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may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance.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. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. 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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.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: March 1, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3371 Filed 3–9–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0083]

Draft Guidance for Industry on Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccines; Availability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: Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccines,'' dated March 2006. The draft guidance document is intended to provide to sponsors of trivalent inactivated influenza vaccines guidance on the clinical data needed to support a Biologics License Application (BLA). The draft guidance summarizes clinical development approaches to facilitate and expedite the licensure of new trivalent inactivated influenza vaccines and addresses both traditional and accelerated approval.

DATES: Submit written or electronic comments on the draft guidance by June 8, 2006 to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug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, suite 200N, 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 CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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: Valerie A. Butler, 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 draft document entitled ''Guidance for Industry: Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccines,'' dated March 2006. The draft guidance is intended to provide to sponsors of trivalent inactivated influenza vaccines guidance on the clinical data needed to support a BLA. The draft guidance summarizes clinical development approaches to facilitate and expedite the licensure of new ''split virus'' trivalent inactivated influenza vaccines and addresses both traditional and accelerated approval. The approaches are also applicable to vaccines made with other manufacturing processes; e.g., whole virus inactivated, cell-culture based inactivated, recombinant protein, and adjuvanted influenza vaccines. The draft guidance does not address live attenuated influenza vaccines or influenza vaccines that do not contain a hemagglutinin component. The draft guidance also does not address the nonclinical development of investigational vaccines, or the chemistry, manufacturing, control, or inspection of the manufacturing facility needed for licensure.

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 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 draft 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 information collection provisions in this guidance for 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. 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 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 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.

IV. 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: February 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3370 Filed 3–9–06; 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 Fees

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS), is announcing a fifty cent 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 $4.75. There will be no change to the $8.00 self-query fee.

DATES: This change will be effective May 9, 2006.

FOR FURTHER INFORMATION CONTACT: Mark Pincus, Branch Chief, Practitioner Data Banks Branch, Office of Workforce Evaluation and Quality Assurance, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Rm 8C–103, 5600 Fishers Lane, Rockville, MD 20857, Tel: 301–443–2300, E-mail: *policyanalysis@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The current fee structure ($4.25 per name) was announced in the **Federal Register** on April 22, 2003 (68 FR 19837) and became effective on July 1, 2003. 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 section 60.12(b) of the regulations, as well as allowable costs pursuant to Public Law 109–77, as amended, and Title II, Division F, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Act for the Consolidated Appropriations Act, 2005, Public Law 108–447. These laws require 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 increasing all the entity query fees by $0.50 per name. The practitioner self-query fee remains at $8.00. This price increase is justified after an evaluation of the Data Bank's operational costs. At the current fee of $4.25, the Data Bank is unable to recover full costs of operation. In keeping with the Act, and pursuant to the requirements of section 60.12 of the regulations, there are not sufficient funds to recover the full costs of operating the Data Bank without a fee increase.

When a query is for information on one or more physicians, dentists or other health care practitioners, the appropriate fee will be $4.75 multiplied by the number of individuals about whom information is being requested. For examples, see the table below.

Query method	Fee per name in query	Examples
Entity query (via internet with electronic payment)	$4.75	10 names in query. 10 × $4.75 = $47.50.
Practitioner self-query	8.00	One self-query = $8.00.

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**.

Dated: March 3, 2006.

Elizabeth M. Duke,

Administrator.

[FR Doc. E6–3323 Filed 3–9–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Healthcare Integrity and Protection Data Bank: Change in User Fees

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: In accordance with final regulations at 45 CFR part 61, implementing the Healthcare Integrity and Protection Data Bank (HIPDB), the Department is authorized to assess a fee on all requests for information, except requests from Federal agencies. In accordance with § 61.13 of the HIPDB regulations, the Department is announcing an adjustment from $4.25 to $4.75 in the fee charged for each query submitted by authorized entities. There will be no change to the current $8 self-query fee.

EFFECTIVE DATE: This change will be effective May 9, 2006.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Office of External Affairs, (202) 619–0089.

SUPPLEMENTARY INFORMATION:

User Fee Amount

Section 1128E(d)(2) of the Social Security Act (the Act), as added by section 221(a) of the Health Insurance Portability and Accountability Act of 1996, specifically authorizes the establishment of fees for the costs of processing requests for disclosure and for providing information from the Healthcare Integrity and Protection Data Bank (HIPDB). Final regulations at 45 CFR part 61 set forth the criteria and procedures for information to be reported to and disclosed by the HIPDB. The Act also requires that the Department recover the full costs of operating the HIPDB through such user fees. In determining any changes in the amount of the user fee, the Department employs the criteria set forth in § 61.13(b) of the HIPDB regulations.