FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 25, 1997.

A. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. Caisse Nationale de Credit Agricole, Paris, France; to acquire Credit Agricole Indosuez, Paris, France, and thereby indirectly acquire Indosuez Investment Management Services, Inc., Menlo Park, California, and thereby engage in investment management and advisory services, pursuant to § 225.28(b)(6) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, July 7, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–18098 Filed 7–9–97; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 797]

FY 1997; Studies To Evaluate the Epidemiologic and Laboratory Characteristics of Human Immunodeficiency Virus (HIV) Infection Among United States Blood and Plasma Donors

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for cooperative agreements to provide assistance for epidemiologic surveillance studies of human immunodeficiency virus (HIV) in U.S. blood and plasma donors. These studies will be conducted to describe the epidemiology of human immunodeficiency virus (HIV), other retroviruses, and related conditions in persons whose blood tests positive for HIV antibody, HIV antigen, or other related laboratory markers. Additional funds will be available for laboratory studies of the genetic variation of HIV among blood and plasma donors and other selected populations.

CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of HIV Infection. (For ordering a copy of ''Healthy People 2000,'' see the Section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

Authority

This program is authorized under Sections 301(a) and 317(k)(2) of the Public Health Service Act (42 U.S.C. 241(a) and 247b(k)(2)), as amended. Applicable program regulations are set forth in 42 CFR Part 52, entitled ''Grants for Research Projects.''

Smoke-Free Workplace

CDC strongly encourages all cooperative agreement recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants include all nonprofit and for-profit blood centers and organizations and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, and other public and private organizations, State and local health departments or their bona fide agents or instrumentalities, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations, and small, minority- or women-owned businesses are eligible to apply.

Note: Organizations described in section 501(c)(4) of the Internal Revenue Code of 1986 that engage in lobbying are not eligible to receive Federal grant/cooperative agreement funds.

Availability of Funds

Approximately $1,200,000 will be available in FY 1997 to fund approximately 5–10 awards. It is expected that the average award will be approximately $200,000, with a range from $20,000 to $800,000. It is expected that approximately 2 new and 6 competing renewal awards will be made and that awards will begin on or about September 30, 1997. Awards will be funded for a 12-month budget period within a project period of up to 5 years. Funding estimates may vary and are subject to change.

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

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of Department of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997

appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. Section 503 of this new law, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Public Law No. 104–208 (September 30, 1996), provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

In the United States, about 8 million people donate approximately 14 million units of whole blood each year; donors also give about 12 million units of plasma for use in making immune globulin, clotting factors, and other products. During the last decade, improved donor screening and education and better laboratory tests for blood-borne viruses have markedly increased the safety of the nation's blood supply.

The Centers for Disease Control and Prevention has monitored data from the routine testing of blood donors since the first HIV antibody screening test was licensed in 1985. Since 1988, CDC has collaborated with the National American Red Cross and other major blood collection agencies to systematically evaluate the characteristics of HIV-infected donors through detailed interviews and follow-up. From 1988 to 1995, the seroprevalence of HIV among blood donors decreased threefold, from approximately 1 in 4,000 to 1 in 12,000 donors. This decrease was due in part to the elimination of seropositive donors from the repeat donor pool. However, HIV seroprevalence among first-time donors has also declined. Because persons with known risks for HIV infection are actively discouraged from donating, information about HIV-infected donors identified during the screening process is valuable for further improving donor deferral procedures and may offer clues to emerging patterns of HIV transmission.

Current estimates of the residual risk of HIV transmission from blood transfusion are based on mathematical models; these models require estimates of the incidence of HIV infection among blood donors and the length of the infectious window period. A recent analysis suggested that there was a risk of 1 case of HIV transmission for every 450,000 to 660,000 donations of screened blood. This estimate is much smaller than earlier estimates, principally because of the improved sensitivity of enzyme immunoassay screening tests for HIV antibody. The ability to monitor the risk of HIV transmission by blood transfusion depends on methods for maintaining surveillance of incident HIV infection among blood donors and characterizing the infectious window period.

Since March 1996, donated blood has also been screened for HIV p24 antigen. On average, p24 antigen tests become positive approximately 6 days before enzyme immunoassays for HIV antibody. Surveillance conducted by CDC, the National American Red Cross, and other blood collection agencies suggest that p24 antigen screening has thus far done little to improve blood safety; however, it has raised issues concerning counseling and exclusion of donors who have false positive test results and donors who may seek testing by a more sensitive test than is routinely offered. In addition, concerns have been raised over the presence of HIV strains poorly detected by commonly used screening assays (e.g., group O). As testing technology continues to evolve, blood donation provides a critical setting for evaluating the performance characteristics of existing and new screening techniques, as well as their potential impact on blood safety.

