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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0124]

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Certifier A. Corbin

Draft Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion" dated June 2002. The draft guidance document, when finalized, is intended to provide recommendations to blood collection or transfusion facilities on reporting fatalities related to blood or blood component collection or blood transfusion to FDA's Center for Biologics Evaluation and Research (CBER).

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DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by [insert date 90 days after date of publication in the FEDERAL REGISTER]. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics

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Evaluation and Research, 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.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 or electronic 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:

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301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Notifying FDA of Fatalities

Related to Blood Collection or Transfusion" dated June 2002. Under 21 CFR 606.170(b), fatalities related to blood collection or transfusion are required to be reported to CBER. The draft guidance document is intended to provide recommendations to a blood collection or transfusion facility on reporting fatalities related to blood or blood component collection or blood transfusion to CBER.

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.

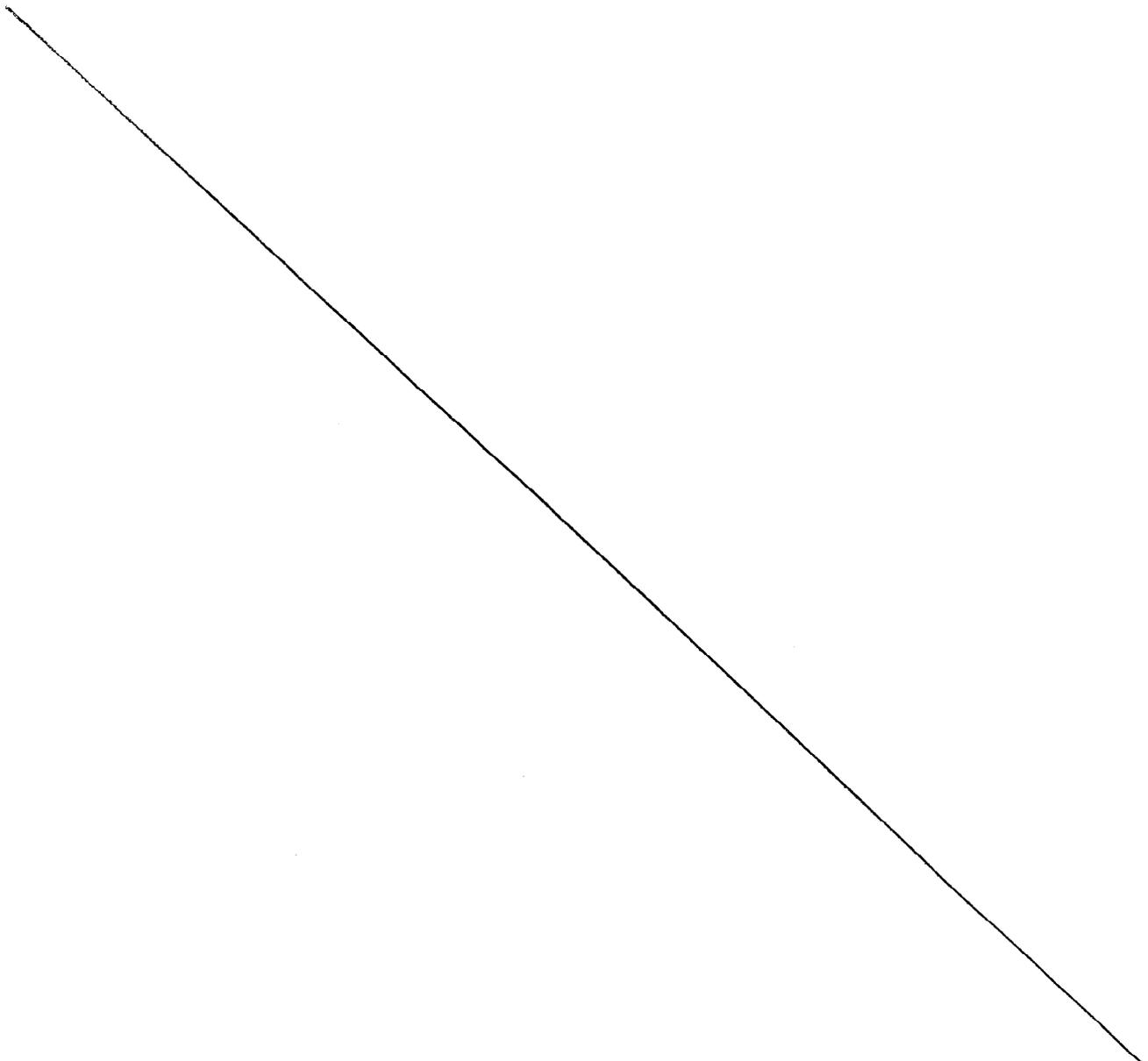
## II. Comments

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 [insert date 90 days after date of publication in the FEDERAL REGISTER]. 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 either <http://www.fda.gov/cber/guidelines.htm> or  
<http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 4/26/02  
April 26, 2002.



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Margaret M. Dotzel,  
Associate Commissioner for Policy.

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

