

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0462]

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Certifier R. LEDESMA

DMB

Draft Guidance for Industry: Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes; Availability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 entitled Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes" dated October 2004. The draft guidance provides sponsors or investigators, with criteria for testing the efficacy and safety of oxygen therapeutics as substitutes for red blood cells, and guidance on the design of clinical trials to assess risk/benefit ratio of such use. The draft guidance, when finalized, would supercede the "Points to Consider on the Safety Evaluation of Hemoglobin-Based Oxygen Carriers," dated August 27, 1990, and replaces the draft "Guidance for Industry: Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers" dated September 1997.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication the Federal Register*] to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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 The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, suite 200N, 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 entitled Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes” dated October 2004. The draft guidance, when finalized, would supercede the “Points to Consider on the Safety Evaluation of Hemoglobin-Based Oxygen Carriers,” dated August 27, 1990, and replaces the draft “Guidance for Industry: Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers” dated September 1997. The draft guidance provides you, as a sponsor or investigator, with criteria for testing the efficacy and safety of oxygen therapeutics as substitutes

for red blood cells, and guidance on the design of clinical trials to assess risk/benefit ratio of such use. While the draft guidance is restricted to use of oxygen therapeutics as substitutes for red blood cells, this may not be the only indication being evaluated for these investigational new drugs. The draft guidance should not discourage innovation in the development of appropriate endpoints for and the design of clinical trials for other uses of oxygen therapeutics.

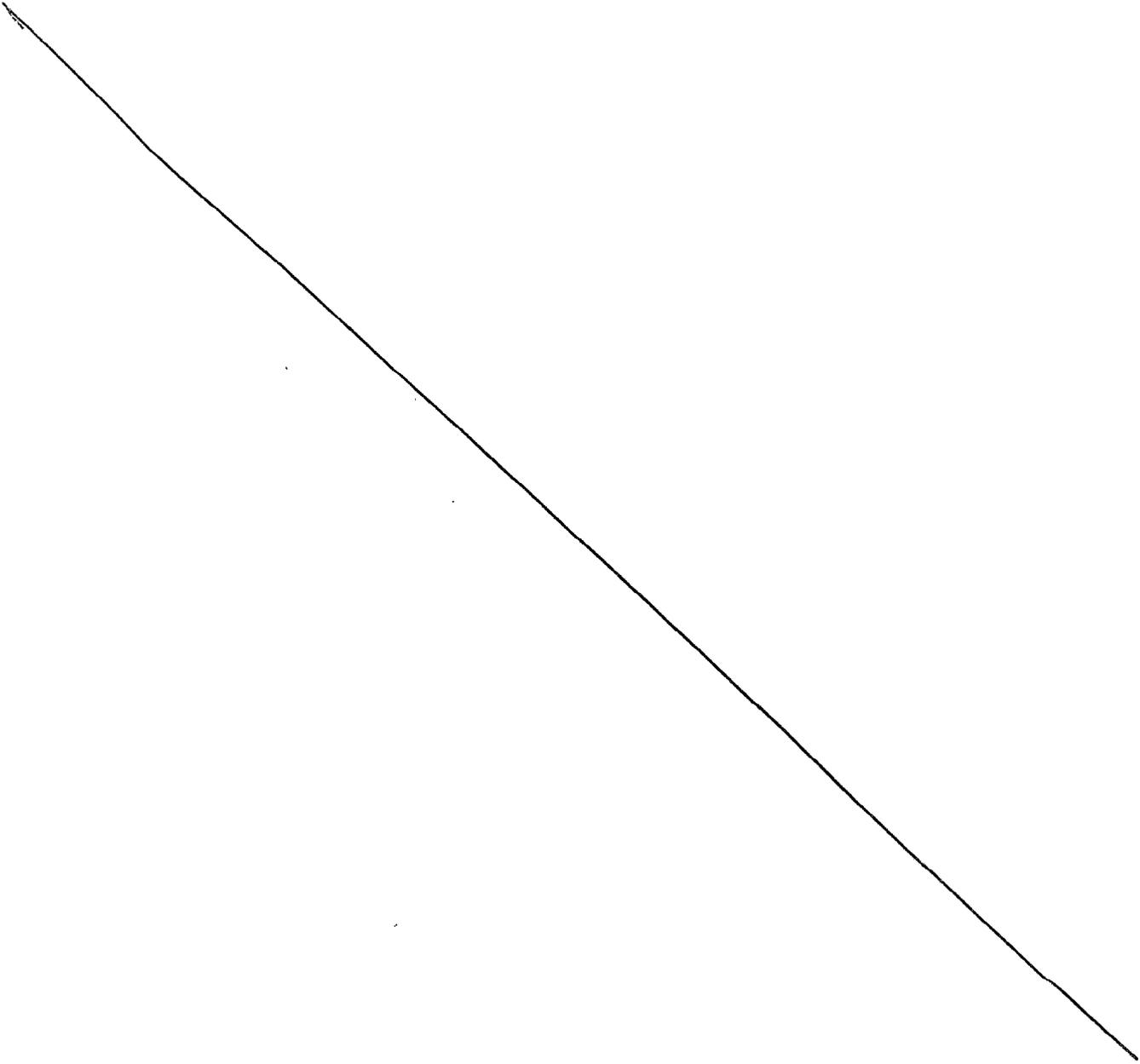
The draft guidance was revised based on, in part, presentations and discussions obtained at a workshop entitled “Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes” held on September 27 and 28, 1999, and public comments received on the September 1997 draft guidance. The workshop was sponsored by CBER, FDA, and co-sponsored by the National Heart, Lung, and Blood Institute, National Institute of Health, the Department of Defense, U.S. Army Medical and Material Command, and the Armed Services Blood Program Office.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance. Submit a single copy of electronic

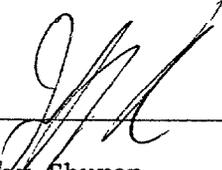
comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in 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 draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

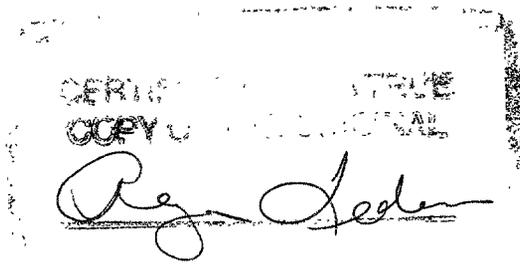
Dated: 10/20/04
October 20, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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