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Display Date	6/7/00
Effective Date	6/8/00
Certified	J. Windsor

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1267]

Draft "Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria" dated May 2000. The draft guidance document provides recommended questions for deferral of donors at increased risk for malaria. The guidance document also provides the recommendations for donor questioning regarding travel to vacation resorts located in malarious regions. The draft guidance document currently being announced, when finalized, will replace the recommendations in the guidance entitled "Recommendations for Deferral of Donors for Malaria Risk" dated July 26, 1994.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of "Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria" dated May 2000 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

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:

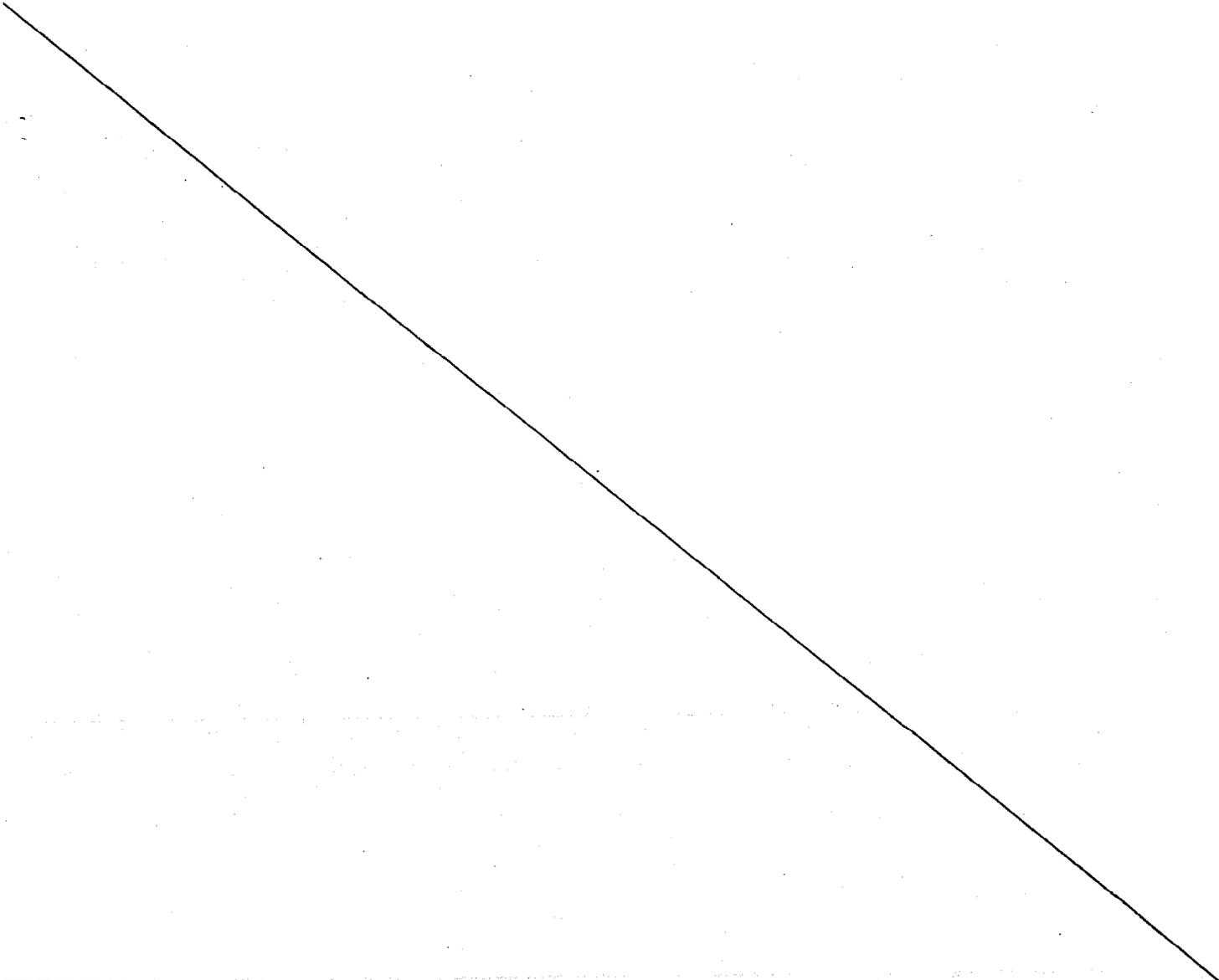
I. Background

FDA is announcing the availability of a draft guidance document entitled "Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria" dated May 2000. The draft guidance document recommends questions to be asked of donors to determine possible exposure to malaria. The draft guidance document also provides recommendations for deferral of donors for malarial risk. The recommendations apply only to donations containing intact Red Blood Cells or platelets. Donations used for preparing plasma or plasma derivatives devoid of intact Red Blood Cells or platelets are excluded. The draft guidance document currently being announced, when finalized, will replace the recommendations in the guidance entitled "Recommendations for Deferral of Donors for Malaria Risk" dated July 26, 1994.

The draft guidance document represents the agency's current thinking on malarial risks for prospective donors. 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 to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by [*insert date 90 days after date of publication in the Federal Register*]. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to 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.

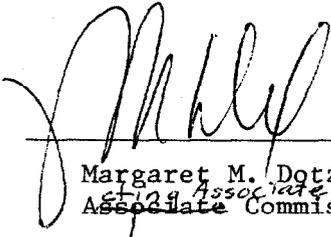


III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: 5/18/00

May 18, 2000



Margaret M. Dotzel
~~Associate~~ Commissioner for Policy

6-2-00
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[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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