I. How do authorized officials of restaurants, similar retail food establishments, and vending machine operators register?

Authorized officials of restaurants, similar retail food establishments, and/or vending machine operators electing to be subject to the requirements of section 4205 may register by visiting http://www.fda.gov/menulabeling. FDA prefers that the information be submitted by e-mail by typing complete information into the form (PDF), saving it on the registrant’s computer, and sending it by e-mail to http://menulawregistration@fda.hhs.gov. If e-mail is not available, the registrant can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and send it to FDA either by faxing the completed form to 301–436–2804 or mailing it to the Center for Food Safety and Applied Nutrition, Compliance Information Branch (HFS–681), 5600 Fishers Lane, Rockville, MD 20857.

J. Will each registrant receive a confirmation of the registration?

Initially, FDA will not provide automatic confirmation of registrations. We recommend that registrants save a copy of the completed form and evidence that it has been transmitted to FDA electronically, by fax, or by mail.

K. What does it mean to be “registered”? Pending promulgation of regulations, FDA considers that an authorized official of any restaurant or similar retail food establishment, or of any vending machine operator, that completely and accurately provides the information described in response to sections II.G and II.H of this document, has registered the restaurant or similar retail food establishment, or vending machine operator.

L. How will future changes to the voluntary registration program be announced?

FDA is required to propose regulations implementing the provisions of section 4205. We intend to include in those proposed regulations further specifications about the voluntary biannual registration of restaurants, similar retail food establishments, and vending machine operators that are not otherwise subject to the requirements of section 4205.

III. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in the Federal Food, Drug and Cosmetic Act and established by section 4205 of the Affordable Care Act. 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 collections of information in section 4205 of the Affordable Care Act have been approved under OMB control number 0910–0664.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this notice. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 20, 2010.

David Dorsey,
Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–18123 Filed 7–21–10; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Transport of Laboratory Personnel Potentially Exposed to Infectious Agents From Fort Detrick, Frederick, MD to the National Institutes of Health Clinical Research Center, Bethesda, MD; (NIH Transportation EIS); Record of Decision

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services (DHHS), has decided, after completion of a Final NIH Transportation EIS and a thorough consideration of the public comments on the Draft NIH Transportation EIS, to implement the Proposed Action, which was identified as the Preferred Alternative in both the Draft EIS and the FEIS. This action involves the transport of laboratory personnel suspected of having potential occupational exposure to infectious agents under study at the NIH located at Fort Detrick, Maryland, to the Special Clinical Studies Unit at the NIH Bethesda, Maryland Campus for observation and, if necessary, treatment.

FOR FURTHER INFORMATION CONTACT:
Valerie Nottingham, Chief of Environmental Quality Branch, DEP,
ORF, NIH, Building 13, Room 2S11, 9000 Rockville Pike, Bethesda, MD 20892. Fax (301) 480–8056. nihnepa@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Decision

After careful review of the environmental consequences in the FEIS for the Transport of Laboratory Personnel Potentially Exposed to Infectious Agents from Fort Detrick, Maryland to the National Institutes of Health Clinical Center, Bethesda, Maryland, and consideration of public comment throughout the NEPA process, the NIH has decided to implement the Proposed Action, described below as the Selected Alternative.

Selected Alternative

The Selected Alternative is the Preferred Alternative, identified in the Draft and Final NIH Transportation EIS as the transport of laboratory personnel suspected of having occupational exposure to infectious agents under study at the NIBC, located at Fort Detrick, Maryland, to the Special Clinical Studies Unit, at the NIH Bethesda, Maryland Campus.

