DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0019]

Guidance for Industry and Food and Drug Administration Staff: Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle; 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 and FDA Staff: Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle'' dated November 2007. The guidance document serves as the special control for the automated blood cell separator device operating on a centrifugal or filtration separation principle intended for the routine collection of blood and blood components, and describes a means by which the device may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify the automated blood cell separator device operating by centrifugal separation principle into class II (special controls).

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, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER 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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle'' dated November 2007. This special controls guidance identifies the relevant classification regulation that provides a description of the applicable automated blood cell separator device. In addition, other sections of this special control guidance list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with general controls, will ordinarily address the risks associated with these automated blood cell separators.

In the **Federal Register** of March 10, 2005 (70 FR 11990), FDA announced the availability of the draft guidance of the same title. FDA received one comment on the proposed rule and draft guidance and that comment was considered as the rule and guidance were finalized. The guidance announced in this notice finalizes the draft guidance dated January 2005.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0594.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the 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 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.

IV. 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: November 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–23281 Filed 11–29–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Pretesting of NIAID's HIV Vaccine Research Communications Messages

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Allergy and Infectious Diseases (NIAID), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 28, 2007, page 49282 and allowed 60-days for public comment. One public comment was received and was addressed in the OMB request. The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection: Title: Pretesting of NIAID's HIV Vaccine Research Communications Messages. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This is a request for clearance to pretest messages, materials and program activities produced for the NIAID HIV Vaccine Research Education Initiative (NHVREI). The primary objectives of the pretests are to (1) assess audience knowledge, attitudes, behaviors and other characteristics for the planning/development of health messages, education products, communication strategies, and public information programs; and (2) pretest these health messages, products, strategies, and program components while they are in