

2. What is the frequency of occurrence of pathogenic strains of *V. parahaemolyticus* in molluscan shellfish, and what are the numbers of viable pathogenic organisms at time of consumption? How are levels present in the bivalves at the time of consumption related to the initial levels in the growing waters?

3. What is known about the dose-response relationship from outbreak, epidemiological, animal and other studies? What are the differences in dose-response relations among different strains and serotypes of *V. parahaemolyticus*, and among the different human susceptible subpopulations?

4. What is the role of postharvest handling that may be influencing the numbers of *V. parahaemolyticus* in oysters? What reductions in risks can be achieved by intervention strategies such as depuration or relaying?

5. What is the adequacy of current scientific knowledge, and where should future research be focused to reduce the uncertainty in the risk estimate?

### III. Scope of the Risk Assessment

Risk assessment is separate from risk management and risk communication. Thus, FDA's risk assessment will determine the relationships between molluscan shellfish, *V. parahaemolyticus* and illnesses; it will not determine an acceptable level of pathogenic *V. parahaemolyticus*.

To accurately assess the exposure to pathogenic *V. parahaemolyticus*, the consumption of raw molluscan shellfish, especially oysters, will be considered. Exposure is a function of the *V. parahaemolyticus* prevalence in the shellfish and the consumption patterns of the population. The number of pathogenic *V. parahaemolyticus* in raw molluscan shellfish at consumption is the critical exposure information. Modeling will be used when *V. parahaemolyticus* data are collected during outbreaks, and at retail outlets to estimate actual exposure.

The risk assessment will produce estimates of illness for levels of pathogenic *V. parahaemolyticus* likely to be consumed by different subpopulations. All assumptions and uncertainties will be identified and documented.

FDA expects the risk assessment to provide the scientific underpinnings FDA needs to develop food safety policies that reduce the risk of disease resulting from ingestion of *V. parahaemolyticus* in molluscan shellfish, and other seafood consumed raw. Among other things, FDA anticipates that the data from the risk

assessment will assist in determining the principal factors that should be considered in developing criteria for closing of shellfish waters to harvest in order to prevent illness and reopening waters after outbreaks of *V. parahaemolyticus* are over.

### IV. Request for Data and Information

FDA is requesting scientific data and information that will allow it to respond to the questions under section II of this document. The purpose of this request for data is to gather relevant information to facilitate a valid risk assessment of *V. parahaemolyticus* with the larger goal of providing a sound scientific basis for the food safety policies relating to raw molluscan shellfish contaminated with *V. parahaemolyticus*. FDA does not intend to utilize the submitted data and information to support future enforcement activity against seafood producers submitting the data. Accordingly, it is acceptable that data submitted in response to this notice be "blinded" in the sense that the data need not identify the particular seafood producer or processor that was the source of the samples underlying the results.

Two copies of the scientific data and information are to be submitted, except that individuals may submit one copy. Scientific data and information should be addressed to the Dockets Management Branch (address above) and be identified with the docket number found in brackets in the heading of this document. Received materials may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Roderick, G. E., M. A. Hood, and N. J. Blake, *Medical Clinics of North America*, 66:665-673, 1982.
2. Takikawa, I., *Yokohama Medical Bulletin*, 9:313-322, 1958.
3. Aiso, K. and K. Fujiwara, *Annual Report of the Institute of Food Microbiology*, Chiba University, 15:34-38 1963.
4. Chai, T-J. and J. Pace, *Goodborne Disease Handbook*, p. 395 to 425, Marcel Dekker, NY, 1993.
5. Hlady, W. G. and K. C. Klontz, *Journal of Infectious Diseases*, 173:1176-1183, 1996.
6. Hally, R. J., R. A. Rubin, H. S. Fraimow, and M. L. Hoffman-Terry, *Digestive Disease and Sciences*, 1995.
7. Olson, Jr., J. C., *International Symposium on Vibrio parahaemolyticus*, Saikon Publishing Co., Tokyo, pp. 259-261, 1974.

8. Barker, W. H., Jr., *Lancet*, 1:551-554, 1974.

9. Nolan, C. M. et al, *Diagnostic Microbiology Infectious Disease*, 2:119-128, 1984.

10. CDC, *Journal of the American Medical Association*, 280:126-127, 1998.

11. Angulo, F., P. M. Griffin, and R. V. Tauxe, CDC, personal communication, 1998.

12. CDC, *Morbidity and Mortality Weekly Report*, vol. 48, 1999.

13. Sample, T. and M. Goza, FDA, personal communication, 1998.

14. Sanyal, S. C. and P. C. Sen, *International Symposium on Vibrio parahaemolyticus*, p. 227 to 230, Saikon Publishing Co., Tokyo, 1974.

15. Fishbein, M., B. Wentz, W. L. Landry, and B. MacEachern, *International Symposium on Vibrio parahaemolyticus*, p. 53 to 58, Saikon Publishing Co., Tokyo, 1974.

16. *Japanese National Institute of Infectious Diseases*, Infectious Agents Survey Report, vol. 20, No. 1, 1999.

17. *Japanese National Institute of Infectious Diseases*, Infectious Agents Survey Report, vol. 17, No. 7, 1996.

18. Miyamoto, Y. et al., *Journal of Bacteriology*, 100:1147-1149, 1969.

19. Akeda, Y., K. Nagayama, K. Yamamoto, and T. Honda, *Journal of Infectious Diseases*, 176:822-824, 1997.

20. Honda, T., M. Shimizu, Y. Takeda, and T. Miwatani, *Infection and Immunity* 14:1028-1033, 1976.

21. ISSC and FDA, *Guide for the Control of Molluscan Shellfish*, U.S. DHHS, Washington, DC. p. 406, 1997.

22. Fisher, L. M., *Shellfish Sanitation*, Public Health Reports No. 1178, U.S. Public Health Service, Washington, D.C., 1927.

23. Doyle, M. P., *Lancet*, 336:1111-1115, 1990.

Dated: April 29, 1999.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

[FR Doc. 99-11318 Filed 5-6-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-194]

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this

collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection*

*Request:* Extension of a currently approved collection;

*Title of Information Collection:*

Medicare Disproportionate Share Adjustment Procedure and Criteria and Supporting Regulations in 42 CFR, Section 412.106;

*Form No.:* HCFA R-194;

*Use:* Regulation sets up an alternative process for hospitals that choose to have their disproportionate share adjustment statistics calculated based on their cost reporting periods rather than the Federal fiscal year.

*Frequency:* On occasion;

*Affected Public:* Business or other for-profit, and Not-for-profit institutions;

*Number of Respondents:* 100;

*Total Annual Responses:* 100;

*Total Annual Hours Requested:* 100.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 28, 1999.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 99-11461 Filed 5-6-99; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, NIAAA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NIAAA.

*Date:* June 4, 1999.

*Open:* 8:30 a.m. to 8:45 a.m.

*Agenda:* To discuss administrative details.

*Place:* National Institutes of Health, Building 1, Wilson Hall, 9000 Rockville Pike, Bethesda, MD 20892.

*Closed:* 8:45 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate the laboratory of clinical studies.

*Place:* National Institutes of Health, Building 1, Wilson Hall, 9000 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Benedict J. Latteri, Acting Deputy Director, Division of Intramural Clinical and Biological Research, National Institute on Alcohol Abuse and Alcoholism, 9000 Rockville Pike, Room 1B58, Building 31—MSC 2088, Bethesda, MD 20892-2088, 301-402-1227.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: May 3, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy, National Institutes of Health.*

[FR Doc. 99-11539 Filed 5-6-99; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Aging Special Emphasis Panel.

*Date:* May 13, 1999.

*Time:* 1 p.m. to Adjournment.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, 7201 Wisconsin Avenue, Bethesda, MD 20814, (Telephone Conference Call).

*Contact Person:* Arthur Schaerdel, DVM, The Bethesda Gateway Building, 7201 Wisconsin Avenue/suite 2C212, Bethesda, MD 20892, (301) 496-9666.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: May 3, 1999.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 99-11540 Filed 5-6-99; 8:45 am]

BILLING CODE 4140-01-M