Background

The National Institute of Allergy and Infectious Diseases (NIAID), a component of NIH, is the occupant of an Integrated Research Facility (IRF) at Fort Detrick, Maryland, as part of the National Interagency Biodefense Campus (NIBC). The IRF and other participating agencies within the NIBC will contain specially designed laboratories (referred to as bio-safety level -2, -3, and -4 laboratories) and animal research facilities for conducting biodefense and emerging infectious disease research. It is proposed that laboratory personnel suspected of having potential occupational exposure to infectious agents under study at the NIBC located at Fort Detrick, Maryland, be transported to the Special Clinical Studies Unit at the NIH Bethesda, Maryland Campus, for observation and, if necessary, treatment. The NIH identified the Preferred Alternative as the Proposed Action Alternative based on several factors. First, the special design of the Special Clinical Studies Unit allows for optimal evaluation and treatment of employees with potential occupational exposure to infectious pathogens. This facility will be fully staffed with experts in infectious disease scientists resident at other facilities of the NIH Bethesda, Maryland Campus. Second, the NIH has taken great care to analyze the safety and security aspects of all such activities and has developed procedures and requirements to assure the safety of employees, visitors, patients, and the surrounding communities. A Vulnerability Assessment (VA) was also developed in order to complement the basic EIS process. This VA, developed on the same premise as a Threat Risk Assessment was developed in accordance with the requirements stipulated in Federal regulations, as specified in Title 9, Part 121, Section 11, and guidance provided by the DHS (FEMA 2007). Based on this VA it was concluded that any risk during transportation was negligible and would not pose an unacceptable level of risk. Any transport of patients would be well coordinated with the NIH, Fort Detrick Directorate of Emergency Services, Frederick County Police, Montgomery County Police, and the Maryland State Police. Based on the potentially exposed individual’s condition, security concerns, weather conditions, traffic conditions, and other factors, a transport plan and route would be developed, notification to the appropriate security, police, and fire departments made, and a request for escort services placed with the Maryland State Police.

Alternatives Considered

The Final NIH Transportation EIS analyzed two alternatives, the No Action Alternative and the Proposed Action Alternative; to transport laboratory personnel potentially exposed to infectious agents from Fort Detrick, Maryland to the Special Clinical Studies Unit at the NIH Bethesda, Maryland Campus, for monitoring, evaluation and, if necessary, treatment. The NIH identified the Preferred Alternative as the Proposed Action Alternative based on several factors. First, the special design of the Special Clinical Studies Unit allows for optimal evaluation and treatment of employees with potential occupational exposure to infectious pathogens. This facility will be fully staffed with experts in infectious disease scientists resident at other facilities of the NIH Bethesda, Maryland Campus. Second, the NIH has taken great care to analyze the safety and security aspects of all such activities and has developed procedures and requirements to assure the safety of employees, visitors, patients, and the surrounding communities. A Vulnerability Assessment (VA) was also developed in order to complement the basic EIS process. This VA, developed on the same premise as a Threat Risk Assessment was developed in accordance with the requirements stipulated in Federal regulations, as specified in Title 9, Part 121, Section 11, and guidance provided by the DHS (FEMA 2007). Based on this VA it was concluded that any risk during transportation was negligible and would not pose an unacceptable level of risk. Any transport of patients would be well coordinated with the NIH, Fort Detrick Directorate of Emergency Services, Frederick County Police, Montgomery County Police, and the Maryland State Police. Based on the potentially exposed individual’s condition, security concerns, weather conditions, traffic conditions, and other factors, a transport plan and route would be developed, notification to the appropriate security, police, and fire departments made, and a request for escort services placed with the Maryland State Police.

The NIH Special Clinical Studies Unit is a state-of-the-art facility located on the NIH Bethesda, Maryland Campus. The special design of the Special Clinical Studies Unit allows for optimal evaluation and treatment of employees with potential occupational exposure to infectious pathogens. This facility will be fully staffed with experts in infectious diseases who will be conducting applied research. This unit could easily be made available to laboratory personnel potentially exposed to infectious pathogens while conducting research within biocontainment laboratories located at Fort Detrick. Evaluation and/or treatment at the Special Clinical Studies Unit would also allow for consultations from prominent infectious disease scientists resident at other facilities of the NIH Bethesda, Maryland Campus.

