

journals and presentation at professional conferences; (10) collaborates with partners to develop new and combined vaccines that can be integrated into national and international immunization programs; (11) participates in trials of new and combined vaccines; (12) participates in international as well as domestic vaccine safety research activities; and (13) conducts research and evaluates alternative approaches for administering vaccines to enhance safety.

Dated: September 12, 2002.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02-24034 Filed 9-20-02; 8:45 am]

BILLING CODE 4160-18-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0388]

Guidance for Industry on Establishing Pregnancy Exposure Registries; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing the availability of a final guidance entitled "Establishing Pregnancy Exposure Registries." The guidance is intended to provide sponsors with guidance on how to establish pregnancy exposure registries to monitor the outcomes of pregnancies exposed to specific medical products.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Dianne L. Kennedy, Center for Drug Evaluation and Research (HFD-970), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2364, kennedyd@cder.fda.gov; or Toni M. Stifano, Center for Biologics Evaluation and Research (HFM-600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6190, stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Establishing Pregnancy Exposure Registries." Pregnancy exposure registries are recognized as one method of obtaining information on risks associated with exposure to medical products during pregnancy. The guidance is intended to provide sponsors with recommendations on how to establish pregnancy exposure registries, to help ensure the quality and integrity of registry data, and to help ensure the adequacy of document registry research methods.

In June 1999, FDA announced the availability of a draft guidance entitled "Establishing Pregnancy Registries" (64 FR 30041, June 4, 1999). Comments received on the draft guidance revealed that several general areas of the guidance needed revision and/or clarification.

Based on the comments received and on discussions with FDA's Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs on June 3, 1999 (64 FR 23340) and March 28 to 29, 2000 (65 FR 10811), the agency revised and/or clarified several sections of the guidance, including (1) When it is recommended that a registry be conducted, (2) use of comparison groups, (3) promotion of a registry and (4) regulatory reporting requirements. In addition, the name of the guidance was changed from "Pregnancy Registries" to "Pregnancy Exposure Registries" to more accurately reflect the nature of these types of studies and to differentiate them from more classic retrospective registries (e.g., cancer registries and birth defect registries).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on pregnancy exposure

registries. 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 statutes and regulations.

II. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>. To obtain the guidance document by fax call the FAX Information System at 1-888-CBER-FAX or 301-827-3844.

Dated: September 16, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-24037 Filed 9-20-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

National Park Service

Information Collection; Request for Extension

AGENCY: National Park Service, Interior

ACTION: Notice of request for extension of a currently approved information collection.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the National Park Service's intention to request an extension for a currently approved information collection in support of its Concession Management Program.

DATES: Comments in this notice must be received no later than November 22, 2002.

ADDITIONAL INFORMATION OR COMMENTS:

Contact Cynthia Orlando, Concession Program Manager, National Park Service, 1849 C Street, NW., (2410), Washington, DC 20240 or 202/513-7144.

SUPPLEMENTARY INFORMATION:

Title: Proposed Sale of Concession Operations.

OMB Number: 1024-0126.

Expiration Date of Approval: August 31, 2002.

Type of Request: Extension of a currently approved information collection.

Abstract: The National Park Service (NPS) authorizes private businesses known concessioners to provide necessary and appropriate visitor facilities and services in areas of the National Park System. Concession authorizations may be assigned, sold, transferred or encumbered by the concessioner subject to prior written approval of the NPS. The NPS requires that certain information be submitted for a review prior to the consummation of any sale, transfer, assignment, or encumbrance.

16 U.S.C. 3 provides that no contract, lease, permit or privilege granted for the purpose of providing accommodations for visitors to the national parks shall be assigned or transferred by such grantee, permittees, or licenses without the approval of the NPS, first obtained in writing. It further provides that the NPS may authorize concessioners to execute mortgages and issue bonds, shares of stock, and other evidences or interest in or indebtedness upon their rights, properties and franchises, for the purposes of installing, enlarging or improving plant and equipment and extending facilities for the purposes of installing, enlarging or improving plant and equipment and extending facilities for the accommodation of the public within national parks and monuments. 16 U.S.C. 20(3) also provides that the possessory interest of a concessioner may be assigned, transferee, encumbered, or relinquished. Regulations at 36 CFR part 51 require that certain information be submitted for review by the NPS prior to the consummation of any sale, transfer, assignment or encumbrance.

The information requested is used to determine whether or not the proposed transaction will result in decreased services to the public, the lack of a reasonable opportunity for profit over the remaining term of the authorization, or rates in excess of existing approved rates to the public. In addition, pursuant to the regulations at 36 CFR, Part 51, the value of rights for intangible assets such as the concession contract, right of preference in renewal, user days, or low fees belong to the Government. If any portion of the purchase price is attributable either directly or indirectly to such assets, the transaction may not be approved. The amount and type of

information to be submitted varies with the type and complexity of the proposed transaction. Without such information, the NPS would be unable to determine whether approval of the proposed transaction would be adequate.

Estimate of Burden: Approximately 8 hours per response.

Estimated Number of Respondents: Approximately 20.

Estimated Number of Responses per Respondent: One.

Estimated Total Annual Burden on Respondents: 1600 Hours.

A list of information required to be submitted with a request for sale, assignment, transfer or encumbrance of a concession authorization is set forth at 36 CFR 51.7.

Send comments regarding the accuracy of the burden estimate, ways to minimize the burden, including the use of automated collection techniques or other forms of information technology, or any other aspect of this collection to: Cynthia L. Orlando, Concession Program Manager, National Park Service, Department of the Interior, 1849 C Street, NW., (2410), Washington, DC 20240.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: September 13, 2002.

Richard G. Ring,

Associate Director for Park Operations and Education.

[FR Doc. 02-24044 Filed 9-20-02; 8:45 am]

BILLING CODE 4310-70-M

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Contract Award and Negotiations

AGENCY: National Park Service, Interior.

ACTION: Public notice.

SUMMARY: Public notice is hereby given that the National Park Service proposes to award a temporary concession contract authorizing the operation of mobile food services for the public within the Jamaica Bay Unit, Gateway National Recreation Area, New York for a term not to exceed two years.

DATES: Thirty (30) days after date of publication in the **Federal Register**.

ADDRESSES: Concession Program Manager, National Park Service, Northeast Region, Concession Management Program, 15 State Street, Boston, MA 02109-3572.

SUPPLEMENTARY INFORMATION: This temporary concession contract is being

awarded to the Dover Gourmet Corporation, Plainview, New York. It is necessary to award the contract in order to avoid interruption of visitor services.

The action is issued pursuant to 36 CFR 51.24(a). This is not a request for proposals and no prospectus is being issued at this time. Gateway National Recreation Area is in the process of reviewing its visitor services plans for this location to develop a long-term strategy. This temporary contract will allow the continuation of services to the public during the planning process. You may be placed on a mailing list for receiving information regarding any future competitive solicitation by sending a written request to the above address.

Dated: July 18, 2002.

Chrysandra L. Walter,

Acting Regional Director, Northeast Region.

[FR Doc. 02-24041 Filed 9-20-02; 8:45 am]

BILLING CODE 4310-70-M

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Contract Extension

AGENCY: National Park Service, Interior.

ACTION: Public notice.

SUMMARY: Pursuant to 36 CFR 51.23, public notice is hereby given that the National Park Service proposes to extend the following expiring concession contract for a period of up to three years, or until such time as a new contract is awarded, whichever occurs sooner.

SUPPLEMENTARY INFORMATION: The listed concession authorization will expire by its terms on December 31, 2002. The National Park Service has determined that the proposed extension is necessary in order to avoid interruption of visitor services and has taken all reasonable and appropriate steps to consider alternatives to avoid such interruption. This extension will allow the National Park Service to complete and issue a prospectus leading to the competitive selection of a concessioner for a new long-term concession contract covering this operation.

Concessioner ID No.	Concessioner name	Park
STLI002	Evelyn Hill, Inc..	Statue of Liberty National Monument.

EFFECTIVE DATE: January 1, 2003.