

For those reasons, I concur with accepting the proposed consent orders.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Proposed Collections; Comment Request

The Department of Health and Human Services, Office of the Secretary will periodically publish summaries of proposed information collection projects and solicit public comments in compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Officer on (202) 690-6207.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects 1. Federal Government-wide Automated Assurance and Institutional Review Board Registration System—NEW—The Office of Human Research Protection is proposing a Government-wide standardized, automated process for filing the assurance pertaining to the protection of human subjects in research, and for registering Institutional Review Boards (IRBs). Respondents: Research Institutions; Burden Information for the Assurance—Annual Number of Respondents: 1,334; Average Burden per Response: 2 hours; Total Annual Burden for Assurance: 2,668—Burden Information for IRB Registration—Annual Number of Respondents: 667; Average Burden per Response: 1 hour; Total Annual Burden for IRB Registration: 667 hours—Total Burden: 3335 hours.

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200

Independence Avenue SW., Washington, DC 20201. Written comments should be received within 60 days of this notice.

Dated: December 7, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Susceptibility of Foodborne Pathogens from Humans, Food, and Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), announces that funds may be available to support an unsolicited grant application submitted by the Fundacion Mexicana para la Salud, Int. Hospital O'Horan, Merida, Yucatan, Mexico. The applicant has requested funds to study the epidemiology of *Salmonella*, *Campylobacter* and generic *Escherichia coli* in four states in Mexico to better define the susceptibility patterns of the pathogens and the risk factors associated with drug resistance, particularly quinolone resistance.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Peggy L. Jones, Division of Contracts and Procurement Management (HFA-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7160. Correspondence hand-carried or commercially delivered should be addressed to 5630 Fishers Lane (HFA-520), rm. 2129, Rockville, MD 20857.

Regarding the programmatic aspects of this notice: David B. Batson, Office of Research (HFV-502), Center for Veterinary Medicine, Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301-827-8021.

SUPPLEMENTARY INFORMATION:

I. Objectives

The specific objectives of the proposed project are to: (1) Develop effective surveillance of antimicrobial resistance in foodborne pathogens in human, food, and veterinary laboratories at the four participating sites; (2) standardize the methods for

isolation, identification, and antimicrobial susceptibility testing of foodborne pathogens at these four sites; (3) determine the prevalence of *Salmonella* spp., *Campylobacter* spp., and quinolone-resistant generic *E. coli* in asymptomatic and ill humans, poultry, pork, beef, and healthy food animals on farms; (4) identify and compare susceptibility profiles of the *Salmonella* spp., *Campylobacter* spp., and generic *E. coli* isolates; and (5) assess the importance of direct and indirect contact with food-animals as risk factors for quinolone-resistance in these isolates.

II. Eligible Applicants

Assistance will only be provided to the Fundacion Mexicana para la Salud because of the following:

1. The Fundacion Mexicana para la Salud is the only organization that submitted an unsolicited application for the purpose stated above.

2. The project proposed by the applicant specifically addresses the National Antimicrobial Resistance Monitoring System objectives in general and international objectives for the establishment of an international data base.

3. The knowledge of sources of exposure to drug resistant pathogens in Mexico would provide information that could be made available to travelers and would also assist in making assessments of the levels of fluoroquinolone resistance in domestic cases of illness acquired from animal food products imported from Mexico and Guatemala.

4. An international data base can provide information to the international community on the level of antimicrobial drug resistance in foodborne pathogens, providing a means for assessing public health concerns.

5. The proposal would benefit CVM and the international community in the establishment of an international data base for antimicrobial susceptibility and enhance food safety activities globally.

III. Funding

We anticipate that approximately \$371,144, which is the requested level of funding, or some lesser amount will be made available in fiscal year (FY) 2001 to fund this project. It is expected that the award will begin sometime in FY 2001 and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may change. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.