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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier J. Cooke

Food and Drug Administration

[Docket No. 2003D-0163]

Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome or Exposure to Severe Acute Respiratory Syndrome; 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: Revised 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 September 2003. The guidance provides revised recommendations to blood establishments for assessing donor suitability and blood product safety with respect to SARS. The guidance document applies to Whole Blood and blood components intended for transfusion (including red blood cells for immunization) and blood components including recovered plasma, Source Leukocytes and Source Plasma intended for use in further manufacturing into injectable products or noninjectable products. The guidance announced in this document supersedes the 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.

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

ADDRESSES: Submit written requests for single copies of the 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 request. The guidance 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 Division of Dockets Management (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: 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 document entitled "Guidance for Industry: Revised 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 September 2003. The guidance provides revised recommendations to blood establishments for assessing donor suitability and blood product safety with respect to SARS. The guidance

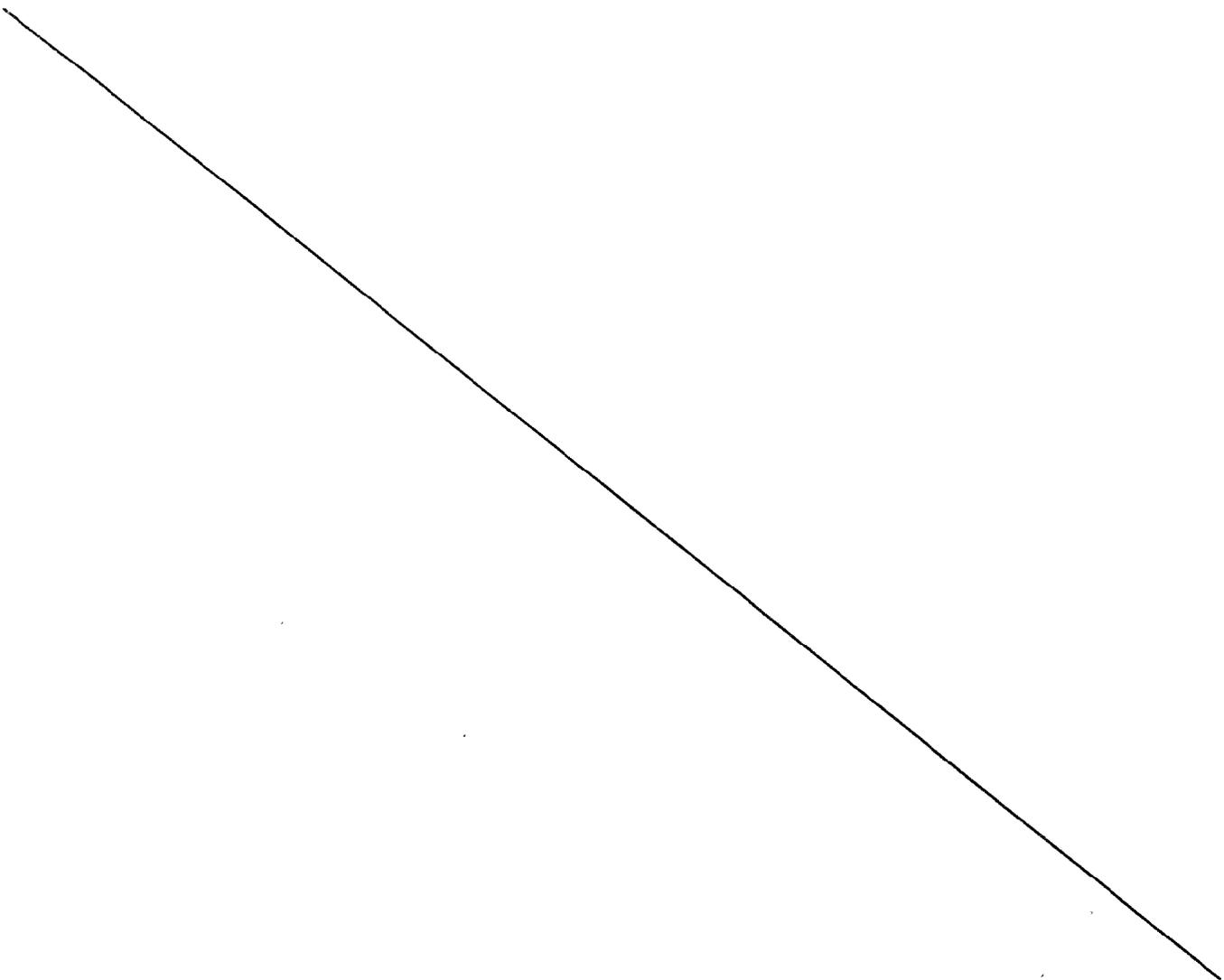
document applies to Whole Blood and blood components intended for transfusion (including red blood cells for immunization) and blood components including recovered plasma, Source Leukocytes and Source Plasma intended for use in further manufacturing into injectable products or noninjectable products. FDA developed the recommendations in the guidance in consultations with other public health service agencies of the Department of Health and Human Services. The guidance announced in this document supersedes the 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 (68 FR 20015, April 23, 2003).

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance 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.

II. Comments

The agency is soliciting public comment, but is implementing this guidance immediately. The agency has determined that prior public participation is not appropriate or feasible because there is an immediate need for clarification concerning whether FDA recommends that establishments continue to screen donors on the basis of travel to SARS-affected areas during time periods when the Centers for Disease Control has identified no areas as currently affected by SARS. Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see

ADDRESSES) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management 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: 9/12/03
September 12, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



J. Cooke

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