

## 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](mailto: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**Draft Guidance for Industry on Animal Models--Essential Elements to Address Efficacy Under the Animal Rule**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**SUMMARY:** FDA is announcing the availability of a draft guidance entitled "Animal Models--Essential Elements to Address Efficacy Under the Animal Rule."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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by March 23, 2009.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

individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder.guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm> or <http://www.regulations.gov>.

Dated: January 12, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-936 Filed 1-16-09; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0008]

#### Draft Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act." The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the act) addressing the agency's treatment of certain citizen petitions and petitions for stay of agency action (collectively, petitions), as well as related applications. The draft guidance describes how FDA will determine if the new provisions apply to a particular petition and how FDA will determine if a petition would delay approval of a pending abbreviated new drug

application (ANDA) or 505(b)(2) application. The draft guidance also describes how FDA will interpret the requirements that such petitions include a certification and that supplemental information or comments to such petitions include a verification. The draft guidance also addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the agency has not yet made a decision on approvability.

**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, including comments regarding the proposed collection of information, 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. 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:

Nancy Boocker, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6244, Silver Spring, MD 20993-0002, 301-796-3601.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act." The draft guidance provides information regarding FDA's current thinking on interpreting section 914 of Title IX of FDAAA (Public Law 110-85). Section 914 of FDAAA added new section 505(q) to the act (21 U.S.C. 355(q)) and governs certain citizen petitions and petitions for stay of agency action that request that FDA take any form of action related to a pending application submitted under section

505(b)(2) or 505(j) of the act. The draft guidance describes FDA's interpretation of section 505(q) of the act regarding how the agency will determine if: (1) The provisions of section 505(q) addressing the treatment of citizen petitions and petitions for stay of agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending ANDA or a 505(b)(2) application. The draft guidance also describes how FDA will interpret the provisions of section 505(q) requiring that: (1) A petition include a certification and (2) supplemental information or comments to a petition include a verification. Finally, the draft guidance addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the agency has not yet made a decision on approvability.

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 citizen petitions and petitions for stay of action that are subject to section 505(q) of the act. 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 individuals may submit one paper copy. Comments are to be identified 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.

##### III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501-3520) (the PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal