Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics 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 guidance document. 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: Nathaniel L. Geary, 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 document entitled ''Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier'' dated July 2001. The guidance document is intended to assist those applicants who qualify and wish to participate in CBER's Red Blood Cells Immunization Program (RBCIP) pilot. A manufacturer is qualified if it: (1) Holds an unsuspended and unrevoked biologics license for Source Plasma, (2) seeks to supplement the license to include an RBCIP, (3) plans to use already thawed and deglycerolized Immunogen Red Blood Cells (IRBC) from an outside supplier, and (4) has identified an outside supplier of IRBC who holds an unsuspended and unrevoked biologics license for Source Plasma that already includes CBER's authorization for an RBCIP.

In the **Federal Register** of July 18, 2000 (65 FR 44537), FDA announced the availability of a draft guidance document entitled ''Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier'' dated June 2000. FDA received no comments from the public on this draft guidance document. The guidance document announced in this notice finalizes the draft guidance document with minor editorial changes.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on a pilot program specific to the immunization of Source Plasma donors using IRBC obtained from an outside supplier, either from an outside manufacturer, under a contractural agreement, or from an outside facility under the same managerial control as the applicant facility. 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

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 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 http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: June 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17254 Filed 7–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2213]

Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors; 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: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors'' dated July 2001. The guidance document provides guidance to blood establishments on when to invalidate donor test results based on control reagents required by the Clinical Laboratory Improvement Act of 1988 (CLIA). The implementation of additional quality control procedures that involve the use of external control reagents should enhance overall testing accuracy and blood safety. The guidance document announced in this notice finalizes the draft guidance document entitled ''Draft Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors'' dated September 1999.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors'' 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 guidance 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 document.

Submit written comments on the 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: Revised

Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors'' dated July 2001. The guidance document provides recommendations for blood establishments in integrating current CLIA requirements for when to invalidate donor test results based on CLIA required control reagents. The guidance document announced in this notice finalizes the draft guidance document entitled ''Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors'' announced in the **Federal Register** of September 1, 1999 (64 FR 47847). The guidance document also supersedes the January 3, 1994 guidance document entitled ''Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking with regard to the invalidation of test results based on the CLIA required control reagents. 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. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any 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 this guidance 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 or http://www.fda.gov/ohrms/dockets/default.htm

Dated: June 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17255 Filed 7–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Practitioner Data Bank; Change in User Fee

The Health Resources and Services Administration (HRSA), Department of Health and Human Services (DHHS), is announcing a one dollar increase in the fee charged to entities authorized to request information from the National Practitioner Data Bank (NPDB) for all queries. The new fee will be $5.00 and there, will be no change to the $10.00 self-query fee.

The current fee structure ($4.00 per name) was announced in the **Federal Register** on January 29, 1998 (63 FR 4460). All entity queries are submitted and query responses received through the NPDB's Integrated Query and Reporting Service (IQRS) and paid via an electronic funds transfer or credit card.

The NPDB is authorized by the Health Care Quality Improvement Act of 1986 (the Act), Title IV of Public Law 99–660, as amended (42 U.S.C. 11101 *et seq.*). Section 427(b)(4) of the Act authorizes the establishment of fees for the costs of processing requests for disclosure and of providing such information.

Final regulations at 45 CFR part 60 set forth the criteria and procedures for information to be reported to and disclosed by the NPDB. Section 60.3 of these regulations defines the terms used in this announcement.

In determining any changes in the amount of the user fee, the Department uses the criteria set forth in § 60.12 (b) of the regulations, as well as allowable costs pursuant to Title II of the Labor, Health and Human Services, Education, and Related Agencies Appropriations Bill for Fiscal Year 2001, P.L. 106–554, enacted Dec. 21, 2000. This Act requires that the Department recover the full costs of operating the Data Bank through user fees. Paragraph (b) of the regulations states:

''The amount of each fee will be determined based on the following criteria:

(1) Use of electronic data processing equipment to obtain information—the actual cost for the service, including computer search time, runs, printouts, and time of computer programmers and operators, or other employees,

(2) Photocopying or other forms of reproduction, such as magnetic tapes—actual cost of the operator's time, plus the cost of the machine time and the materials used,

(3) Postage—actual cost, and

(4) Sending information by special methods requested by the applicant, such as express mail or electronic transfer the actual cost of the special service.''

Based on analysis of the comparative costs of the various methods for filing and paying for queries, the Department is raising all the entity query fees by $1.00 per name. The practitioner self-query fee remains at $10. This price increase is necessitated by increased technical labor costs, equipment upgrades, and improvements to the NPDB's computer system. Since the last fee increase, the system has been migrated from QPRAC, a dial-up client server system, to the web-based IQRS. The IQRS provides a secure mechanism for faster, more convenient, reporting and querying.

This change is effective October 1, 2001.

When a query is for information on one or more physicians, dentists, or other health care practitioners, the appropriate fee will be $5.00 multiplied by the number of individuals about whom information is being requested. For examples, see the table below.

The Department will continue to review the user fee periodically, and will revise it as necessary. Any changes in the fee and their effective date will be announced in the **Federal Register**.

Query method	Fee per name in query	Examples
Entity query (Via Internet with electronic payment).	$5.00	10 names in query. 10x$5=$50.00.
Practitioner self-query	10.00	One self-query=$10.00.