is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects 1. Organizing an Institutional Investigation Assistance Program: A Feasibility Study—NEW—A review group charged with examining the Office of Research Integrity's role in handling allegations of research misconduct developed numerous recommendations. One of the recommendations stated that ''HHS should encourage the development of a consortium-based approach to be used by awardee institutions that do not have the capacity to conduct the fact-finding process, or at which there is otherwise inadequate institutional or organizational capacity.'' The Office of Research Integrity is proposing a survey of research institutions, educational institutions and related organizations to assess the expressed level of interest in the development of consortia. Respondents: Businesses or other for-profit, non-profit institutions; Number of Respondents: 1,000; Burden per Response: 20 minutes; Total Burden: 333 hours.

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington DC, 20201. Written comments should be received within 60 days of this notice.

Dated: January 23, 2001.

Kerry Weems,

Acting Deputy Assistant Secretary, Budget.

[FR Doc. 01–2540 Filed 1–29–01; 8:45 am]

BILLING CODE 4150–31–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0545]

Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods'' dated January 2001. The guidance document provides recommendations to blood establishments for the use of FDA cleared automated blood cell separators for the collection of both single and double units of red blood cells. The guidance document also describes information to be included in a licensed application or supplement. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods'' dated July 1998.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods'' 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 guidance.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, 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 guidance document entitled ''Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods'' dated January 2001. The guidance document provides recommendations to blood establishments for the use of FDA cleared automated blood cell separators for the collection of both single and double units of red blood cells. The guidance document includes recommendations for donor selection criteria and product quality control and describes registration, licensing, and other procedures. The guidance document announced in this notice has been revised based on comments received on the draft guidance document entitled ''Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods'' announced in the **Federal Register** of July 27, 1998 (63 FR 40129), and finalizes that draft guidance document.

This guidance is being issued consistent with FDA's good guidance regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking with regard to collecting red blood cells by automated apheresis methods. 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 statutes and regulations. 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. This document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of this 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 guidance document at http://www.fda.gov/cber/guidelines.htm.

Dated: December 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–2489 Filed 1–29–01; 8:45 am]

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