are not necessary to provide reasonable assurance of the safety and effectiveness of the device. By February 19, 1998, FDA will provide guidance on how to request such an exemption.

Dated: January 15, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–1485 Filed 1–16–98; 12:00 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Immunology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on February 2, 1998, 9:30 a.m. to 6:30 p.m.

Location: Parklawn Bldg., conference rooms D & E, 5600 Fishers Lane, Rockville, MD.

Contact Person: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12516. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss proposed prescription home use labeling for a unitized bladder cancer tumor marker assay used to aid in the detection of bladder cancer recurrence. Also, the committee will discuss, make recommendations, and vote on a premarket approval application for a free PSA (prostate-specific antigen) assay. The assay is intended to be used in men over the age of 50 with a negative digital rectal examination and a total serum PSA measurement of 4.0 to 10.0 nanograms/milliliter. The free PSA/total PSA ratio aids in the differentiation between benign and malignant prostate disease.

Procedure: On February 2, 1998, from 10 a.m. to 6:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 29, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 29, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On February 2, 1998, from 9:30 a.m. to 10 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). FDA staff will present to the committee confidential information regarding present or future issues.

FDA regrets that it was unable to publish this notice 15 days prior to the February 2, 1998, Immunology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Immunology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 15, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–1418 Filed 1–15–98; 3:51 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0007]

Draft ''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;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the 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 document is intended to assist applicants in the preparation of the content and format of the chemistry, manufacturing, and controls (CMC) section and the establishment description section of a biologics license application (BLA), revised Form FDA 356h for human plasma-derived biological products, animal plasma, or serum-derived products. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and FDA Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: 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.

ADDRESSES: Submit written requests for single copies of the draft guidance 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'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests.

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