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

[FR Doc. 00–32394 Filed 12–19–00; 8:45 am]

BILLING CODE 6750–01–M

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.

[FR Doc. 00–32388 Filed 12–19–00; 8:45 am]

BILLING CODE 4160–17–M

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.

Dated: December 11, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32378 Filed 12–19–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D 1618]

Draft ''Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis'' dated December 2000. The draft guidance document provides recommendations to blood establishments that wish to distribute blood and blood components collected from individuals with diagnosed hereditary hemochromatosis without indicating the donor's disease on the container label, or collect blood more frequently than every 8 weeks without a physical examination and certification of the donor's health by a physician on the day of donation. This draft guidance document identifies the conditions under which FDA will consider approving the above as alternative procedures, or variances, to the current regulations, and provides guidance on what to submit when requesting these variances. These recommendations apply to all blood establishments, whether or not they hold a U.S. License for the manufacture of blood and blood components.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by March 20, 2001.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis'' dated December 2000, to the Office of Communication, Training, and Manufacturers Assistance (HFM 40), Center for Biological 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 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 draft 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: Paula S. McKeever, 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 draft guidance document entitled ''Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis'' dated December 2000. This document identifies the conditions under which FDA will consider approving the above as alternative procedures, or variances, to the current regulations, under the provisions of 21 CFR 640.120 and provides guidance on what to submit when requesting these variances.

On April 29, 1999, the Public Health Service Advisory Committee on Blood Safety and Availability (ACBSA) recommended that the Department of Health and Human Services (DHHS) ''create policies that eliminate incentives to seek [blood] donation for purposes of phlebotomy'' from patients with diagnosed hemochromatosis who require phlebotomy as therapy for their disease. Further, as undue incentives to donate blood for transfusion (rather than being therapeutically phlebotomized) are removed, DHHS ''should create policies that eliminate barriers to using this resource'' to augment the country's blood supply (Ref. 1).

On August 10, 1999, the Commissioner of Food and Drugs made a commitment to consider case-by-case exemptions to existing blood labeling and donor suitability regulations for blood establishments that can verify that therapeutic phlebotomy for hemochromatosis is performed at no expense to the patient (Ref. 2). FDA additionally committed itself to work with the Health Care Financing Administration in ensuring that the financial incentives for persons with hereditary hemochromatosis (HH) to donate blood for transfusion are removed. This issue was further discussed at the FDA Blood Products Advisory Committee meeting on September 16, 1999 (Ref. 3). The statutory authority and scope of jurisdiction of HCFA limits its ability to reduce or eliminate costs of treatment for HH patients, many of whom are covered by private insurers, or do not have health insurance. Thus, for the foreseeable future, if blood centers wish to distribute blood collected from donors with HH without disease labeling, they will have the responsibility of removing financial incentives for these donors. Each blood center will have to evaluate the advantages of entering these donors into their donor pool.

The draft guidance document is being issued consistent with the final rule on good guidance practices (21 CFR 10.15; 65 FR 56468, September 19, 2000). The draft guidance document represents the agency's current thinking on blood collection from individuals with hereditary hemochromatosis. 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 statute, regulations, or both. 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. References

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

1. Nightingale, S. D., Summary of Advisory Committee Meeting of April 29 and 30, 1999. May 13, 1999. http://www.hhs.gov/partner/bloodsafety/04 99sum.html

2. Henney, J. E., Memorandum Blood Donations by Individuals with Hemo chromatosis, August 10, 1999. http://www.hhs.gov/partner/bloodsafety/JEH8 10jpg

3. Blood Products Advisory Committee, 64th Meeting, September 16, 1999. http://www.fda.gov/ohrms/dockets/ac/cber99.htm-Blood Products Advisory Committee

III. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance