

*Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material* (21 CFR part 109) to establish a regulatory limit for *L. monocytogenes* of 100 colony forming units per gram in foods that do not support growth of the microorganism.

Petitioners assert that the requested regulatory limit would establish a science-based standard for the presence of *L. monocytogenes* in such foods, noting that their request is based on new and emerging evidence that consumer protection is a function of the organism's cell numbers in food, and not its mere presence. Petitioners further assert that a regulatory limit will permit FDA and the food industry to distinguish products for which increased scrutiny is prudent from those for which greater attention will not yield a corresponding benefit to public health. Petitioners state that a risk-based approach to *L. monocytogenes* is consistent with the comprehensive risk assessment undertaken by FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service, in which the agencies concluded that "targeted initiation of new or enhanced controls may be needed to achieve further reductions in the incidence of listeriosis." In addition, petitioners assert that there is general scientific agreement that low levels of *L. monocytogenes* are not uncommon in the food supply and that such low levels are regularly consumed without apparent harm.

For over 15 years, FDA has been working with its Federal, State, and local food safety counterparts to reduce the incidence of foodborne illness in the United States, including illness caused by *L. monocytogenes*. The action requested in the petition directly bears on the safety of the food supply and FDA's longstanding effort. Accordingly, FDA is requesting public comment on the petition as well the submission of any relevant data or information that could assist the agency's evaluation of or its response to the petition.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the petition. 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. If your comments are based on scientific data or

other evidence, please submit copies of such information with your comments. The petition and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Practitioner Data Bank: Change in Self-Query Fee

**AGENCY:** Health Resources and Services Administration, DHHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA), Department of Health and Human Services (DHHS), is announcing a two-dollar decrease in the fee charged to practitioners who request information about themselves (self-query) from the National Practitioner Data Bank (NPDB). The new fee to self-query the NPDB will be \$8.00. There will be no change to the \$4.25 entity fee.

**DATES:** The fee is effective on July 1, 2004.

#### FOR FURTHER INFORMATION CONTACT:

Darryl Gray, Acting Director, Division of Practitioner Data Banks, Bureau of Health Professions, Health Resources and Services Administration, 7519 Standish Place, Suite 300, Rockville, Maryland 20857, Tel: (301) 443-2300. E-mail: [policyanalysis@hrsa.gov](mailto:policyanalysis@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** The current fee structure (\$10.00 per self-query) was announced in the **Federal Register** on April 22, 2003 (68 FR 19837). All self-queries are submitted and query responses received through the NPDB's Integrated Query and Reporting Service (IQRS) and paid via credit card.

The NPDB is authorized by the Health Care Quality Improvement Act of 1986 (the Act), Title IV of Pub. L. 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, Division E, Labor, Health and Human Services, and Education, and Related Agencies Appropriations 2004, Pub. L. 108-199, enacted on January 23, 2004. 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 current operational costs involved with processing self-queries, the Department is reducing the self-query fee by \$2.00. The cost reduction is justified based on the NPDB's transition from a paper reporting and querying process to an all electronic, web-based system, the IQRS. This move to online reporting and querying has streamlined the operational processes required to manage self-query requests. In addition, other enhancements to the IQRS, such as online filing and payment for self-queries have resulted in decreased operational expenditures. In keeping with the Act, and pursuant to the requirements of § 60.12 of the regulations, there are sufficient funds to recover the full costs of operating the Data Bank with a decrease in the self-query fee.

According to the new fee schedule, a practitioner will be charged \$8.00 per self-query submitted to the NPDB. The entity fee for querying the NPDB will remain \$4.25 per name. For examples, see the table below.

| Query method  | Fee per name in query | Examples                                     |
|---|-----------------------|--|
| Entity query (via Internet with electric payment) ..... | \$4.25                | 10 names in query.<br>10 × \$4.25 = \$42.50. |
| 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: May 18, 2004.

**Dennis P. Williams,**

*Deputy Administrator.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Proposed Information Collection: Request for Public Comment: 30-Day Notice**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Request for public comment: 30 day proposed information collection: IHS Scholarship Program Application.

**SUMMARY:** In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity

for public comment on proposed information collection projects, the Indian Health Service (IHS) 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 project was previously published in the **Federal Register** (66 FR 66912) on February 24, 2004 and allowed 60-days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30-days for public comment to be submitted directly to OMB.

*Proposed Collection: Title:* 0917-0006, "IHS Scholarship Program Application." *Type of Information Collection Request:* Previously Approved Collection. *Form Number(s):* IHS-856, 856-2, through 856-8, IHS-815, IHS-816, IHS-817, IHS-818, D-02, F-02, F-04, G-02, G-04, H-07, H-08, J-04, J-05, K-03, K-04, and L-03. Reporting formats are contained in an IHS Scholarship Program application booklet. *Need and Use of Information Collection:* The IHS Scholarship Branch

needs this information for program administration and uses the information to solicit, process and award IHS Pre-graduate, Preparatory and/or Health Professions Scholarship grantees and monitor the academic performance of awardees, to place awardees at payback sites, and for awardees to request additional program. The IHS Scholarship Program plan to streamline the application to reduce the time needed by applicants to complete and provide the information and the plan to use information technology to make the application electronically available on the internet have been delayed. *Affected Public:* Individuals, not-for-profit institutions and State, local or Tribal Government. *Type of Respondents:* Students pursuing health care professions.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of responses per respondent, Annual number of responses, Average burden hour per response, and Total annual burden hour(s).

| Data collection instruments(s)             | Number of respondents | Response per respondent | Total annual response | Burden hour per response * | Annual burden hours |
|--|-----------------------|-------------------------|-----------------------|----------------------------|---------------------|
| Scholarship Application (IHS-856) .....    | 1500                  | 1                       | 1500                  | 1.00 (60 min)              | 1500                |
| Checklist (856-2) .....                    | 1500                  | 1                       | 1500                  | 0.13 (8 min)               | 195                 |
| Course Verification (856-3) .....          | 1500                  | 1                       | 1500                  | 0.70 (42 min)              | 1050                |
| Faculty/Employer Application (856-4) ..... | 1500                  | 2                       | 3000                  | 0.83 (50 min)              | 2490                |
| Justification (856-5) .....                | 1500                  | 1                       | 1500                  | 0.75 (45 min)              | 1125                |
| Federal Debt (856-6) .....                 | 1500                  | 1                       | 1500                  | 0.13 (8 min)               | 195                 |
| MPH only (856-7) .....                     | 25                    | 1                       | 25                    | 0.83 (50 min)              | 21                  |
| Accept/Decline (856-8) .....               | 650                   | 1                       | 650                   | 0.13 (8 min)               | 84                  |
| Receipt of Application (815) .....         | 1500                  | 1                       | 1500                  | 0.03 (2 min)               | 45                  |
| Address Change Notice (816) .....          | 25                    | 1                       | 25                    | 0.02 (1 min)               | 5525                |
| Scholarship Program Agreement (817) .....  | 850                   | 1                       | 850                   | 0.05 (3 min)               | 43                  |
| Stipend Checks (D-02) .....                | 100                   | 1                       | 100                   | 0.13 (8 min)               | 13                  |
| Enrollment (F-02) .....                    | 1300                  | 1                       | 1300                  | 0.13 (8 min)               | 169                 |
| Academic Problem/Change (F-04) .....       | 50                    | 1                       | 50                    | 0.13 (8 min)               | 6                   |
| Request Assistance (G-02) .....            | 217                   | 1                       | 217                   | 0.13 (8 min)               | 28                  |
| Summer School (G-04) .....                 | 193                   | 1                       | 193                   | 0.10 (6 min)               | 19                  |
| Health Professions Contract (818) .....    | 850                   | 1                       | 850                   | 0.05 (3 min)               | 33                  |
| Placement (H-07) .....                     | 250                   | 1                       | 250                   | 0.18 (11 min)              | 45                  |
| Graduation (H-08) .....                    | 250                   | 1                       | 250                   | 0.17 (10 min)              | 43                  |
| Site Preference (J-04) .....               | 150                   | 1                       | 150                   | 0.13 (8 min)               | 20                  |
| Travel Reimb (J-05) .....                  | 150                   | 1                       | 150                   | 0.10 (6 min)               | 15                  |
| Status Report (K-03) .....                 | 250                   | 1                       | 250                   | 0.25 (15 min)              | 63                  |
| Preferred Assignment (K-04) .....          | 200                   | 1                       | 200                   | 0.75 (45 min)              | 150                 |
| Request of Deferment (L-03) .....          | 20                    | 1                       | 20                    | 0.13 (8 min)               | 3                   |
| <b>Total</b> .....                         | <b>15,830</b>         |                         |                       |                            | <b>7,380</b>        |

\*For ease of understanding, burden hours are also provided in actual minutes.