are expected to be made in late 2002. Any DHHS position regarding international control of these drugs will be preceded by another Federal Register notice soliciting public comments as required by section 201(d)(2)(B) of the CSA.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding the drugs by May 9, 2002. This abbreviated comment period is necessary to allow sufficient time to prepare and submit the domestic information package by the deadline imposed by WHO. 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8493 Filed 4–8–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anthrax Vaccines: Efficacy Testing and Surrogate Markers of Immunity; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), in cooperation with the Department of Defense (DoD), is announcing the following public workshop: ''Anthrax Vaccines: Efficacy Testing and Surrogate Markers of Immunity.'' The workshop will discuss possible strategies for the efficacy testing of investigational anthrax vaccines.

Date and Time: The public workshop will be held on April 23, 2002, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Jay P. Sanford Auditorium on the campus of the Uniformed Services University of Health Sciences (USUHS), 4301 Jones Bridge Rd., Bethesda, MD 20814.

Contact: Kerry Davis, Science Applications International Corp. (SAIC), 5340 Spectrum Dr., suite N, Frederick, MD 21703, 301–619–7078, FAX 301–698–6188, e-mail: kerry.davis@det.amedd.army.mil.

Registration: Preregistration is required and must be completed by April 12, 2002. Contact Kerry Davis (see ''*Contact*'' for address) for information about registration, including registration fees. Seating is limited.

If you need special accommodations due to a disability, please contact Kerry Davis at least 7 days in advance of the meeting.

Transcripts: You may request public workshop transcripts in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857. The transcripts will be available approximately 15 working days after the meeting at the cost of 10 cents per page. The public workshop transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm

SUPPLEMENTARY INFORMATION: CBER, in cooperation with DoD, is holding a public workshop entitled ''Anthrax Vaccines: Efficacy Testing and Surrogate Markers of Immunity.'' The workshop will discuss: (1) Pathogenesis of *Bacillus anthracis*, (2) animal models of anthrax, (3) immunogenicity data available from human clinical trials of anthrax vaccines, and (4) identification of surrogate markers and possible strategies. The workshop's goal is to expedite the development of anthrax vaccines by providing additional information about efficacy testing of these vaccines.

Dated: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8463 Filed 4–8–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0037]

Public Informational Meeting on Antimicrobial Resistance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: ''Public Informational Meeting on Antimicrobial Resistance.'' The purpose of this public meeting is to provide the general public the opportunity to hear speakers from the agency, industry, and others to provide information on the issue of antimicrobial resistance so the public can fully participate in the public dialogue about the issue. Attendees will be invited to ask questions during the meeting.

Date and Time: The meeting will be held on April 26, 2002, from 9:30 a.m. to 4:30 p.m. Walk-in registration will begin at 9 a.m. You may submit written or electronic comments at any time, but in order for your comments to be included with others in conjunction with this meeting, please submit comments no later than 180 days after the meeting. Please include the Docket No. 02N–0037 on your comments.

Addresses: The meeting will be held at the Capital Hilton Hotel, Congressional Room, 1001 16th St. (16th and K Sts.), Washington, DC, 202–393–1000. Submit written comments 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. Comments should be identified with the full title and the Docket No. 02N–0037 on your comments.

For General Information Contact: Vash Klein, Center for Veterinary Medicine (CVM) (HFV–12), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, e-mail: cvmmeet@cvm.fda.gov.

For Information About Registration Contact: Ben Horsley, The Shipley Group, at 888–270–2157, FAX 888–270–2158.

Registration: Registration is required. There is no registration fee for the meeting. Limited space is available, and early registration is encouraged. Information about the meeting and the registration form are available on the Internet at www.fda.gov/cvm, click on Antimicrobial Resistance, then scroll down to PUBLIC MEETINGS, April 26, 2002 — *Consumer Meeting on Antimicrobial Resistance*. Please mail or fax the registration form to: FDA/CVM Enrollments —The Shipley Group, Inc., 1584 South 500 West, suite 201, Woods Cross, UT 84087; Ben Horsley at 888–270–2157 or 801– 298–7800, FAX 888–270–2158 or 801–298–7820. Additional information about the meeting and the agenda will be available on the Internet (www.fda.gov/cvm) before the meeting.

Oral Presentations: Please submit requests for oral presentations by April 22, 2002, to FDA/CVM, Attn: Consumer Meeting, Docket No. 02N–0037, 7500 Standish Pl., (HFV–12), rm. 3503,

Rockville, MD 20855. All presentations may be provided on Powerpoint (disk or CD, or e-mailed in advance to cvmmeet@cvm.fda.gov). No zip disks, slide presentations, or overheads can be accommodated.

If you need special accommodations due to a disability, please contact Vash Klein at least 7 days in advance.

Dated: April 4, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8567 Filed 4–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0096]

Draft ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV'' dated March 2002. The draft guidance document would inform all establishments that manufacture Whole Blood that FDA has licensed a nucleic acid test (NAT) to identify human immunodeficiency virus type 1 (HIV–1) and hepatitis C virus (HCV) in Whole Blood donations. The draft document recommends that manufacturers implement licensed HIV–1 and HCV NAT within 6 months of issuance of a final guidance and notify FDA of such implementation by specified procedures.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by July 8, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the document 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: Nathaniel L. Geary, 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 document entitled ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV,'' dated March 2002. FDA's final rule (66 FR 31146, June 11, 2001) entitled ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents'' became effective on December 10, 2001. Under 21 CFR 610.40(b), manufacturers ''must perform one or more such [screening] tests as necessary to reduce adequately and appropriately the risk of transmission of communicable disease'' (66 FR 31146 at 31162). In the preamble to the final rule, we said that the standard for adequate and appropriate testing will change as FDA approves new testing technology. We explained that, ''* * * we intend to regularly issue guidance describing those tests that we believe would adequately and appropriately reduce the risk of transmission of communicable disease agents'' (66 FR 31146 at 31149).

The availability of NAT to identify HIV–1 and HCV will change the testing protocol for adequately and appropriately reducing the risk of transmission of those diseases. The draft document recommends that manufacturers implement HIV–1 and HCV nucleic acid testing within 6 months of issuance of a final guidance. The draft guidance specifies how you should notify FDA of such implementation as required under 21 CFR 601.12.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on this topic. 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 requirement of the applicable statutes and regulations. 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

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by July 8, 2002. Two copies of any written comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the 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 document at http://www.fda.gov/cber/guidelines.htm or http://www/fda.gov/ohrms/dockets/default.htm.

Dated: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8464 Filed 4–8–02; 8:45 am]

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