The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by FAX by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products or Animal Plasma or Serum-Derived Products.'' The draft guidance provides general information for the CMC and establishment description section of the BLA, Form FDA 356h for human plasma-derived biological products, animal plasma, or serum-derived products.

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a new harmonized Form FDA 356h entitled ''Application to Market a New Drug, Biologic, or an Antibiotic for Human Use.'' The new harmonized form is intended to be used by applicants for all drug and biological products. The new harmonized form when fully implemented will allow biological product manufacturers to submit a single application, the BLA, instead of two separate license application submissions, a product license application (PLA) and an establishment license application (ELA).

The draft guidance document represents the agency's current thinking on content and format of the CMC, and establishment description information section of a license application for human plasma-derived biological products, animal plasma, or serum-derived products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written comments to the Dockets Management Branch (address above) regarding the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by April 21, 1998, to ensure their adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests for copies should be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document by using the World Wide Web (WWW). For WWW access connect to CBER at ''http://www.fda.gov/cber/guidelines.htm.''

Received comments will be considered in determining whether further revision of the draft guidance document is warranted.

Dated: January 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1293 Filed 1–20–98; 8:45 am]

BILLING CODE 4160–01–F

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.

SUMMARY: The Food and Drug Administration is announcing the availability of a new section to the draft guidance entitled ''Frequently Asked Questions About the New FDA Tobacco Regulations.'' The draft guidance addresses the questions most frequently asked by retailers, consumers and others about the age and photo identification requirements of the final rule restricting the sale of cigarettes and smokeless tobacco to protect children and adolescents. The new section on enforcement procedures addresses questions raised by retailers and others concerning the amount of penalties that FDA intends to seek for third and subsequent violations of the age and identification requirements.

DATES: Submit written comments on the draft guidance by April 21, 1998.

ADDRESSES: The draft guidance entitled ''Frequently Asked Questions About the New FDA Tobacco Regulations,'' and the amendment are 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: Mary M. Lyda, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, rm. 14–101, Rockville, MD 20857, 301–827–3360.

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 (21CFR 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.

The draft guidance answers questions most frequently asked by retailers, consumers, and others concerning these requirements and the agency's enforcement plans. To ensure that retailers are complying with the requirements, FDA has commissioned State officials to conduct compliance checks, during which adolescents, accompanied by State officials, attempt to purchase cigarettes or smokeless tobacco from retailers. The guidance

states that for a first violation of the age and identification requirements, FDA will issue a letter notifying the retailer that it was out of compliance and informing the retailer that FDA will schedule a followup compliance check. The guidance explains that the second time a retailer is out of compliance FDA will seek civil money penalties in the amount of $250.00.

The new section that FDA is making available addresses questions concerning the amount of penalties that FDA intends to seek for third and subsequent violations of the age and photo ID provisions of the regulation. FDA intends to seek $1,500.00 for a third violation, $5,000.00 for a fourth violation, and $10,000.00 for a fifth violation. The new section provides more information concerning the civil money penalty process under which a retailer may pay the penalty or request a hearing to contest it. Because some of the answers contained in the new section represent FDA's current interpretation of new regulatory requirements, the additions constitute guidance. Therefore, FDA is publishing the new section in draft and is soliciting public comment. FDA will review received comments and, if appropriate, revise the document in response to comments.

The draft guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Interested persons may, on or before April 21, 1998, submit written comments regarding this draft guidance to the Dockets Management Branch, address above. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 12, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–1344 Filed 1-20-98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Center for Scientific Review Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review Small Business Innovation Research.

Name of SEP: Biological and Physiological Sciences.

Date: February 23, 1998.

Time: 2 p.m.

Place: NIH, Rockledge 2, Room 4212, Telephone Conference.

Contact Person: Dr. Nabeeh Mourad, Scientific Review Administrator, 6701 Rockledge Drive, Room 4212, Bethesda, MD 20892, (301) 435–1222.

Name of SEP: Biological and Physiological Sciences.

Date: March 2–3, 1998.

Time: 8 a.m.

Place: Bethesda Marriott Hotel, Bethesda, MD.

Contact Person: Dr. Nabeeh Mourad, Scientific Review Administrator, 6701 Rockledge Drive, Room 4212, Bethesda, MD 20892, (301) 435–1222.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 14, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–1317 Filed 1–20–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting of the National Advisory Council for Human Genome Research

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Council for Human Genome Research, National Human Genome Research Institute, February 12–13, 1998, Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD.

This meeting will be open to the public on Thursday, February 12, 8:30 a.m. to approximately 3 p.m., to discuss administrative details or other issues relating to committee activities. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting will be closed to the public on February 12, from 3 p.m. to recess, and on February 13, from 8:30 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Elke Jordan, Deputy Director, National Human Genome Research Institute, National Institutes of Health, Building 31, Room 4B09, Bethesda, MD 20892, (301) 496–0844, will furnish the meeting agenda, rosters of Committee members and consultants, and substantive program information upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Jane Ades, (301) 594–0654, two weeks in advance of the meeting.

(Catalogue of Federal Domestic Assistance Program No. 93.172, Human Genome Research)

Dated: January 14, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–1321 Filed 1–20–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Neurological Disorders and Stroke Council of the National Institute of Neurological Disorders and Stroke, February 12–13, 1998, Building 31, Conference Room 6, National Institutes of Health, which was published in the **Federal Register** on December 29, 1997, (62 FR 67645).

The information regarding the date and time for the closed session was incorrect. The Council meeting will be open to the public on February 12 from 8:30 a.m. to approximately 3 p.m. and will be closed on February 12, approximately 3 p.m. to recess and February 13, 8:30 a.m. to adjournment.