On June 20, 2008, the NIH published a Notice of Intent (NOI) in the Federal Register (73 FR 35145) announcing its intent to prepare the NIH Transportation EIS and start the public scoping period. The scoping period started with the NOI, and continued through August 4, 2008. The NOI also invited interested parties to attend two public scoping meetings which were held on July 8, 2008, at the C. Burr Artz Library, in Frederick, Maryland, and on July 10, 2008, at the Bethesda-Chevy Chase Service Center in Bethesda, Maryland. The NIH invited the public to submit comments during the scoping period by U.S. mail, e-mail, and through written and verbal comments submitted at the public scoping meetings. All comments received during the public scoping comment period, as well as written and oral comments received at the two public scoping meetings were considered during the preparation of the Draft EIS. A summary of the major comments received from the scoping comment period was included in the Draft EIS.

The Draft NIH Transportation EIS was distributed to interested parties. A notice of availability for the Draft NIH Transportation EIS was published in the Federal Register on May 22, 2009 (74 FR 24006). The formal comment period for the Draft NIH Transportation EIS lasted for 60 days beginning on May 25, 2009, and ending on July 24, 2009. During this comment period, public meetings were held in Frederick, Maryland on June 15, 2009, and Bethesda, Maryland on June 18, 2009. In addition, Federal agencies, state and local government entities were provided copies of the Draft NIH Transportation EIS and encouraged to submit comments via the U.S. mail, e-mail, and in person at two public meetings. The NIH considered all comments in evaluating the accuracy and adequacy of the Draft NIH Transportation EIS and to determine whether its text needed to be corrected, clarified, expanded, or otherwise revised. The Draft NIH Transportation was then edited and amended, as appropriate, and a Final EIS prepared. A Comment Resolution Appendix, showing how comments on the draft were addressed, was added to the document as Appendix C.
The NIH considered varying alternative actions, such as upgrading the existing clinic at Fort Detrick, constructing a new facility at Fort Detrick, and the use of existing medical facilities, Frederick Memorial Hospital (FMH) in Frederick, Maryland area. All of these alternative actions were determined to be unable to provide the required level of care for the laboratory personnel who will be working at NIBC. Committing FMH space and staff for the continued observation required for such a situation would impact normal operations, have a negative impact on the quality of medical services FMH could provide on a regular basis, and not provide the potentially exposed individual with the best possible care. Most importantly, however, should these individuals become symptomatic, use of such health care facilities would not provide the level of care necessary for optimal treatment unable to assure an acceptable level of protection of the health and safety of the general public. This possible alternative was, therefore, determined to be unacceptable and was eliminated from further analysis.

Upgrading the existing facility or constructing a health care facility within the Fort Detrick Campus was also considered unreasonable. A treatment health care facility that could provide for an acceptable level of services and allow for an extended stay of individuals potentially exposed to infectious agents and medical staff would require a full time medical and scientific staff. Such a staff would have to be sufficient to meet all potential needs for observation, monitoring and medical care. Such a facility and staff would be inactive most of the time. Such an alternative, moreover, would remove these key scientific experts from other active projects and would be disruptive to ongoing research projects.

Factors Involved in the Decision

Resource Impacts

The FEIS describes potential environmental effects of the Selected Alternative. These potential effects are documented in Chapter 4 of the Final NIH Transportation EIS. Any adverse environmental effects will be avoided or mitigated through strict adherence to procedures and compliance with regulatory and NIH requirements. Potential impacts on air quality and noise levels are all within government standards (Federal, state, and local). The NIH does not expect any long-term negative effects on the environment or on the members of the communities through which transport may occur.

Summary of Impacts

The following is a summary of potential impacts resulting from the Selected Alternative that the NIH considered when making its decision. No adverse cumulative effects were identified during the NEPA process. Likewise, no unavoidable or adverse impacts from implementation of the Selected Alternative were found.

Land Use

The Selected Alternative would not be expected to have the potential to impact existing land use patterns.

Climate

The Selected Alternative would not be expected to have the potential to impact climate.

Air Quality

The Selected Alternative would not be expected to have the potential to significantly impact air quality within the affected area.

Water Resources

The Selected Alternative would not be expected to have the potential to impact water resources within the affected area.

Ecology

The Selected Alternative would not be expected to have the potential to significantly impact the ecology of the affected area.

Parks and Recreational Facilities

The Selected Alternative would not be expected to have the potential to impact the parks and recreational facilities of the affected area.

Socioeconomic Environment

The Selected Alternative would not be expected to have the potential to impact the socioeconomic environment of the affected area.

Environmental Justice

The Selected Alternative would not be expected to have disproportionately high or adverse impact on low income or minority populations of the affected area.

Geology and Soils

The Selected Alternative would not be expected to have the potential to impact the geology or soils of the affected area.

Historic and Archeological Resources

The Selected Alternative would not be expected to have the potential to impact the historical or archeological resources of the affected area.

Noise

The Selected Alternative would not be expected to have the potential to significantly impact existing noise levels of the affected area.

Emergency Response

The Selected Alternative would not be expected to have the potential to impact the delivery of emergency services to the affected area.

Safety and Security

The NIH has established procedures, which include notification of first responder units of the affected area and a request for escort services from the Maryland State Police, prior to any transport of laboratory personnel suspected of incurring occupational exposure to infectious agents while conducting research at the NIBC at Fort Detrick, Maryland to the NIH Bethesda, Maryland Campus. Accordingly, the Selected Alternative would not be expected to have the potential to impact the safety and security of the affected area.

Cumulative Impacts

The Selected Alternative, when considered in conjunction with other known and proposed actions would not be expected to have a significant cumulative impact on the affected area.

Practicable Means To Avoid or Minimize Potential Environmental Harm from the Selected Alternative

All practicable means to avoid or minimize adverse environmental effects from the Selected Action have been identified and incorporated into the action. The proposed action will be subject to the existing NIH pollution prevention, waste management, and safety, security, and emergency response procedures as well as existing environmental permits where applicable. Best management practices, spill prevention and control plans and all safety and security measures will be followed appropriately. All personnel involved in transport would be trained on pre-planned responses in the event of an accident or mechanical failure. All Emergency Response Technicians (EMT) or EMT-Paramedics would be medically certified. No additional mitigation measures have been identified.

Pollution Prevention

All federal, state, and local requirements to protect the environment and public health will be met with the Selected Alternative.
Monitoring and Enforcement Program

The NIH will develop a monitoring and enforcement program to ensure that all practicable mitigation measures developed for under the Selected Alternative are fully implemented.

Conclusion

Based upon review and careful consideration, the NIH has decided to implement the Selected Alternative. The decision was based upon review and careful consideration of the potential impacts identified in the FEIS and public comments received throughout the NEPA process.

Date: July 19, 2010.

Daniel G. Wheeland,
Director, Office of Research Facilities Development and Operations, National Institutes of Health.

[FR Doc. 2010–18106 Filed 7–22–10; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Administration for Children and Families

Request for Public Comment and Consultation Meetings on the Adoption and Foster Care Analysis and Reporting System (AFCARS)

AGENCY: Department of Health and Human Services, Administration for Children and Families, Administration on Children, Youth and Families, Administration for Children and Families, Children’s Bureau.

ACTION: Request for Public Comment and Consultation Meetings on the Adoption and Foster Care Analysis and Reporting System (AFCARS).

SUMMARY: Section 479 of the Social Security Act (the Act) requires that the Administration for Children and Families (ACF) develop and write regulations to implement a system for the collection by title IV–E agencies of data relating to adoption and foster care. The resultant Adoption and Foster Care Analysis and Reporting System (AFCARS) has been operating since 1994 and is administered by the Children’s Bureau (CB) in ACF. AFCARS collects case level information on all children in foster care for whom the title IV–E agency has responsibility for placement and care and on children adopted under the auspices of the title IV–E agency. We issued a Notice of Proposed Rulemaking (NPRM) on January 11, 2008 (73 FR 2082) that proposed to amend the AFCARS regulations at 45 CFR 1355.40 and the appendices to part 1355 [http://edocket.access.gpo.gov/2008/E7-24860.htm]. The proposal would modify the requirements for title IV–E agencies to collect and report data to ACF on children in out-of-home care and in subsidized adoption or guardianship arrangements with the title IV–E agency. Due to the enactment of the Fostering Connections to Success and Increasing Adoptions Act of 2008 (Pub. L. 110–351) and the substantial changes it introduced in title IV–E, we intend to issue a new AFCARS NPRM. To inform development of the new NPRM we request that interested parties comment on the questions below.

DATES: Written comments must be submitted to the office listed in the ADDRESSES section below on or before October 21, 2010. Please see SUPPLEMENTARY INFORMATION for additional details on consultation meetings.

ADDRESSES: Interested persons may submit written comments by any of the following methods:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

• E-mail: CBComments@acf.hhs.gov. Please include “Comments on AFCARS Federal Register Notice” in the subject line of the message.

• Mail or Courier Delivery: Jan Rothstein, Division of Policy, Children’s Bureau, Administration on Children, Youth and Families, Administration for Children and Families, 1250 Maryland Avenue, SW., 8th Floor, Washington, DC 20024.

Instructions: Please be aware that mail sent to us may take an additional 3–4 days to process due to changes in mail handling resulting from the anthrax crisis of October 2001. If you choose to use an express, overnight, or other special delivery method, please ensure first that they are able to deliver to the above address. We urge you to submit comments electronically to ensure they are received in a timely manner. All comments received will be posted without change to http://www.regulations.gov including any personal information provided. Comments provided to us during a meeting or in writing in response to this Federal Register notice will receive equal consideration by ACF.

FOR FURTHER INFORMATION CONTACT: Jan Rothstein, Children’s Bureau, 1250 Maryland Ave., SW., 8th Floor, Washington, DC 20024; (202) 401–5073.

SUPPLEMENTARY INFORMATION: Please respond to any or all of the questions below. It would be helpful if your comment identifies the question to which you are responding. If you have additional comments, please identify them by citing to 45 CFR part 1355 or the 2008 NPRM, as applicable.

Reporting Population

Fostering Connections provides Tribes with the option to operate a foster care, adoption assistance and, at tribal option, a kinship guardianship assistance program under title IV–E of the Social Security Act (the Act). The Secretary is to apply title IV–E of the Act to Tribes operating the program directly in the same manner as to States except where directed by law. Further, Tribes continue to have the ability to enter into title IV–E agreements with States to operate part of the program on behalf of Indian children.

1. How should data collection and reporting requirements in AFCARS change for State and Tribal title IV–E agencies, if at all, to provide a comprehensive national picture of children in foster care and those adopted with the involvement of a title IV–E agency?

In the 2008 NPRM, we proposed expanding the reporting populations to include children placed in the child welfare agency’s responsibility for placement and care wherever they are placed and to include children in subsidized guardianships. We believed this information would facilitate a greater understanding of a child’s entire out-of-home care experience, which in turn affects the foster care experience and permanency outcomes.

2. Under what circumstances should a child be included in the AFCARS reporting population for foster care, adoption or guardianship?

• What are the barriers to obtaining information on all children in a child welfare agency’s placement and care responsibility?

• What information should an agency collect on children in its placement and care responsibility who are placed in detention, psychiatric facilities and other settings other than foster family homes, group homes and child care institutions?

• What information do agencies currently collect on children in finalized adoptions and guardianships?

Federal Oversight Activities

The Children’s Bureau uses AFCARS data to support a number of our oversight activities in relation to the title IV–B and IV–E plans, including the Child and Family Services Reviews.

3. What case level data on foster care, adoption and guardianship is important for agencies to collect and report to ACF on an ongoing basis that can inform future Federal monitoring activities,