (NCEP)of the National Heart, Lung, and Blood Institute (NHLBI) for cholesterol screening; and the recommendations set forth for hypertension screening by the sixthJoint National Report on the Detection, Evaluation and Treatment of High Blood Pressure. Laboratories that perform the screening for cholesterol must be accredited and meet all applicable Federal and State quality assurance standards in the provision of any test performed.

e. Establish cardiovascular disease prevention as the primary focus of interventions, with interventions addressing one or more risk factors for cardiovascular disease: overweight, physical inactivity, inadequate intake of fruit and vegetables and excessive calories and dietary fat. Cigarette smoking, and undiagnosed diabetes may also be addressed as secondary priorities. Some interventions available to the grantee are: strength training programs, culturally-appropriate modifications of the five-day diet, or combined physical activity and nutrition counseling tools. To obtain the statistical power to evaluate the intervention, the program should add cholesterol and blood pressure screenings to a sufficiently large number of NBCCEDP sites. After demonstration

of an effective lifestyle intervention to reduce the risk of cardiovascular disease, recipients may develop a number of other preventive services to be delivered.

f. Implement program/research protocols as developed.

g. Develop abstracts and publications in collaboration with other partners that inform the public, scientific community, and Congress as to the progress and program results.

h. Grantees are expected to use a public health approach in designing an efficient intervention delivery system.

i. If the intervention will be assigned at the level of the site, it is extremely important to provide power calculations justifying the number of sites selected. A method of collecting information for the purpose of program evaluation should be developed and implemented.

2. CDC Activities

a. Assist as needed in the development demonstration project protocols and forms.

b. Participate in workshops and/or teleconferences of the recipients for information-sharing and problem-solving.

c. Provide ongoing consultation and technical assistance to plan, implement, and evaluate program activities.

d. Assist recipients as requested with the analysis of their data and in the development of their abstracts and publications.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the evaluation criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 35 double-spaced pages, printed on one side, with one inch margins, and unreduced font.

Provide a realistic time-phased work plan that addresses the points below. If the first year of the program will be used for planning, the application should detail how each of the preliminary plans will be finalized by detailing the process used and the time line to a final plan.

1. Background and Need

Provide a brief description of the extent of the disease burden. Also describe the background of the health care system to include:

a. The current health care system in whichBCCEDP sites operate and the appropriateness of the health care system for implementing standardized effective interventions, adhering to program protocols, tracking difficult to reach women, and providing timely information on women who have high values of cholesterol and blood pressure;

b. Explanation of all non-cancer-related services currently being provided within the context of the BCCEDP (i.e., are heights and weights measured, is blood pressure routinely taken, is a smoking history obtained, etc.? Are the results of these services recorded so that they are accessible to the BCCEDP?)

c. Describe the current medical care safety network for uninsured persons and how it will be utilized to provide discounted medical care and discounted medications.

2. Infrastructure

Document the current BCCEDP infrastructure including:

a. The number of BCCEDP sites in operation as of January, 2001;

b. The total number of political subdivisions(e.g., counties) and the percentage of these subdivisions that had a BCCEDP site in January, 2001; and

c. During the most recent program year: (1) The average number of women served in the State/Territory/Tribal Service Area each month during the past BCCEDP project year;

(2) The racial/ethnic characteristics of the population served;

(3) The percentage of women with a positive mammogram or pap test who did not go on for further diagnostics and reasons why women did not go on; and

(4) The average length of time between a positive mammogram or pap test and the receipt of a diagnostic test.

3. Collaborative Efforts

Provide a concise collaboration plan, which addresses program methods and analyzing and publishing data. The following areas should be addressed:

a. Meeting and teleconference attendance for the purpose of developing, to the degree possible, scientifically sound protocols, forms, tracking systems, measurements, etc.;

b. Analyzing data and developing abstracts and publications; and

c. Extent of collaboration with university personnel including public or community health experts.

