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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier Jim Cooke

Food and Drug Administration

[Docket No. 03D-0163]

“Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS;” Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS” dated April 2003. The guidance document provides our recommendations for assessing donor suitability and blood product safety with respect to SARS. The guidance applies to whole blood and blood components intended for transfusion and to blood components including recovered plasma, source leukocytes, and source plasma intended for use in further manufacturing into injectable or noninjectable products.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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

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self-addressed adhesive label to assist the office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance 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: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

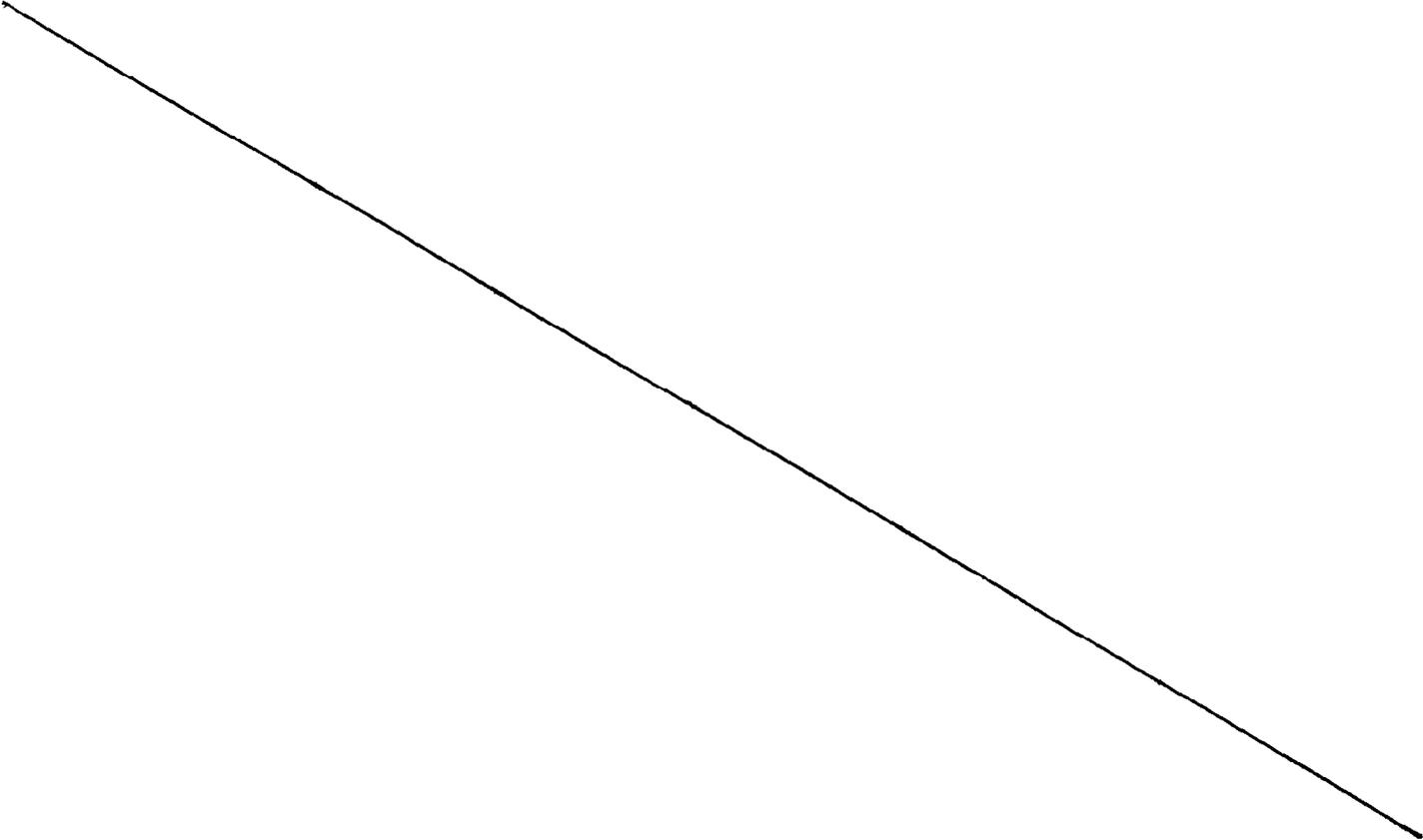
I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS" dated April 2003. This guidance document provides our recommendations for assessing donor suitability and blood product safety with respect to SARS. This guidance applies to whole blood and blood components intended for transfusion and to blood components including recovered plasma, source leukocytes, and source plasma intended for use in further manufacturing into injectable or noninjectable products. FDA developed the recommendations in this guidance in consultation with other

public health service agencies of the Department of Health and Human Services.

II. Comments

The agency is soliciting public comment, but is implementing this guidance immediately because the agency has determined that prior public participation is not appropriate since SARS may pose immediate safety risks to the blood supply. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance document and received comments may be seen 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 guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 4.17.03

April 17, 2003

Jeffrey Shuren

Jeffrey Shuren
Assistant Commissioner for Policy

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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