Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labour, and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In November 2007, the ICH Steering Committee agreed that a draft guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 2: Test for Extractable Volume of Parenteral Preparations General Chapter'' should be made available for public comment. The draft guidance is the product of the Q4B Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q4B Expert Working Group.

The draft guidance provides the specific evaluation results from the ICH Q4B process for the Test for Extractable Volume of Parenteral Preparations General Chapter harmonization proposal originating from the three-party PDG. This draft guidance is in the form of an annex to the core ICH Q4B guidance. Once finalized, the annex will provide guidance to assist industry and regulators in the implementation of the specific topic evaluated by the ICH Q4B process.

This 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the 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 brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: December 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–24434 Filed 12–14–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0330]

Guidance for Industry and Food and Drug Administration Review Staff: Collection of Platelets by Automated Methods; 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 Review Staff: Collection of Platelets by Automated Methods,'' dated December 2007. The guidance document provides to blood establishments and FDA staff revised recommendations for the collection of Platelets by automated methods (plateletpheresis). The guidance is intended to help blood establishments ensure donor safety and the safety, purity, and potency of Platelets collected by an automated blood cell separator device. For the purpose of this document, Platelets collected by automated methods will be referred to by the product name ''Platelets, Pheresis.'' The document contains recommendations for appropriate criteria for a biologics license application or supplement for manufacturing Platelets, Pheresis. The guidance announced in this notice finalizes the draft guidance of the same title dated September 2005, and supersedes the guidance entitled ''Revised Guideline for the Collection of Platelets, Pheresis,'' dated October 1988.

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: Brenda R. Friend, 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 Review Staff: Collection of Platelets by Automated Methods,'' dated December 2007. The guidance provides to blood establishments and FDA staff revised recommendations for the collection of Platelets by automated methods (plateletpheresis). In recent years, many improvements have been made in automated blood cell separator technology, platelet storage stability, and blood cell counting methods. Automated blood cell separator devices are now capable of various plateletpheresis collection procedures including, but not limited to, collection of double and triple platelet components obtained during a single procedure; use of in-process leukocyte reduction; collection of concurrent plasma components; and collection of concurrent Red Blood Cell components. This guidance replaces the draft guidance of the same title, and supersedes the guidance entitled ''Revised Guideline for the Collection of Platelets, Pheresis,'' dated October 1988.

In the **Federal Register** of October 3, 2005 (70 FR 57609), FDA announced the availability of the draft guidance of the same title dated September 2005. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes: (1) Revised recommendations for donor selection and management, (2) revised recommendations for collection performance qualification criteria, and (3) revised recommendations on quality control monitoring. The guidance announced in this notice finalizes the draft guidance dated September 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 requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in part 211 (21 CFR part 211), subpart J (Records and Reports) have been approved under OMB control number 0910–0139; the collections of information in part 606 (21 CFR part 606), subpart I (Records and Reports) have been approved under OMB control numbers 0910–0116 and 0910–0458; the collections of information in §§ 606.100(b) and (c), 606.110(a), 606.121, 606.122, 21 CFR 640.25, and 21 CFR 640.27 have been approved under OMB control number 0910–0116; the collections of information in §§ 211.22, 211.80, 211.100(b), and 211.160 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR 610.2 have been approved under OMB control number 0910–0206; and the collections of information in 21 CFR 601.12 and 610.60 have been approved under OMB control number 0910–0338.

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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

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: December 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–24385 Filed 12–14–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for the opportunity for public comment on proposed data collection projects [Section 3506 (c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13], the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on (a) whether the agency needs to collect the proposed information to properly perform its functions and whether the information has any practical utility; (b) whether the agency's estimate of the burden of the proposed collection of information is accurate; (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 for respondents (*e.g.*, by using automated collection techniques or other forms of information technology).

Proposed Project: Ryan White HIV/AIDS Program Part F Dental Services Report (OMB No. 0915–0151)—Extension

The Dental Reimbursement Program (DRP) and the Community Based Dental Partnership Program under Part F of the Ryan White HIV/AIDS Program offer funding to accredited dental education programs to support the provision of