4. Program Planning

Describe how the program will decide the following:

a. Site selection, approximate number, characteristics of and the proportion that will receive WISEWOMAN services and an annual estimate of women served;

b. Public health screening and intervention services to be provided along with a time line for determining and implementing screening and intervention services (allowable screening and diagnostic procedures for the demonstration programs include resting pulse, blood pressure, serum total cholesterol (nonfasting), HDL-cholesterol (nonfasting), height and weight measurements, automated blood chemistry (to assess blood glucose, potassium, calcium, creatinine, uric acid, triglyceride, or micronutrient levels), urine analysis(including urine cotinine), and paper and pencil tests, interviews, or computerized methods that measure level of physical activity, dietary intake, smoking, osteoporosis risk status, immunization status, or other chronic disease risk factors or preventable health problems). Tests that require the participant to fast should be considered diagnostic tests and not public health screening tests. One fasting LDL–C test or fasting lipoprotein profile will be allowed when ordered as a diagnostic test. The use of program funds for other diagnostic tests will require substantial justification by the program;

c. Letters of support for WISEWOMAN from a number of State/Territorial/Tribal BCCEDP site directors, medical staff involved in diagnostic testing and provision of discounted medications, and university personnel;

d. A staffing plan that appoints at least two professional staff members to work full-time on WISEWOMAN, or a plan for hiring such staff members and describe the WISEWOMAN evaluation team with information on their experience and academic degrees;

e. A method for tracking women through the system and after they leave the system (for the purpose of bringing them back for further screening, intervention, and behavioral follow-up), for case management that includes assurances that women will have access to medical care facilities, for flagging women who need immediate referral (i.e. those with alert values) because of extremely high blood pressure (180 systolic blood pressure or 110 diastolic blood pressure), cholesterol (>400 mg/dL), or glucose levels (>375 mg/dL); and

f. How the program will track women, the number and types of standardized lifestyle interventions received, and the costs of the intervention.

5. Screening and Intervention

Document the ability of the program to screen and intervene upon women enrolled in the WISEWOMAN program including implementation of WISEWOMAN screening activities, the rationale and guidelines for implementing WISEWOMAN

intervention activities, methods for reaching women for this and the use of staff such as outreach workers to address differing barriers.

6. Evaluation

Submit a preliminary evaluation design to examine the impact of chronic disease risk factors intervention(s) on lowering blood pressure and improving cholesterol profiles at six and 12 months after intervention. The plan should include:

a. The extent to which a university or prevention research center at a university will be involved in the evaluation design;

b. The preliminary evaluation questions to be answered;

c. The type of evaluation design (e.g. randomized controlled design) and rationale for using this type of design;

d. Length of follow-up and measurement intervals;

e. Protocol used to ensure that the maximum number of women will return for each evaluation;

f. Statistical techniques that will be used to analyze the data with preliminary estimates of the sample size needed to achieve adequate statistical power; and

g. A plan for pilot testing the methods outlined in the initial research protocols, including methods of screening, proposed lifestyle interventions, delivery system for lifestyle interventions, availability of discounted care and medications, and program evaluation.

One type of evaluation might from a number of sites, compare blood pressure and cholesterol, and risk behaviors for CVD in those assigned to a ''usual care'' (e.g., hypertension and cholesterol screening, referral, and follow-up with minimal intervention) group with those assigned to ''special intervention'' (e.g., added screening for overweight, poor dietary habits, physical inactivity, cigarette smoking, or undiagnosed diabetes followed up by interventions such as special classes, support groups, physician prescriptions, extra follow-up efforts, and/or community programs such as food co-ops, walking clubs, or smoking cessation programs) group. In this case, a discussion of the method that will be used to keep the usual care group from knowing and adopting the interventions that are being implemented in other areas of the clinic is extremely important. Other designs may be proposed given sufficient justification of the scientific method. Special interventions should assure more intensive and frequent behavioral follow-up consistent with counseling recommendations. Assignments to ''usual care'' or ''special intervention'' groups could be at the clinic or individual level. Random assignment to level of intervention is preferred.

7. Budget and Justification

Provide a detailed budget and line-item justification that is consistent with the stated objectives, purpose, and planned activities of the project. Identify the required 60/40 cost distribution of program funds in the requested itemized budget by using separate columns for each. CDC WISEWOMAN requires use of funds in accordance with Pub. L. 101–354.

Budget for the following travel:

a. Up to two persons to attend one training session during the year (two to three days). Topic and place to be determined.

b. Up to two persons to Atlanta, GA to participate in the 2002 NCCDPHP Annual Chronic Disease Conference(four days).

c. One person to attend the Physical Activity and Public Health Course that is held at Sea Pines, South Carolina in September 2002 [Cost for seven to eight day package is $1150 for the registration, lodging, and meals. Airfare is not included] or one person to participate in a non-CDC sponsored professional meeting directly relevant to the program.

Budget for collecting and reporting cost data and minimum data elements. Section 1505 (42 U.S.C. 300n–1) requires that applicants provide assurances that the grant funds be used in the most cost-effective manner.

8. Human Subjects

State whether or not Human subjects are involved in this proposal. CDC Institutional Review Board approval is required.

9. Women, Ethnic, and Racial Groups

Describe how the CDC/ATSDR policy requirements will be met regarding the inclusion of women, ethnic, and racial groups in the proposed research. (See Women, Racial, and Ethnic Minorities in the Evaluation Criteria and Other Requirements sections.)

F. Submission and Deadline

Submit the original and two copies of CDC form 0.1246. Forms are available in the application kit and at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm.

On or before August 20, 2001, submit the application to the Grants Management Specialist identified in Section J., ''Where to Obtain Additional Information''.

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

1. Received on or before the deadline date; or

2. Sent on or before the deadline date. (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.)

Late Applications: Applications which do not meet the criteria in 1. or 2. above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria (100 Points)

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC:

1. Background and Need; Women, Racial, and Ethnic Groups (15 Points)

The extent of the disease burden and the need among the priority populations, including a description of gaps in the scientific knowledge with regard to preventing cardiovascular disease or other chronic diseases in the selected priority populations. (10 points); The extent to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research (5 points).

2. Infrastructure (10 Points)

The strength of the State/Territorial/Tribal BCCEDP program as evidenced by the number of BCCEDP sites and the percentage of subdivisions (e.g., counties) within the State/Territory/Tribal Service Area that had a BCCEDP site in January, 2000; the average number of women served each month during the past BCCEDP project year; the racial/ethnic characteristics of the population served; the percentage of women with a positive mammogram or pap test who did not go on for further diagnostics and reasons why they didn't; and the average length of time between a positive test and the receipt of a diagnostic test.

3. Collaborative Efforts (5 Points)

Ability to collaborate and extent of proposed collaboration with other WISEWOMAN projects to develop joint program methods and analyze data.

4. Program Plan (30 Points)

The adequacy and appropriateness of the preliminary program plan as indicated by:

a. The likelihood that program plans and protocols will be finalized within the first year;

b. Proposed site selection, the approximate number of sites to receive WISEWOMAN services, the characteristics of the sites, the proportion of State/Territorial/Tribal BCCEDP sites that will receive WISEWOMAN services, and estimated number of women who are expected to receive such services in the first, second, and subsequent years;

c. Letters of support for WISEWOMAN from the State/Territorial/Tribal BCCEDP site directors and medical staff;

d. A staffing plan;

e. A proposed tracking system for women for referral and follow up and the number and types of interventions provided; and

5. Screening and Interventions (15 Points)

Proposed public health screening and intervention services to be provided along with a time line for determining and implementing screening and intervention services. The adequacy and quality of the proposed rationale and guidelines for implementing eachWISEWOMAN screening and intervention activity; the methods for reaching women from the State/Territorial/Tribal BCCEDP for the purpose of WISEWOMAN screening and intervention; the extent and use of outreach workers to address barriers to program involvement, behavioral change, and maintaining contact for future health screenings and interventions.

6. Evaluation Plan (25 Points)

The extent to which the preliminary evaluation plan provides an appropriate design to examine the impact of chronic disease risk factor intervention(s) on lowering blood pressure and improving cholesterol profiles; collaboration with partners including university partners; evaluation; and data analysis.

7. Budget and Justification (Not Scored)

The extent to which the proposed budget is adequately justified, reasonable, and consistent with this program announcement.

8. Human Subjects (Not Weighted)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements:

Provide CDC with original plus two copies of—

1. Progress reports on a quarterly basis;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in Section J., ''Where to Obtain Additional Information''. The following additional requirements are applicable to this program. For a complete description of each, see Attachment II in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized by sections 1501–1509 (42 U.S.C. 300k–300n–4a) of the Public Health Service Act, as amended. This program is also authorized by the Consolidated Appropriations Act, 2000, Pub. L. 106–113. The Catalogue of Federal Domestic Assistance (CFDA) number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page on the Internet: http://www.cdc.gov. Click on ''Funding'' then ''Grants and Cooperative Agreements''.

Should you have questions after reviewing the contents of all the documents, business management assistance may be obtained from: Glynnis Taylor, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Announcement 01098, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2752, E-mail address: gld1@cdc.gov.

For program technical assistance, contact: Julie C. Will, Division of Nutrition and Physical Activity, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Hwy, NE., Atlanta, Georgia 30341–4146, Telephone: (770) 488 6024, E-mail address: jxw6@cdc.gov.

Dated: July 2, 2001.

John L. Williams,

Director, Procurement and Grants Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–17039 Filed 7–9–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1254]

Determination of Regulatory Review Period for Purposes of Patent Extension; Gabitril

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Gabitril and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

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

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical