long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: February 24, 1997

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–4959 Filed 2–26–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97D–0041]

The Small Entity Compliance Guide On: Regulations to Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco in Order to Protect Children and Adolescents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised compliance guide entitled, ''The Small Entity Compliance Guide On: Regulations to Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco in Order to Protect Children and Adolescents (21 CFR Part 897).'' The revised compliance guide is intended to help small entities comply with the final rule restricting the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents. This action is being taken under the Small Business Regulatory Enforcement Fairness Act.

DATES: Comments may be submitted at any time.

ADDRESSES: The revised compliance guide entitled ''The Small Entity Compliance Guide On: Regulations to Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco in Order to Protect Children and Adolescents (21 CFR Part 897)'' is available on the Internet at ''http://www.fda.gov/'', or a paper copy may be ordered free of charge by calling 1–800–FDA–4KIDS. Submit written comments on the revised compliance guide to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The revised compliance guide and received comments are available for public examination in the

Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Anne M. Kirchner, Office of Policy (HF–23), 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. The final rule covers three general classes of nicotine-containing products: Cigarettes, cigarette tobacco, and smokeless tobacco. The final rule applies to manufacturers, distributors, and retailers who make, distribute, or sell such products.

Beginning on February 28, 1997, Federal regulation will prohibit retailers from selling cigarettes, cigarette tobacco, or smokeless tobacco to persons under the age of 18, and will require retailers to verify the age of all customers under the age of 27 by checking a photographic identification for date of birth. Under the current schedule, starting August 28, 1997, the remaining provisions of the rule will be effective, except for the sponsorship provision, which will be effective on August 28, 1998.

Under the Small Business Regulatory Enforcement Act (Pub. 104–121), FDA is announcing the availability of the revised compliance guide which is intended to help small businesses comply with the requirements of the new rule. An earlier version of the compliance guide was previously available on the Internet and in paper form. The agency believes that the rulemaking process provided ample opportunity to comment on issues concerning all the underlying regulatory provisions of the rule. However, FDA is soliciting comments on the guide itself and may amend the guide periodically as a result of comments received. The agency is making available at this time a revised compliance guide which covers all of the access restrictions even though it is the photographic identification for date of birth requirement that becomes effective first. Therefore, in submitting comments, persons should consider the implementation dates of the provisions described in the guide.

Dated: February 20, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4793 Filed 2–26–97; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Special Project Grants and Cooperative Agreements; Maternal and Child Health Services; Federal Set-Aside Program; Comprehensive Hemophilia Centers, Genetic Services, and Maternal and Child Health Improvement Projects

AGENCY: Health Resources and Services Administration (HRSA).

ACTION: Notice of availability of funds.

SUMMARY: The HRSA announces that approximately $10.2 million in fiscal year (FY) 1997 funds will be available for grants and cooperative agreements for the following activities: Maternal and Child Health (MCH) Special Projects of Regional and National Significance (SPRANS), including genetic disease testing, counseling and information services; and special MCH improvement projects (MCHIP) which contribute to the health of mothers, children, and children with special health care needs (CSHCN). All awards will be made under the program authority of section 502(a) of the Social Security Act, the MCH Federal Set-Aside Program. Within the HRSA, SPRANS grants are administered by the Maternal and Child Health Bureau (MCHB). Grants for SPRANS research and training are being announced in a separate notice. No new SPRANS hemophilia program grants will be funded in FY 1997.

Of the approximately $52.1 million available for SPRANS genetics and MCHIP activities in FY 1997, about $10.2 million will be available to support approximately 63 new and competing SPRANs renewal projects, at a cost of about $161,900 per project. The actual amounts available for awards and their allocation may vary depending on unanticipated program requirements and the volume and quality of applications. Awards are made for grant periods which generally run from 1 to 5 years in duration. Funds for grants under the MCH Federal Set-Aside Program are appropriated by Public Law 104–208.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The MCH Block Grant Federal Set-Aside Program addresses issues related to the Healthy People 2000 objectives of improving maternal, infant, child and adolescent health and developing service systems for children with special health care needs. Potential applicants may obtain a copy of Healthy People 2000 (*Full Report:* Stock No. 017–001–00474–0) or Healthy People 2000 (*Summary Report:* Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office Washington, DC 20402–9325 (telephone: 202–512–1800).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

ADDRESSES: Federal Register notices and application guidance for MCHB programs are available on the World Wide Web via the Internet at address: http://www.os.dhhs.gov/hrsa/mchb. Click on the file name you want to download to your computer. It will be saved as a self-extracting (Macintosh or) WordPerfect 5.1 file. To decompress the file once it is downloaded, type in the file name followed by a <return>. The file will expand to a WordPerfect 5.1 file.

For applicants for SPRANS grants and cooperative agreements who are unable to access application materials electronically, a hard copy (Revised PHS form 5161–1, approved under OMB clearance number 0937–0189) may be obtained from the HRSA Grants Application Center. Requests should specify the category or categories of activities for which an application is requested so that the appropriate forms, information and materials may be provided. The Center may be contacted by: Telephone Number: 1–888–300–HRSA, FAX Number: 301–309–0579, E-mail Address: HRSA.GAC@ix.netcom.com. Completed applications should be returned to: Grants Management Officer, HRSA Grants Application Center, 40 West Gude Drive, Suite 100, Rockville, Maryland 20850. Please indicate the appropriate CFDA # for the application being submitted (see table below).

DATES: Potential applicants are invited to request application packages for the particular program category in which they are interested, and to submit their applications for funding consideration. Deadlines for receipt of applications differ for the several categories of grants. These deadlines are as follows: