commercial poultry industry from the introduction of highly pathogenic avian influenza H5N1, these actions have the added benefit of mitigating the risk of human exposure to the virus. Because the USDA/APHIS import restrictions adequately address risks to human health, HHS/CDC is announcing the intent to lift its embargo against imports of birds and unprocessed bird products from those same countries and solicits comments on this proposal. All of the bird embargoes that are currently in force under USDA regulations will remain in force. HHS/CDC will work closely with USDA/APHIS to monitor the international situation regarding HPAI H5N1 outbreaks and will take additional action if it identifies human health risks that are not adequately contained by USDA regulatory actions.

DATES: Written comments must be received on or before February 20, 2009. Comments received after January 21, 2009 will be considered to the extent possible.

ADDRESSES: You may submit written comments to the following address: Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Attn: Rescission Notice, 1600 Clifton Road, NE., MS E–03, Atlanta, Georgia 30333.

You may submit written comments electronically via the Internet at the following Address: *http://regulations.gov*, or via e-mail to *DGMQpubliccomments@cdc.gov*.

FOR FURTHER INFORMATION CONTACT: Stacy M. Howard, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 1600 Clifton Road, NE., MS E–03, Atlanta, Georgia 30333; telephone 404–498–1600.

SUPPLEMENTARY INFORMATION:

Background

On February 4, 2004, the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services issued an order to ban immediately the import of all birds (Class: *Aves*) from specified countries, subject to limited exemptions for returning pet birds of U.S. origin and certain processed bird-derived products. HHS/CDC took this step because birds from these countries can potentially infect humans with avian influenza (influenza A/[H5N1]). Countries affected by the February 4, 2004, order included Cambodia, Indonesia, Japan, Laos, People's Republic of China (including Hong Kong Special Administrative Region [SAR]), South Korea, Thailand, and Vietnam. This order was further amended on March 10, 2004, to lift the embargo of birds and bird products from the Hong Kong SAR because of the documented control of the outbreak there and the absence of highly pathogenic avian influenza H5N1 cases in Hong Kong's domestic bird populations. Following the documentation of highly pathogenic avian influenza H5N1 in commercial birds in additional countries, HHS/CDC issued amendments to the February 4, 2004, order that added these countries to its embargo: Malaysia on September 28, 2004; Kazakhstan, Romania, Russia, Turkey, and Ukraine on December 29, 2005; Nigeria on February 8, 2006; India on February 22, 2006; Egypt on February 27, 2006; Niger on March 2, 2006; Albania, Azerbaijan, Cameroon, and Burma (Myanmar) on March 15, 2006; Israel on March 20, 2006; Afghanistan on March 21, 2006; Jordan on March 29, 2006; Burkina Faso on April 10, 2006; Pakistan on April 10, 2006; Gaza, the West Bank, and the Ivory Coast (Côte d'Ivoire) on April 28, 2006; Sudan on May 16, 2006; Djibouti on June 2, 2006; and Kuwait on February 28, 2007.

The HHS/CDC February 4, 2004, order and subsequent amendments have complemented simultaneous actions taken by the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA). USDA/APHIS amended its regulations to prohibit or restrict the importation of birds, poultry, and unprocessed birds and poultry products from regions that have reported the presence of highly pathogenic avian influenza H5N1 in poultry. *See* 9 CFR 93.101, 93.201, 94.6, & 95.30. As the United Nations Food and Agriculture Organization and the World Organization for Animal Health (OIE) have confirmed additional cases of highly pathogenic avian influenza (H5N1) in commercial birds, USDA/APHIS has added additional countries and regions to its ban.

HHS/CDC believes that the actions taken to date by USDA/APHIS adequately mitigate the human health risks associated with birds and unprocessed bird products imported from the countries of concern, and that the HHS/CDC order of February 4, 2004, and subsequent amendments are no longer needed. HHS/CDC announces its intent to lift its embargo of birds and unprocessed bird products from specified countries to ensure a more coordinated federal response to the control of highly pathogenic avian influenza H5N1.

Dated: January 9, 2009.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention.

[FR Doc. E9–1029 Filed 1–16–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: ACF–IV–E–1 Foster Care and Adoption Assistance Financial Reporting Form.

OMB No.: 0970–0205.

Description: State agencies administer the Foster Care and Adoption Assistance Programs under Title IV–E of the Social Security Act. The Administration for Children and Families provides Federal funding at the rate of 50 percent for most of the administrative costs and at other rates for other specific categories of costs as detailed in Federal statutes and regulations. This form is submitted quarterly by each State to estimate the funding needs for the upcoming fiscal quarter and to report expenditures for the fiscal quarter just ended. The information collected in this report is used by this agency to calculate quarterly Federal grant awards and to enable oversight of the financial management of the programs.

Part 3 of this form had also been used to collect semiannual budget projections. In response to the publication of the **Federal Register** Notice on October 10, 2008, comments from the ACF budget office indicated that this information is now available from other sources and the information previously collected on Part 3 is no longer needed. We are, therefore, deleting Part 3 of this form.

Respondents: State agencies (including the District of Columbia and Puerto Rico) administering the Foster Care and Adoption Assistance programs under Title IV–E of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Form ACF–IV–E–1	52	41	6	3,328

Estimated Total Annual Burden Hours: 3,328.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: January 13, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–953 Filed 1–16–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0007]

Draft Guidance for Industry on Animal Models--Essential Elements to Address Efficacy Under the Animal Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: FDA is announcing the availability of a draft guidance entitled ''Animal Models--Essential Elements to Address Efficacy Under the Animal Rule.'' When human efficacy studies are neither ethical nor feasible, animal efficacy studies may be relied on under the Animal Rule to support approval or licensure of a drug or biological product. This guidance identifies and discusses the critical characteristics of an animal model that should be addressed when developing products for approval under the Animal Rule. The guidance is intended to help sponsors determine whether the model meets the requirements of the Animal Rule.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by March 23, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Rosemary Roberts, Office of Counter-Terrorism and Emergency Coordination, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3342, Mail Stop 3329, Silver Spring, MD 20993, 301–796–2210 or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Animal Models--Essential Elements to Address Efficacy Under the Animal Rule.'' The purpose of this draft guidance is to assist sponsors to identify the critical characteristics of an animal model that should be addressed when efficacy of an investigational product will be established under the ''Animal Rule'' (see 21 CFR 314.600; 21 CFR 601.90). Critical characteristics include, but are not limited to, information regarding the natural history of the condition to be treated in humans and animals, the challenge agent, route of exposure to the challenge agent, and the timing of intervention with the study drug. Data from human experience with the etiologic agent or with the intervention, when available, may support applicability of the animal model. The information described in the draft guidance is relevant for any animal model being considered as a basis for establishing efficacy under the Animal Rule and is intended to help determine whether the model meets the requirements of the Animal Rule.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on animal models when addressing efficacy under the animal rule. 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that