Although incidence and prevalence of HIV infection are lower among blood donors than among unselected populations, the routine screening of very large numbers of repeat blood donors identifies substantial numbers of persons with recently acquired HIV infection. A newly developed, ''detuned'' enzyme immunoassay can identify HIV infections acquired during a relatively recent interval among first-time, as well as repeat, donors and among other significant populations. Defining the epidemiologic and laboratory characteristics of these recently infected persons is important for understanding the evolution of the HIV epidemic in the U.S. For example, HIV genomes from such persons are needed for larger studies of subtype variation and primary drug resistance.

Purpose

The purpose of these awards is to support research for epidemiologic surveillance studies to gain a greater understanding of the HIV epidemic and the safety of the U.S. blood supply. In particular, studies with flexibility to support surveillance of other transfusion-transmissible agents in addition to HIV will be considered.

I. Surveillance and Interview Studies of Blood and Plasma Donor Populations

A. Monitor the prevalence and incidence of HIV infection in blood and plasma donors at selected centers throughout the U.S. and Puerto Rico.

B. Analyze the demographic, behavioral, and laboratory characteristics of HIV-infected and non-infected donors to strengthen the effectiveness of donor screening and deferral processes.

C. Estimate the risk of HIV transmission from screened blood and plasma.

D. Identify persons and characteristics of persons recently infected with HIV.

II. Laboratory Studies of Blood and Plasma Donors and Other Significant Populations

A. Evaluate the effectiveness of screening blood donations for HIV–1 p24 antigen.

B. Evaluate the performance of proposed or potential HIV screening tests (e.g., amp-RT and viral RNA assays).

C. Describe the evolution of laboratory markers during the interval between acquisition of HIV infection and seroconversion (including the ''window period'').

D. Conduct molecular epidemiologic studies of HIV and related viruses in blood and plasma donors and other populations of epidemiologic significance. These studies could include surveillance for non-B HIV subtypes, primary antiretroviral drug resistance, and segregation of viral strains according to demographic and behavioral risk characteristics.

Applications should indicate whether they are addressing research issues identified under sections I. or II. above, or both. Applications for sections I. and II. will be evaluated separately.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities listed under A. (Recipient Activities), and CDC shall be responsible for conducting activities listed under B. (CDC Activities). The applications should be presented in a manner that

demonstrates the applicant's ability to address the proposed activities in a collaborative manner with CDC.

A. Recipient Activities

1. Develop research study protocols, consent forms, questionnaires, and data collection methods.
2. Identify, recruit, obtain informed consent from, and enroll an adequate number of study participants as determined by study protocols and program requirements.
3. Conduct epidemiologic studies at specified sites using approved study protocols established through the recipient's participation with CDC and other collaborating institutions.
4. Perform selected laboratory tests according to established research protocols. Store all HIV seropositive sera and additional specimens (sera or cells) as may be required by the research study designs.
5. Participate in the development and maintenance of data management systems for the study.
6. Share data and specimens with other collaborators when appropriate to answer specific research questions.
7. Analyze study data and present findings in scientific presentations and publications.

B. CDC Activities

1. Provide technical assistance in the design and conduct of the research.
2. Provide technical guidance in the development of study protocols, consent forms and questionnaires, including training and pretesting as necessary.
3. Assist in designing a data management system. As requested, carry out central data management functions.
4. As requested, perform selected laboratory tests.
5. Provide specimens for selected laboratory studies.
6. Facilitate collaboration among the different sites including laboratories and consultants.
7. Collaborate with recipients in the analysis of research information and the presentation of research findings.

Technical Reporting Requirements

1. An original and two copies of annual progress reports are required no later than 90 days after the end of the budget period. The annual reports for current awardees will be submitted with the renewal application.
2. Final financial status and performance report is also required no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, Procurement and Grants Office, CDC.

Application Content

Applications must be developed in accordance with PHS Form 5161–1 and the instructions outlined under the following section headings. The application should provide a detailed description of first-year activities and only briefly describe future-year activities. To assist in evaluating the application, please limit the number of pages to 25 plus attachments.

A. Executive Summary

B. Table of Contents

C. Background and Needs

1. Demographic and geographic characteristics of the proposed study population.
2. Reported cases of AIDS and/or HIV infection, patterns of behavioral risk correlated illnesses (e.g., syphilis, hepatitis, etc.) in the study population.
3. Previous efforts to conduct similar studies and uses of the resulting data.

D. Capacity

1. Demonstrated knowledge, ability and resources to conduct epidemiologic or laboratory studies.
2. Ability to enroll and evaluate adequate numbers of eligible study participants or to obtain and examine appropriate numbers and types of laboratory specimens.
3. Position descriptions for all key project personnel. These may be included in the appendix but should be referenced in the text.

E. Goals and Objectives

1. List one or more goals for the project.
2. List specific measurable outcome objectives related to program development and implementation; training and data quality; data analysis and dissemination, including potential plans for linkage with other data systems; and program evaluation.

F. Methods/Activities

1. Describe activities related to each objective.
2. Specify timelines for completing each activity.
3. Designate personnel resources and assignments to specific project activities.

G. Project Evaluation

1. Evaluation plan should contain specific activities to collect data to measure program development and implementation.
2. Describe how information will be obtained, prepared in specific reports, and used to improve the program.

H. Budget

1. Line-item descriptive justification for personnel, travel, supplies and other services should be submitted. Applicant should be precise about the purpose of each budget item as it relates to the project.
2. If applicable, applicants requesting funding for contracts should include the name of the person or firm to receive the contract, the method of selection, the period of performance, and a description of the contracted service requested.
3. Funding levels for years two and through five should be estimated.

I. Supporting Materials

1. Curriculum vitae and job descriptions of critical staff.
2. Letters of endorsement and/or collaboration of participating centers, agencies and/or State or local public health departments.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

1. The applicant demonstrates the knowledge, ability and resources to conduct epidemiologic or laboratory studies of HIV and related viruses in U.S. blood and plasma donors or other populations of epidemiologic significance. (30 points)
2. The applicant demonstrates the ability to enroll and evaluate adequate numbers of eligible study participants (e.g., HIV-seropositive donors) or to obtain and examine appropriate numbers and types of laboratory specimens. (25 points)
3. The applicant presents a sound plan for conducting and evaluating program activities. If tests of clinical significance are performed, the application should include a plan for notifying study subjects. (15 points)
4. The applicant proposes objectives that are measurable, specific, time-phased, and related to required recipient activities and program purpose. (10 points).
5. The applicant demonstrates willingness to cooperate in a study with CDC and other collaborating institutions. (10 points)
6. The size, qualifications, and time allocation of the proposed staff and the availability of facilities are adequate for the study. (10 points)
7. The budget is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized. (Not scored)
8. Procedures are adequate for the protection of human subjects, whether

or not exempt from the Department of Health and Human Services (DHHS) regulations. (Not scored) Recommendations on the adequacy of protections include: (a) Protections appear adequate and there are no comments to make or concerns to raise; (b) protections appear adequate, but there are comments regarding the protocol; (c) protections appear inadequate and the Objective Review Group (ORG) has concerns related to human subjects; or (d) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

Funding Priority

Priority will be given to competing continuation applications from satisfactorily performing projects over applications for projects not already receiving support under the program. Projects will be awarded so that the composite of projects reflects the geographic and demographic distribution of the study population.

Executive Order 12372 Review

Applications are not subject to review under Executive Order 12372, Intergovernmental Review of Federal Programs.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.944, Human Immunodeficiency Virus (HIV)/ Acquired Immunodeficiency Virus Syndrome (AIDS) Surveillance.

Other Requirements

1. Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

2. Human Subjects

This program involves research on human subjects. Therefore, all applicants must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved with or support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

3. HIV Program Review Panel

Recipients must comply with the document entitled Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992) (a copy is in the application kit). To meet the requirements for a program review panel, recipients are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a State or local health department. The names of the review panel members must be listed on the Assurance of Compliance form CDC 0.1113, which is also included in the application kit. The recipient must submit the program review panel's report that indicates all materials have been reviewed and approved.

4. Patient Care

Applicants should provide assurance that all HIV-infected patients enrolled in their studies will be linked to an appropriate local HIV care system that can address their specific needs such as medical care, counseling, social services, and therapy. Details of the HIV care system should be provided, describing how patients will be linked to the system. Funds will not be made available to support the provision of direct care for study participants.

5. Women, Racial and Ethnic Minorities

It is the policy of the CDC to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947–47951 (a copy is included in the application kit).

6. Confidentiality

Recipients must describe confidentiality and security provisions to protect data collected through HIV/ AIDS surveillance, including copies of local data release policies; employee training in confidentiality provisions; State laws, rules, or regulations pertaining to the protection or release of surveillance information; and physical security of hard copies and electronic files containing confidential surveillance information. Recipients must describe any laws, rules, regulations, or health department policies that require or permit the release of patient identifying information collected under the HIV/ AIDS surveillance system to entities outside of the public health department and measures the health department has taken to ensure that the confidentiality of individuals reported to the surveillance system is protected from further or unlawful disclosure.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (OMB Number 0937–0189) must be submitted to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mail Stop E–15, Atlanta, Georgia 30305 on or before August 11, 1997.

1. Deadline

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

A. Received on or before the stated deadline date; or

B. Sent on or before the deadline date and received in time for submission to the independent review group. (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 accepted as proof of timely mailing.)

2. Late Applications

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

Where To Obtain Additional Information

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mail Stop E–15, Atlanta, Georgia 30305, telephone (404) 842–6575, Email address vxm7@cdc.gov. The announcement will be available on one of two Internet sites on the publication date: CDC's home page at http://www.cdc.gov, or at the Government Printing Office home page (including free access to the **Federal Register**) at http://www.access.gpo.gov.

Programmatic technical assistance may be obtained from Dr. Richard Steketee or Dr. Marta Gwinn, Division of HIV/AIDS Prevention, National Center for HIV, STD, TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mail Stop E–46, Atlanta, Georgia 30333, telephone (404) 639–2090. Eligible applicants are encouraged to call before developing and submitting their application. Please refer to Announcement Number 797 when requesting information.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report: Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report: Stock No. 017–001–00473–1) referenced in the Introduction from the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: July 3, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–18062 Filed 7–9–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreement for a National Center for the Prevention of Childhood Agricultural Injury, Program Announcement 737: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Disease, Disability, and Injury Prevention and Control SEP: Cooperative Agreement for a National Center for the Prevention of Childhood Agricultural Injury, Program Announcement 737.

Time and Date: 8:30 a.m.-4:30 p.m., August 4, 1997.

Place: Corporate Square Building 11, Conference Room A, Corporate Square Boulevard, Atlanta, Georgia 30326.

Status: Closed.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 737.

The meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Contact Person for More Information: Ann Cronin, Office of Extramural Coordination and Special Projects, National Institute for Occupational Safety and Health, CDC, M/S D36, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–2277.

Dated: July 03, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–18061 Filed 7–9–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0261]

Frequently Asked Questions About the New FDA Tobacco Regulations: Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration is announcing the availability of a draft guidance entitled ''Frequently Asked Questions About the New FDA Tobacco Regulations.'' The draft guidance is intended to address the questions most frequently asked by retailers, consumers, and others about the age and identification requirements of the final rule restricting the sale of cigarettes and smokeless tobacco to protect children and adolescents.

DATES: Submit written comments on the draft guidance by September 8, 1997.

ADDRESSES: The draft guidance entitled ''Frequently Asked Questions About the New FDA Tobacco Regulations,'' is available on the Internet at http://www.fda.gov/, or a paper copy may be ordered free of charge by calling 1–888–FDA–4KIDS.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Anne M. Kirchner, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, rm. 14–72, Rockville, MD 20857, 301–827–0867.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 28, 1996 (61 FR 44396), FDA issued a final rule to restrict the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents (21 CFR part 897). The final rule covers three general classes of nicotine-containing tobacco products: Cigarettes, loose cigarette tobacco, and smokeless tobacco. The final rule applies to manufacturers, distributors, retailers, and importers who make, distribute, sell, and import such products.

Since February 28, 1997, the final rule has prohibited retailers from selling cigarettes, loose cigarette tobacco, or smokeless tobacco to persons under the age of 18, and has required retailers to verify the age of customers under the age of 27 by checking an identification (ID) card which contains the bearer's photograph and birth date.

Before the age and ID requirements took effect, FDA officials held a series of public meetings in 10 metropolitan areas and produced a national videoconference to explain the new requirements and to answer questions from retailers, consumers, public health officials, and others. FDA agreed to make available written answers to the questions most frequently asked at these meetings.

The draft guidance that FDA is making available answers these questions, as well as questions that FDA has received on its toll-free hotline and